# SOMERSET MINOR AILMENTS SCHEME

## PROTOCOLS FOR REGISTERED COMMUNITY PHARMACISTS

### Version 1.0

<table>
<thead>
<tr>
<th>Document Reference:</th>
<th>P:\Directorate\Primary Care Development\Community Pharmacy\Enhanced Services\Minor Ailments Scheme\MAS-protocol (Mar-13) (v1-0 final)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Originator/Author:</td>
<td>Ana Alves, Practicing Professional LPN-Pharmacy, NHS Somerset</td>
</tr>
<tr>
<td>Acknowledgments:</td>
<td>Stephen Du Bois, Chair Pharmacy-LPN, NHS Somerset</td>
</tr>
<tr>
<td>Approved by:</td>
<td>Richard Wood, Associate Director – Pharmacy, Dentistry and Optometry</td>
</tr>
<tr>
<td>Date issued:</td>
<td>March 2013</td>
</tr>
<tr>
<td>Review date:</td>
<td>31st December 2014 or in light of significant changes in best practice</td>
</tr>
</tbody>
</table>

### Version 2.0

| Reviewed by: | Sue Mulvenna, Pharmacist Lead for NHS England BNSSSG Area Team 23.12.14 |
| Changes made: | Sodium Cromoglicate 2% eye drops changed from PGD to protocol; changes to nitrofurantoin PGD in light of 2014 MHRA guidance; removal of trimethoprim PGD in light of concerns about bacterial resistance to this antibiotic |
| Review date: | Before end of MAS SLA, 31st March 2015, with a view to aligning with Somerset CCG urgent care plans. |
## Somerset Minor Ailments Scheme Protocols for Registered Community Pharmacists

<table>
<thead>
<tr>
<th>Reference</th>
<th>Content</th>
<th>Page No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Introduction</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>General criteria and considerations</td>
<td>4</td>
</tr>
<tr>
<td><strong>Protocols</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAS T1</td>
<td>Aciclovir 5.0% cream (2g)</td>
<td>9</td>
</tr>
<tr>
<td>MAS T2</td>
<td>Clotrimazole 500mg pessary (1)</td>
<td>11</td>
</tr>
<tr>
<td>MAS T3</td>
<td>Clotrimazole 1% cream (20g)</td>
<td>13</td>
</tr>
<tr>
<td>MAS T4</td>
<td>Fluconazole 150mg capsule (1)</td>
<td>15</td>
</tr>
<tr>
<td>MAS T5</td>
<td>Loratadine 10mg tablets (30)</td>
<td>17</td>
</tr>
<tr>
<td>MAS T6</td>
<td>Miconazole nitrate 2.0% cream (30g)</td>
<td>19</td>
</tr>
<tr>
<td>MAS T7</td>
<td>Sodium Cromoglicate 2.0% eye-drops</td>
<td>21</td>
</tr>
</tbody>
</table>

### Summary of Patient Group Directions

**IMPORTANT:** The prescription only medicines detailed in the following pages must be supplied under the relevant Patient Group Directions. Pharmacists must be authorised by name to use the relevant Patient Group Direction (PGD) (Pharmacists must have signed the authorisation sheets of the relevant PGD, which must also have been signed-off by the relevant authorising manager in their company.)

<table>
<thead>
<tr>
<th>Reference</th>
<th>Content</th>
<th>Page No</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAS T8</td>
<td>Chloramphenicol 0-5% eye-drops and Chloramphenicol 1.0% eye ointment</td>
<td>24</td>
</tr>
<tr>
<td>MAS T9</td>
<td>Nitrofurantoin 50mg capsules</td>
<td>30</td>
</tr>
<tr>
<td>MAS T10</td>
<td>Retapamulin 1% ointment</td>
<td>34</td>
</tr>
<tr>
<td></td>
<td>Other Minor Ailment Scheme Documents</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td>References to national/local policies or guidelines</td>
<td>41</td>
</tr>
<tr>
<td></td>
<td>Professional considerations</td>
<td>42</td>
</tr>
<tr>
<td></td>
<td>Protocol Authorisation for Registered Pharmacists</td>
<td>43</td>
</tr>
</tbody>
</table>
INTRODUCTION

The NHS Somerset Minor Ailments Scheme is delivered using a combination of this protocols and Patient Group Directions (PGDs). The protocols are intended for the supply of General Sales List (GSL) or Pharmacy medicines (P-meds) when supply is within the terms of the products licensed indications. PGDs are required for the supply of medicines where the product to be supplied is a Prescription-only medicine (POM).

Below is a list of the conditions to be treated under the scheme, the indication for treatment, the product to be supplied, the legal category of the product and the method by which the product is to be supplied:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Indication</th>
<th>Product(s)</th>
<th>Legal category</th>
<th>Supply by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cold sores (Herpes labialis)</td>
<td>The topical treatment of <em>Herpes simplex</em> virus (HSV) infections of the lips and face (<em>Herpes labialis</em>)</td>
<td>Aciclovir 5.0% cream (5g)</td>
<td>GSL or Pharmacy medicine</td>
<td>Protocol</td>
</tr>
<tr>
<td>Candídiasis / balanitis</td>
<td>The treatment of vaginal candidiasis</td>
<td>Clotrimazole 500mg pessary (1 pessary)</td>
<td>GSL or Pharmacy medicine</td>
<td>Protocol</td>
</tr>
<tr>
<td></td>
<td>The treatment of candidal vulvitis, candidal balanitis, or cutaneous candidiasis</td>
<td>Clitorimazole 1% cream (20g tube)</td>
<td>GSL or Pharmacy medicine</td>
<td>Protocol</td>
</tr>
<tr>
<td></td>
<td>The treatment of genital candidiasis, acute or recurrent vaginal candidiasis, or candidal balanitis</td>
<td>Fluconazole 150mg capsule (1 capsule)</td>
<td>Pharmacy medicine</td>
<td>Protocol</td>
</tr>
<tr>
<td>Allergic rhinitis / allergic conjunctivitis</td>
<td>The prophylaxis and symptomatic treatment of acute allergic rhinitis and chronic allergic rhinitis</td>
<td>Loratadine 10mg tablets</td>
<td>Pharmacy medicine</td>
<td>Protocol</td>
</tr>
<tr>
<td></td>
<td>The prophylaxis and symptomatic treatment of acute allergic conjunctivitis and chronic allergic conjunctivitis</td>
<td>Sodium Cromoglicate 2.0% eye-drops</td>
<td>Pharmacy medicine</td>
<td>Protocol</td>
</tr>
</tbody>
</table>

Continued overleaf...
<table>
<thead>
<tr>
<th>Condition</th>
<th>Indication</th>
<th>Product(s)</th>
<th>Legal category</th>
<th>Supply by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mycotic infections of the skin and nails</td>
<td>The treatment of mycotic infections of the skin and nails such as Athlete’s foot (Tinea pedis infection) and Ringworm (Tinea corporis infection).</td>
<td>Miconazole nitrate 2·0% cream (30g)</td>
<td>Pharmacy medicine</td>
<td>Protocol</td>
</tr>
<tr>
<td>Bacterial eye infections</td>
<td>The treatment of acute superficial bacterial eye infections including conjunctivitis, blepharitis, styte, and infected meibomian cyst</td>
<td>Chloramphenicol 0·5% eye-drops (10ml)</td>
<td>Prescription-only medicine (POM)</td>
<td>Patient Group Direction</td>
</tr>
<tr>
<td>Uncomplicated Urinary Tract Infections in females</td>
<td>The treatment of urinary tract infections in females aged between 16 years and 65 years</td>
<td>Nitrofurantoin 50mg capsules (12 capsules)</td>
<td>Prescription-only medicine (POM)</td>
<td>Patient Group Direction</td>
</tr>
<tr>
<td>Impetigo</td>
<td>Topical treatment for minor localised impetigo in adults and Children aged nine months and older.</td>
<td>Retapamulin 1% ointment (5g)</td>
<td>Prescription-only medicine (POM)</td>
<td>Patient Group Direction</td>
</tr>
</tbody>
</table>

The Prescription only medicines listed above must be supplied under the relevant Patient Group Directions. Pharmacists must be authorised by name to use the relevant Patient Group Direction (Pharmacists must have signed the authorisation sheet of the PGD, which must also have been signed-off by the relevant authorising manager in their company).

This document should be read in conjunction with the Minor Ailments Scheme enhanced service Service Level Agreement and the relevant Patient Group Directions.
## GENERAL CRITERIA AND CONSIDERATIONS

### A. Eligibility criteria and initial assessment
- Patient presents a minor ailment potentially treatable under a relevant Protocol within this pack;
- Patient is registered with a General Practitioner (GP) in the United Kingdom and gives permission to share relevant information with other healthcare professionals and agencies;
- Determine if the patient is exempt or pays for the applicable NHS prescription charge;
- Valid consent from patient or person with parental responsibility has been obtained. Consider the ethical and legal implications if the biological parent or the child representative is known or suspected to of having no parental responsibility for the child. Refer to the General Pharmaceutical Council and NHS Somerset consent policies;
- Establish patient clinical eligibility and inclusion criteria for the service.

### B. Exclusion criteria
- Any individual who has had a true anaphylactic reaction to a medicine, supplied under the specific Protocol (or any of its components): see the updated Summary of Product Characteristics (SPC) available at [http://www.medicines.org.uk/emc/](http://www.medicines.org.uk/emc/) for a full list of ingredients;
- Known hypersensitivity to any component of a medicine under the specific Protocol or having shown hypersensitivity after previous administration.

### C. Action if patient excluded
- Further explanation to gain consent, if appropriate.
- Refer to patient’s GP or relevant healthcare professional as applicable;
- If a Patient Medication Record (PMR) is available it may be useful to document in patient notes.
<table>
<thead>
<tr>
<th>D. When further Medical Advice should be sought</th>
</tr>
</thead>
<tbody>
<tr>
<td>• If the patient fulfils any of the criteria listed under the “Cautions” section, and the pharmacist supplying medication under any of these Protocols considers it appropriate, further medical advice should be sought and relayed to the patient/carer.</td>
</tr>
<tr>
<td>• The patient should contact a GP or relevant specialist if symptoms do not start to resolve within two to three days after starting the treatment, or if follow-up is regarded as necessary.</td>
</tr>
<tr>
<td>• Patients should be advised to seek medical attention if they develop symptoms of hypersensitivity reactions;</td>
</tr>
<tr>
<td>• Patients should be advised to seek urgent medical attention if they develop early symptoms of anaphylaxis such as breathlessness, swelling, and rash.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>E. Record specific information for the supply / administration of medicines to include details for audit trail and significant events</th>
</tr>
</thead>
<tbody>
<tr>
<td>• It is essential to complete the service pro-forma and record the following in the Patient Medication Record (PMR):</td>
</tr>
<tr>
<td>o Patient’s name, current address, and date of birth;</td>
</tr>
<tr>
<td>o Name, strength, form, and pack-size of medication supplied;</td>
</tr>
<tr>
<td>o Dose, and route of administration;</td>
</tr>
<tr>
<td>o Date supplied and by whom;</td>
</tr>
<tr>
<td>o Make relevant notes as applicable i.e. specific advice about side-effects given to patient/carer relevant to their particular presentation;</td>
</tr>
<tr>
<td>o Signed and dated (where computer records are used health professionals must have individual identifier to enable audit trail);</td>
</tr>
</tbody>
</table>

**All medicines supplied under these Protocols must be labelled in accordance with the Medicines Act 1968 as amended.**

• Additionally the following is to be noted in the patient’s medication records:
  o For children: name and relationship to patient of person with parental responsibility giving consent for supply and treatment;
  o Details of all significant events / incidents / adverse reactions relating to the supply of a medicine under these Protocols.

Continued…
### E. (Continued)
- The patient’s GP should be notified of supplies under these Protocols (including dose, quantity supplied, reason for supply, and date of supply) if consent has been obtained to do so;
- Records (including paper copies of the MAS1 if within 2 years of consultation and supply) must be available for inspection by the PCT at the pharmacy upon request;
- Records of supply should be kept for at least 8 years, or for children, until the child (i.e. any individual under the age of 18 years) is 25 years old or for 8 years after the child’s death. Records may be stored solely in electronically form after 2 years if desired;
- (NB: The product licenses of different manufacturers may vary; products supplied under these Protocols must be licensed for the intended use: check SPC or Product License for details of a manufacturer’s products licensed indications)

### F. Advice to patient / carer
- Advice the patient or carer to read the Patient Information Leaflet (PIL) before using the medicine and that the pharmacy can be contacted if any queries arise;
- Inform the patient of relevant and/or common side-effects and their management (see current SPC and BNF);
- Counselling on self-management strategies and management of the ailment. Written information to support verbal advice should be available and provided in a suitable manner. Use relevant information sources (leaflets, internet, etc.). Information should enable the client to make informed choices about their care and condition;
- The medicines supplied under any of the Protocols are for use of the patient only. It should not be shared with anyone else.
- The patient’s GP should be informed if the patient is likely to request further repeated supplies outside the conditions of these Protocols.
- All medicines should be disposed of in an appropriate manner i.e. unwanted and out of date medicines should be returned to a pharmacy for appropriate disposal.
<table>
<thead>
<tr>
<th>G. Reporting procedure of Adverse Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Any serious adverse reaction to a medicine or its excipients supplied under any of these Protocols should be documented in patient’s medication record; the patient’s GP must also be informed;</td>
</tr>
<tr>
<td>• All significant events/incidents/near misses occurring in relation to the administration of a medicine supplied under these protocols must be reported to the NHS England Area Team in a timely manner. Records should be kept for at least eight years, or for children, until the child (i.e. any individual under the age of 18 years) is 25 years old or for eight years after the child’s death.</td>
</tr>
<tr>
<td>• If an adverse reaction does occur, provide advice and inform the patient’s GP as soon as possible. Discuss with the GP the need to report the reaction to CSM/MHRA using the “Yellow Card” system.</td>
</tr>
</tbody>
</table>
PROTOCOLS

IMPORTANT NOTE:
For the General Sales List (GSL) and Pharmacy medicines detailed in the following pages (pages 9 – 22) Pharmacists must be authorised by name by completing the Protocol authorisation sheet on page 43 of this document, which must also have been signed-off by the relevant authorising manager in their company.
## ACICLOVIR 5.0% w/w CREAM

### 1.1 Defined condition / indication

The topical treatment of *Herpes simplex* virus (HSV) infections of the lips and face (*Herpes labialis*).

### 1.2 Inclusion criteria

Adults and children aged 12 months and over where all the following criteria are met:
- Small isolated lesions are visible;
- Treatment for symptoms concordant with *Herpes labialis* infection is required.

### 1.3 Exclusion criteria

**Known or suspected:**
- Pregnancy;
- Frequently recurrent *Herpes labialis*;
- Immunocompromised individuals;
- Individuals taking immunosuppressant drugs (e.g. oral steroids, cytotoxic drugs, cyclosporine, some antirheumatic drugs);
- Eczema herpeticum (Kaposi’s varicelliform eruption) (Refer urgently);
- Widespread eruptions (lesions) / severe infection, with or without fever / malaise (Refer urgently);
- Herpes simplex infection of mucous membranes.

### 1.4 Cautions / Need for further advice

- *Herpes labialis* lesions close to the eyes;
- Parents / carers of children under six months of age;
- Individuals working with children under six months of age;
- Suspected concurrent / secondary bacterial infection (e.g. impetigo, cellulitis);
- Individuals with eczema / history of eczema.

### 1.5 Action if excluded

- Eczema herpeticum / widespread eruptions with or without fever / malaise: refer urgently.
- Refer to GP or relevant specialist for further investigation if a concurrent sexually transmitted infection (STI) (including genital herpes) is a possibility.
1.6 Description of treatment

- Name, form and strength of medicine: Aciclovir 5.0% \(^w/w\) cream
- Legal Category: General Sales List (GSL) or Pharmacy Medicine (P)
- Dosage and frequency: Thinly smear over lesion(s) five times daily at approximately four hourly intervals
- Duration of treatment: five to ten days
- Total dose number to supply: one 2g tube

1.7 Arrangements for follow up

- Patients should consult their GP or a relevant specialist if the infection has not cleared up after 10 days treatment with Aciclovir 5.0% \(^w/w\) cream;
- Further supplies of Aciclovir 5.0% \(^w/w\) cream for a single episode of herpes labialis should be obtained via a patient-specific direction (i.e. prescription from a GP) or purchased over-the-counter (OTC).
## 2.1 Defined condition / indication

The treatment of vaginal candidiasis.

## 2.2 Inclusion criteria

Female adults and female children aged 16 years and older where all the following criteria are met:

- Individuals exhibiting one or more of the following symptoms characteristic of vaginal candidiasis:
  - Vulval irritation with or without discharge;
  - Pruritis vulvae;
  - White vaginal discharge (typically curd-like) with a distinctive but inoffensive odour;
  - Vulval erythema with or without fissuring;
  - Superficial dyspareunia;
  - ‘External’ dysuria.
- Relief and treatment of one of the following is required:
  - Acute vaginal candidiasis;
- Recurrent vaginal candidiasis (only once in any six month period - c.f. ‘Exclusion criteria’ below).

## 2.3 Exclusion criteria

**Known or suspected:**

- Pregnancy;
- Any individual who has had genital candidiasis more than twice in the preceding six months;
- Women with abnormal or irregular bleeding, or a blood stained or foul smelling vaginal discharge;
- Individuals with genital sores, ulcers, or blisters;
- Individuals or an individual’s partner who has been exposed to a sexually transmitted disease;
- Known or suspected sexually transmitted infections (STIs)
- Lower abdominal pain or dysuria
- Individuals with fever, chills, nausea, vomiting, or diarrhoea
- Hypersensitivity to clotrimazole or ingredients of pessary

## 2.4 Cautions / Need for further advice

- Lactation/breast feeding
- Individuals aged over 60 years
- Known or suspected diabetes
- Hypersensitivity to imidazoles or other vaginal antifungal products
### 2.5 Action if excluded

Refer to patient’s GP or relevant specialist

### 2.6 Description of treatment

- Name, form and strength of medicine: Clotrimazole 500mg pessary
- Legal Category: General Sales List (GSL) or Pharmacy Medicine (P)
- Dosage and frequency: one 500mg pessary to be inserted into the vagina at night as a single dose treatment. Using the applicator provided, the pessary should be inserted as deeply as possible into the vagina. This is best achieved when lying back with legs bent up.
- Total dose number to supply: one pessary

### 2.7 Arrangements for follow up

- Advise the patient to contact their GP for follow-up if necessary i.e. worsening or no improvement of symptoms three days after treatment.
- Refer to GP or relevant specialist for further investigation if a concurrent sexually transmitted infection (STI) is a possibility.
- The patient’s GP should be informed if the patient is likely to request further supplies of clotrimazole 500mg pessary.
### 3.1 Defined condition / indication

ADULTS and CHILDREN aged 16 years and older requiring treatment for candidal vulvitis, or;

ADULTS and CHILDREN aged one years and older requiring treatment for candidal balanitis, or cutaneous candidiasis

### 3.2 Inclusion criteria

Female adults and female children aged 16 years and older with candidal vulvitis

*Or*

Adults and children aged one year and older with candidal balanitis or cutaneous candidiasis where all the following criteria are met:

- Valid consent from patient or person with parental responsibility has been obtained;
- Relief and treatment of one of the following is required:
  - Genital candidiasis;
  - Cutaneous candidiasis (*Candida albicans* infection) (usually located in innertriginous areas (skin folds) e.g. groin, axillae, under breasts, interdigital web spaces, and at the corners of the mouth) (symptoms include redness, pain or burning, itching);
  - Acute vaginal candidiasis (e.g. pruritis vulvae, white vaginal discharge, vulval erythema with fissuring);
  - Recurrent vaginal candidiasis (>one episode in any six month period)
  - Candidal balanitis (e.g. redness, irritation, and soreness of the head of the penis (the glans).)

### 3.3 Exclusion criteria

- Children under the age of 16 years with candidal vulvitis;
- Children under the age of one year with candidal balanitis or cutaneous candidiasis;
- Pregnancy;
- Any individual who has had genital candidiasis or candidal balanitis more than twice in the preceding six months;
- Women with abnormal or irregular bleeding or a blood stained vaginal discharge;
- Men with abnormal penile discharge (leakage);
- Individuals with genital sores, ulcers, or blisters;
- Known or suspected sexually transmitted infections (STIs) or known or expected exposure to a sexually transmitted disease of patient or partner
- Known hypersensitivity or anaphylactic reaction to any component of clotrimazole 1·0% w/w cream, or having shown hypersensitivity after previous administration.
### 3.4 Cautions / Need for further advice

- Clotrimazole 1·0% cream is not suitable for the monotherapy of vaginal candidiasis;
- Lactation/breast feeding.
- Candidal vulvitis is almost invariably associated with vaginal candidiasis. In nearly all cases, therefore, patients should also be supplied with intra-vaginal or systemic treatment.

### 3.5 Action if excluded

- Refer to patient's GP or relevant specialist

### 3.6 Description of treatment

- Name, form and strength of medicine: Clotrimazole 1·0% cream
- Legal Category: General Sales List (GSL) or Pharmacy Medicine (P)
- Dosage and frequency: To be applied to the affected area(s) thinly two or three times daily and rubbed in gently. Treatment should be continued for at least two weeks for candidal infections.
- Total quantity to supply: one 20g tube

### 3.7 Arrangements for follow up

- Advise the patient to contact their GP for follow-up if necessary i.e. worsening or no improvement of symptoms three days after treatment.
- Refer to GP or relevant specialist for further investigation if a concurrent sexually transmitted infection (STI) is a possibility.
- The patient's GP should be informed if the patient is likely to request further supplies of clotrimazole cream.
### 4.1 Defined condition / indication

The treatment of genital candidiasis, acute or recurrent vaginal candidiasis, or candidal balanitis.

### 4.2 Inclusion criteria

Adults and children aged sixteen years and over where all the following criteria are met:

- Relief and treatment of one of the following is required:
  - Genital candidiasis
  - Acute vaginal candidiasis
  - Recurrent vaginal candidiasis (only once in any six month period - c.f. ‘Exclusion criteria’ below);
  - Candidal balanitis.

### 4.3 Exclusion criteria

**Known or suspected:**

- Pregnancy;
- Hepatic impairment.

### 4.4 Cautions / Need for further advice

**Known or suspected:**

- Any individual who has had genital candidiasis or candidal balanitis more than twice in the preceding six months – advise to see GP or GU clinic;
- Concurrent sexually transmitted infection (STI) (e.g. Chlamydia infection) – refer to GP or relevant specialist;
- Individuals receiving corticosteroid or other immunosuppressive treatment, including general radiation: refer to medical practitioner for further investigation if appropriate;
- Immunocompromised or immunodeficient individuals (e.g. individuals suffering with AIDS, leukaemia etc.): refer to medical practitioner for further investigation if appropriate;
- Diabetes: consider poor glycaemic control with resultant glycosuria (refer to GP or relevant specialist for further investigation if appropriate).

### 4.5 Action if excluded

- Refer to GP
4.6 Description of treatment

- Name, form and strength of medicine: Fluconazole 150mg capsule
- Legal Category: Pharmacy medicine (P)
- Dosage, frequency and duration of treatment: One Fluconazole 150mg capsule as a single oral dose
- Total dose number to supply: one capsule

4.7 Arrangements for follow up

- Advise the patient to contact their GP for follow-up if necessary i.e. worsening or no improvement of symptoms three days after treatment.
- Refer to GP or relevant specialist for further investigation if a concurrent sexually transmitted infection (STI) is a possibility.
- The patient’s GP should be informed if the patient is likely to request further supplies of a fluconazole 150mg capsule.
### 5.1 Defined condition / indication
The prophylaxis and symptomatic treatment of acute allergic rhinitis and chronic allergic rhinitis.

### 5.2 Inclusion criteria
Adults and children aged six years and over where:
- Prevention, relief and/or treatment of allergic rhinitis is required.

### 5.3 Exclusion criteria
**Known or suspected:**
- Children under the age of six years or with a body weight less than 30kg;
- Pregnancy;
- Lactation/breast feeding;
- Hepatic impairment;
- Renal impairment.

### 5.4 Cautions / Need for further advice
**Known or suspected:**
- Concomitant pharmacotherapy with macrolide antibiotics (e.g. erythromycin and clarithromycin), systemic ketoconazole, quinidine, fluoxetine, cimetidine, or any other drug that inhibits or are metabolised by cytochrome P450 isoenzymes CYP3A4 and CYP2D6.
- Prostatic hyperplasia (contra-indicated for sedating antihistamines);
- Closed-angle glaucoma (contra-indicated for sedating antihistamines);
- Pyloro-duodenal obstruction (contra-indicated for sedating antihistamines);
- Large or excessive alcohol consumption.

### 5.5 Action if excluded
- Suggest alternative treatments for relief / prophylaxis against symptoms
- Refer to GP for treatment
## 5.6 Description of treatment

- Name, form and strength of medicine: Loratadine 10mg tablets
- Legal Category: Pharmacy medicine (P)
- Dosage and frequency:
  - Adults and children over 12 years of age: 10 mg orally once daily. The tablet may be taken without regard to mealtime.
  - Children 6 to 12 years of age with:
    - Body weight more than 30 kg: 10 mg orally once daily.
    - Body weight 30 kg or less: These tablets are not suitable in children with a body weight less than 30 kg.
- Duration of treatment: one tablet daily for up to four months;
- Total dose number to supply / administer:
  - 30 tablets pack (supply of other packs sizes is not authorised under this Protocol);
  - Each individual supply under this Protocol must not exceed 30 tablets;
  - Repeat supplies to the same individual are allowed at approximately monthly intervals to a maximum of four supplies of 30 tablets in any 12 month period;
- For each supply the patient must meet the inclusion criteria (Section 1.2) and must not be excluded (Section 1.3) of this Protocol.

## 5.7 Arrangements for follow up

- Advise patient of approximate date when a further supply could be made if appropriate and necessary.
### 6.1 Defined condition / indication

The treatment of mycotic infections of the skin and nails such as:
- Athlete’s foot (*Tinea pedis* infection);
- Ringworm (*Tinea corporis* infection)

### 6.2 Inclusion criteria

Adults and children aged one year and older where all the following criteria are met:
- Symptoms include one or more of the following:
  - Well defined red area;
  - Fissuring (especially if infection between toes or fingers);
  - Fine scale on skin;
  - “Shiny” patches on skin;
  - Lesion tending to clear in the middle to give a characteristic ring;
  - Localised itching/irritation.
- Treatment of mycotic infection of the skin is required.

### 6.3 Exclusion criteria

**Known or suspected:**
- Pregnancy;
- Fungal infection of the nails;
- Individuals receiving pharmacotherapy with oral anticoagulants (e.g. warfarin);
- Thrush;
- Infections of involving mucous membranes.

### 6.4 Cautions / Need for further advice

**Known or suspected:**
- Lactation/breast feeding;
- Diabetics with mycotic infections of the feet

### 6.5 Action if excluded

- Refer to GP
### 6.6 Description of treatment

- **Name, form and strength of medicine:** Miconazole nitrate 2.0%\text{w/w} cream
- **Legal Category:** Pharmacy Medicine (P)
- **Dosage and frequency:** To be applied to the affected area(s) thinly two to three times daily and rubbed in gently. Treatment should be prolonged for 10 days after all lesions have disappeared to prevent relapse.
- **Total dose number to supply / administer:**
  - One 30g tube (labelled in accordance with the *Medicines Act 1968* as amended);
  - Any further supply is outside the scope of this Protocol and must be supplied by patient-specific direction (i.e. an NHS FP10 prescription) from an appropriate prescriber.
- **NB:** Miconazole nitrate 2.0%\text{w/w} cream is available in various pack sizes; ONLY the supply of the 30g tube pack size is authorised under this Protocol.

### 6.7 Arrangements for follow up

- Advise the patient to contact their GP for follow-up if necessary i.e. worsening or no improvement of symptoms three days after treatment.
- The patient’s GP should be informed if the patient is likely to request further supplies of miconazole 2% cream.
## 7.1 Defined condition / indication

The prophylaxis and symptomatic treatment of acute allergic conjunctivitis and chronic allergic conjunctivitis.

## 7.2 Inclusion criteria

Adults and children aged three years and over where prevention, relief and treatment of allergic conjunctivitis symptoms is required.

## 7.3 Exclusion criteria

Children under the age of three years.

## 7.4 Cautions / Need for further advice

Patients wearing contact lenses.

## 7.5 Action if excluded

- Refer to patient’s GP or relevant healthcare professional as applicable
- Allergic conjunctivitis of unknown cause and individual has previously been treated with sodium cromoglicate eye-drops (OTC or under PGD or on prescription): refer for further investigation
### 7.6 Description of treatment

- Name, form and strength of medicine: Sodium Cromoglicate 2.0% w/v eye-drops
- Legal Category: **Pharmacy only medicine**
- Dosage and frequency: one or two drops to be instilled into each eye four times a day
- Total dose number to supply / administer:
  - 10 ml (up to four weeks treatment) (Labelled in accordance with the *Medicines Act 1968* as amended)
  - Repeat supplies to the same individual (where cause of allergy has been identified) are allowed at approximately monthly intervals to a maximum of six supplies 10 ml in any 12 month period;
  - Repeat supplies for individuals where cause of allergy has **not** been identified are not permitted.

### 7.7 Arrangements for follow up

- Advise patient of approximate date when a further supply could be made if appropriate and necessary.
SUMMARY OF PATIENT GROUP DIRECTIONS

IMPORTANT NOTE:

The Prescription only medicines detailed in the following pages (pages 24 -34) must be supplied under the relevant Patient Group Directions. Pharmacists must be authorised by name to use the relevant Patient Group Direction (PGD) (Pharmacists must have signed the authorisation sheets of the relevant PGD, which must also have been signed-off by the relevant authorising manager in their company.

Please refer to the relevant PGDs for details.
BNSSSG Patient Group Direction

For the supply of

Chloramphenicol 0.5% eye drops and
Chloramphenicol 1.0% eye ointment

By Community Pharmacists in Somerset to patients for the treatment
of acute superficial bacterial eye infections

under the Somerset Minor Ailments Scheme service level agreement with
NHS England BNSSSG Area team 2014/15

Version number: 2.0

The summary of the condition and its treatment with the medicine under
the relevant Patient Group Direction is included in this document for
reference only. Please refer to the relevant PGDs for the detailed conditions
of treatment and supply.
**Clinical condition**

<table>
<thead>
<tr>
<th>Clinical condition or situation to which this PGD applies</th>
<th>The treatment of acute superficial bacterial eye infections including conjunctivitis, blepharitis, or stye.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inclusion criteria</strong></td>
<td>Adults and children aged one month and older where all the following criteria are met:</td>
</tr>
<tr>
<td></td>
<td>- Valid consent from patient or person with parental responsibility has been obtained. Consider the ethical and legal implications if the biological parent or the child representative is known or suspected to of having no parental responsibility for the child;</td>
</tr>
<tr>
<td></td>
<td>- Patient is registered with a General Practitioner (GP) in the United Kingdom and gives permission to share relevant information with other healthcare professionals and agencies;</td>
</tr>
<tr>
<td></td>
<td>- Individuals exhibiting one or more of the following symptoms characteristic of superficial bacterial eye infections:</td>
</tr>
<tr>
<td></td>
<td>- Diffuse conjunctival injection;</td>
</tr>
<tr>
<td></td>
<td>- Purulent discharge;</td>
</tr>
<tr>
<td></td>
<td>- Discomfort (e.g. burning or gritty sensation);</td>
</tr>
<tr>
<td></td>
<td>- Minimal pruritis;</td>
</tr>
<tr>
<td></td>
<td>- Mild photophobia;</td>
</tr>
<tr>
<td></td>
<td>- Eye-lid inflammation (blepharitis);</td>
</tr>
<tr>
<td></td>
<td>- Infected meibomian cyst (chalazion);</td>
</tr>
<tr>
<td></td>
<td>- Stye;</td>
</tr>
<tr>
<td></td>
<td>- Usually progressing from unilateral to bilateral symptoms;</td>
</tr>
<tr>
<td></td>
<td>- History of close contact with another individual with a bacterial eye infection.</td>
</tr>
<tr>
<td></td>
<td>- Symptoms have been present for two weeks or less;</td>
</tr>
<tr>
<td></td>
<td>- Treatment of acute superficial bacterial eye infection(s) is required.</td>
</tr>
</tbody>
</table>

| **Exclusion criteria**                                   | |
|----------------------------------------------------------| |
|                                                          | - Baby aged less than one month; |
|                                                          | - Known or suspected gonococcal conjunctivitis, viral conjunctivitis, fungal conjunctivitis, corneal ulcer, or keratitis (refer to relevant specialist); |
|                                                          | - Known or suspected ophthalmia neonatorium (gonococcal/ chlamydial conjunctivitis in first three months of life - urgently refer); |
|                                                          | - Known or suspected endophthalmitis (medical emergency: urgently refer to an appropriate specialist); |
|                                                          | - Known or suspected trachoma (chronic infection with *Chlamydia trachomatis*); |
|                                                          | - Known, or suspected, shingles - *Herpes zoster* infection - urgently refer; |
|                                                          | - Severe or recurrent superficial bacterial eye infections; |
|                                                          | - Visual disturbances (except those due to purulent discharge) e.g. reduced visual acuity (blurred vision) with, or without, red eye (urgently refer); |
|                                                          | - Moderate or severe photophobia (urgently refer); |
|                                                          | - Eye pain from within the eye ball (urgently refer); |
### SOMERSET MINOR AILMENTS SCHEME

- Abnormal pupils (urgently refer);
- Foreign body (urgently refer);
- Severe inflammation (urgently refer);
- Concurrent myelotoxic drug therapy;
- Previous use of Chloramphenicol for prolonged periods (may increase the likelihood of sensitisation and resistance);
- Known hypersensitivity to chloramphenical or any component of chloramphenicol 0.5% eye drops or 1% eye ointment

For full details see SPC, link in references

### Cautions/special considerations/ need for further advice

- Pregnancy;
- Lactation/breast feeding;

Eye drops should be used in preference to ointment if other eye drops are being used concurrently (e.g. for glaucoma).

### When further Medical Advice should be sought

If the patient fulfils any of the criteria listed under the “Cautions” section above, and the pharmacist supplying medication under this PGD considers it appropriate, further medical advice should be sought and relayed to the patient/carer.

- In the rare event of a possible sensitisation reaction or severe local irritation occurring with the Chloramphenicol 0.5%/v eye-drops or Chloramphenicol 1·0%/w eye ointment, treatment should be discontinued; the patient should seek further medical advice regarding a possible alternative therapy;
- If visual disturbances, moderate or severe photophobia, marked eye pain, abnormal pupils, loss of visual acuity, marked redness of the eye or severe inflammation develop the patient should urgently seek further medical advice.
- Patients should be advised to seek urgent medical attention if they develop early symptoms of anaphylaxis such as breathlessness, swelling, and rash.
- Advise the patient to contact their GP for follow-up if necessary i.e. worsening or no improvement of symptoms after three or four days of treatment initiating treatment with topical chloramphenicol.
- Patients should consult their GP if their symptoms persist for longer than two weeks.

### Action to be taken if patient excluded

- Document reason for exclusion and any action taken or advice given in the clinical records
- Refer to GP or for urgent medical attention as appropriate

### Action to be taken if patient declines treatment

- Refer to GP or for urgent medical attention as appropriate
## Details of the medicine

| Name, form and strength of medicine | • Chloramphenicol 0.5%w/v eye-drops;  
| | • Chloramphenicol 1.0%w/w eye ointment. |
| Legal category | POM – Prescription Only Medicine |
| Route/method of administration | Topical ophthalmic |
| **Dose and frequency** | o *If eye–drops are used alone:* Initially apply **one drop every two hours** whilst awake then reduce frequency of application to **four times a day** as infection is controlled and continue for 48 hours after infection has been eradicated; or  
| | o *If eye ointment is used alone:* Initially apply four times a day, and as the infection clears continue applying three to four times a day, and continue for 48 hours after infection has been eradicated; or  
| | o *If severe infection use eye-drops in conjunction with eye ointment applied once daily at night:* Initially apply **one drop** of the eye-drops **every two hours**, during the day, then reduce frequency of application to **three times a day**, continuing to apply the eye ointment at night, as infection is controlled and continue for 48 hours after infection has been eradicated. |
| **Duration of treatment** | • Maximum of seven days treatment.  
| | • If symptoms do not start to resolve within three to four days of initiating treatment, the patient should seek further medical advice. |
| **Total number to supply** | • One 10ml bottle of chloramphenicol 0.5%/v eye-drops; or  
| | • One 4g tube of chloramphenicol 1.0%/w eye ointment; or  
| | • One 10ml bottle of chloramphenicol 0.5%/v eye-drops and one 4g tube of chloramphenicol 1.0%/w eye ointment. |
| | Any further supply is outside the scope of this PGD and must be supplied by patient-specific direction (i.e. an NHS FP10 prescription) from an appropriate prescriber. |
| **All Prescription Only Medicines (POMs) must be labelled in accordance with the Medicines Act 1968 as amended** | • Dispensing considerations:  
| | o Pharmacy-Only packs of Chloramphenicol eye-drops or ointment are not licensed for use for more than five days, or in children less than two years therefore cannot be supplied under this PGD. |
| | Take care to select the correct formulation of Chloramphenicol drops i.e. not to be confused with ear drops. |
| **Adverse effects** | • Transient stinging, burning, blurring of vision or irritation may occur after application of eye-drops or eye ointment;  
| Reporting procedure of adverse reactions | - Any serious adverse reaction should be documented e.g. in the consent forms, patient's medical record and the GP should also be informed.
- Any serious adverse events that may be attributable to chloramphenicol eye drops or ointment should be reported to the MHRA using the yellow card system (www.yellowcard.gov.uk) and also follow the local incident reporting procedure. |
| Additional facilities | - Consultation room available for discussion |
| Records to be kept | It is a legal requirement to keep auditable records of administration and supply of medication via a PGD. Information entered into a patient clinical record should include:
- Patient's name, address and date of birth
- Consent given
- Indication
- Name strength form and pack size of medication supplied
- Date supplied
- Information and advice given to the patient.
- Signature/name and GPhC number of pharmacist who supplied the medication, and name and address of pharmacy
- Details of any drug interactions experienced
- Details of any adverse reactions experienced
- Any patient decline or reason for exclusion
- Record that medicine supplied via Patient Group Direction

The GP practice should be informed of the consultation and supply of medication.
Data must be stored in accordance with Caldicott guidance and the Data Protection Act.
A computer or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes within each practice. Check with employer which method of recording is to be used. |
| Follow up | - Adverse effects: Any adverse effects should be documented in the patient's record, the patient's GP practice informed and unusual/persistent side effects should be followed up with a medical practitioner |
Patient information

### Information to be given to patient or carer

- Advise patient on self-management strategies for superficial eye-infections:
  - Infective conjunctivitis is a self-limiting illness that usually settles without treatment within one to two weeks;
  - Remove contact lenses until all symptoms and signs of infection have completely resolved, and any treatment has been completed for 24 hours;
  - Lubricant eye drops may reduce eye discomfort; these are available over the counter;
  - Clean away infected secretions from eyelids and lashes with cotton wool soaked in water;
  - Wash hands regularly, particularly after touching infected secretions, and avoid sharing pillows and towels.

- If the patient uses other eye-drops/eye ointments:
  - In the case of eye-drops, wait at least 10 minutes after use before administering Chloramphenicol;
  - In the case of eye ointments, wait as long as possible before administering Chloramphenicol;

- Application of the eye-drops and/or eye ointment may temporarily blur the patient’s vision. Individuals should not drive or operate machinery until their vision is clear;

- Advise the patient on the importance of regular application and course completion (i.e. continue treatment for 48 hours after infection has cleared up to a maximum of seven days treatment);

- Inform of the main possible side-effects and their management (see SPC, current BNF and “Adverse reactions” section above);

- Advice the patient or carer of person to read the Patient Information Leaflet (PIL) before using the medicine and that the pharmacy can be contacted if any queries arise (any written PIL not produced by the manufacturer must not to be confused with the manufacturer’s PIL for legal and consent purposes);

- The eye-drops should be stored at between 2ºC and 8 ºC. The eye ointment should be stored at room temperature (below 25 ºC);

- The Chloramphenicol 0·5%/v eye-drops or Chloramphenicol 1·0%/w eye ointment supplied is for use of the patient only. It must not be shared with anyone else;

- Patients must dispose of topical ophthalmic preparations containers 28 days after opening even if they are not empty;

- All medicines should be disposed of in an appropriate manner i.e. unwanted and out of date medicines should be returned to a pharmacy for appropriate disposal.
BNSSSG Patient Group Direction

for the supply of

Nitrofurantoin 50mg capsules

By Community Pharmacists in Somerset to patients for the treatment of uncomplicated urinary tract infections

The summary of the condition and its treatment with the medicine under the relevant Patient Group Direction is included in this document for reference only. Please refer to the relevant PGDs for the detailed conditions of treatment and supply.
## Clinical condition

| Background information | Urinary tract infections (UTIs) are very common. They can be painful and uncomfortable, but they usually pass within a few days or can be easily treated with a course of antibiotics. UTIs are more common in women than in men. It's estimated half of all women in the UK will have a UTI at least once in their life, and 1 in 2,000 healthy men will develop one each year. Symptoms of UTI include:  
- pain or a burning sensation when urinating (dysuria)  
- a need to urinate often  
- pain in the lower abdomen |
| Clinical condition or situation to which this PGD applies | The treatment of urinary tract infection in females aged between 16 years and 65 years. |
| Inclusion criteria |  
- All women aged between 16 years and 65 years requiring treatment for an uncomplicated lower urinary tract infection  
- Informed consent obtained and documented in patients clinical record and/or notes  
- Patient is registered with a GP in the United Kingdom and gives permission to share relevant information with other health care professionals. |
| Exclusion criteria |  
- Consent not obtained (if capacity is a problem, refer to GP)  
- Males  
- Under 16 years of age  
- Over 65 years of age  
- Pregnant or breast feeding patients  
- Patients with symptoms which could indicate sepsis e.g. significant flank pain, fever, chills, rigors, confusion, vomiting – refer for urgent medical attention  
- Individuals with known or suspected  
  - G6PD deficiency  
  - Diabetes mellitus  
  - Renal impairment (eGFR < 45ml/min/1.73m² – see MHRA guidance in references)  
  - Hepatic impairment  
  - Acute porphyria  
  - Pulmonary disease  
  - Neurological disorders |
| **Exclusion criteria continued** | o Blood disorders or dyscrasias  
| | o Treatment for HIV  
| | o Significant immunosuppression  
| | - Known hypersensitivity to nitrofurantoin or any component of nitrofurantoin capsules  
| | For full details see SPC, link in references |
| **Cautions/special considerations/need for further advice** | • Nitrofurantoin can interfere with some tests for glucose in the urine  
| | • Individuals currently taking any of the following drugs:  
| | o Probenecid  
| | o Sulphinpyrazone  
| | o Carbonic anhydrase inhibitors i.e. acetazolamide  
| | o Quinolone antibiotics eg ciprofloxacin  
| | o Magnesium trisilicate or calcium salt-based antacids (reduce absorption)  
| | o Oestrogens: Nitrofurantoin may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of oestrogen-containing contraceptive products. Therefore, patients should be warned appropriately and extra contraceptive precautions taken.  
| | o Oral typhoid vaccine: avoid Nitrofurantoin for 3 days before and after |
| **Arrangements for referral for medical advice** | • Refer to GP if patient excluded or if no valid consent |
| **Action to be taken if patient excluded** | • Document reason for exclusion and any action taken or advice given in the clinical records  
| | • Refer to GP or for urgent medical attention as appropriate |
| **Action to be taken if patient declines treatment** | • Refer to GP or for urgent medical attention as appropriate |
## Details of the medicine

<table>
<thead>
<tr>
<th>Name, form and strength of medicine</th>
<th>Nitrofurantoin 50mg capsules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal category</td>
<td>POM – Prescription Only Medicine</td>
</tr>
<tr>
<td>Route/method of administration</td>
<td>Oral</td>
</tr>
<tr>
<td>Dose and frequency</td>
<td>50mg four times daily (every 4 to 6 hours)</td>
</tr>
<tr>
<td>Duration of treatment</td>
<td>Three days</td>
</tr>
<tr>
<td>Total number to supply</td>
<td>Original pack of 30 capsules, labelled as above for three days treatment</td>
</tr>
<tr>
<td>Use outside terms of SPC</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
| Adverse effects                     | • Acute pulmonary reactions which are reversible with cessation of therapy; symptoms include fever, chills, cough, chest pain, dyspnoea;  
  • Peripheral neuropathy (including optical neuritis) with symptoms of sensory as well as motor involvement, which may become severe or irreversible, has been reported infrequently;  
  • Allergic skin reactions: angioneurotic oedema, maculopapular, erythematous or eczematous eruptions, urticaria, and pruritus;  
  • Hepatic reactions including cholestatic jaundice and chronic active hepatitis occur rarely;  
  • Nausea and anorexia; emesis, abdominal pain and diarrhoea are less common gastrointestinal reactions;  
  • Blood dyscrasias which generally return to the normal blood picture with cessation of therapy;  
  
  See the Summary of Product Characteristics (SPC) and the current edition of the BNF for full details and updates. |
| Reporting procedure of adverse reactions | • Any serious adverse reaction should be documented e.g. in the consent forms, patient’s medical record and the GP should also be informed.  
  • Any serious adverse events that may be attributable to nitrofurantoin should be reported to the MHRA using the yellow card system ([www.yellowcard.gov.uk](http://www.yellowcard.gov.uk)) and also follow the local incident reporting procedure. |
| Additional facilities               | • Consultation room available for discussion |
BNSSSG Patient Group Direction

For the supply of

Retapamulin 1% ointment

By Community Pharmacists in Somerset to patients for the topical treatment of minor localised impetigo

The summary of the condition and its treatment with the medicine under the relevant Patient Group Direction is included in this document for reference only. Please refer to the relevant PGDs for the detailed conditions of treatment and supply.
### Clinical condition

**Clinical condition or situation to which this PGD applies**

Adults and Children aged nine months and older requiring topical treatment for minor localised impetigo.

**Inclusion criteria**

Adults and children aged nine months and older where all the following criteria are met:

- Valid consent from patient or person with parental responsibility has been obtained. Consider the ethical and legal implications if the biological parent or the child representative is known or suspected to of having no parental responsibility for the child;
- Patient is registered with a General Practitioner (GP) in the United Kingdom and gives permission to share relevant information with other healthcare professionals and agencies;
- Small isolated lesions are visible;
- Treatment of impetigo is required.

**Exclusion criteria**

- Children under the age of nine months;
- Known or suspected pregnancy;
- Lactation/breast feeding;
- Individuals presenting with extensive or long-standing impetigo lesions (systemic treatment is more appropriate);
- Patients who are systemically unwell as a result of their impetigo (systemic treatment is more appropriate);
- Impetigo infections extending to mucous membranes, or intranasal areas;
- Patients known to be colonised with MRSA;
- Children under the age of 2 taking a medicine that inhibits the CYP3A4 enzyme.
- Any individual who has had a true anaphylactic reaction to Retapamulin or any component of Retapamulin ointment; see SPC for a full list of excipients;
- Known hypersensitivity to any component of the Retapamulin ointment or having shown hypersensitivity after previous administration.
- Maximum skin treated area of 100cm² (adults) or lesion length <10cm or <2% body surface area (children).

**Cautions/special considerations/ need for further advice**

- Impetigo close to eyes (avoid ointment near eyes);
- Retapamulin is a strong inhibitor of CYP3A4. However, since plasma concentrations of retapamulin during topical application have been low it is not expected that concurrent systemic administration of CYP3A4 substrates will result in clinically important inhibition of their metabolism by retapamulin.

**Action to be taken if patient excluded**

- Further explanation to gain consent, if appropriate.
- Refer to patient’s GP or relevant healthcare professional as applicable;
- If a Patient Medication Record (PMR) is available it may be useful to document in patient notes.
| Action to be taken if patient declines treatment | • Refer to GP if appropriate |
Details of the medicine

<table>
<thead>
<tr>
<th>Name, form and strength of medicine</th>
<th>Retapamulin 1% ointment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal category</td>
<td>POM – Prescription Only Medicine</td>
</tr>
<tr>
<td>Route/method of administration</td>
<td>Topical</td>
</tr>
<tr>
<td>Dose and frequency</td>
<td>A thin layer of ointment to be applied to the affected area twice daily.</td>
</tr>
<tr>
<td>Duration of treatment</td>
<td>Five days.</td>
</tr>
</tbody>
</table>
| Total number to supply              | • One 5g tube.  
  (Labelled in accordance with the Medicines Act 1968 as amended)  
  • Any further supply is outside the scope of this PGD and must be supplied by patient-specific direction (i.e. an NHS FP10 prescription) from an appropriate prescriber. |
| Adverse effects                     | • Common: skin irritation;  
  • Uncommon: pain, pruritus, erythema, contact dermatitis.  
  See the Summary of Product Characteristics (SPC) (http://www.medicines.org.uk/emc/) and the current edition of the BNF for full details and updates. |
| Reporting procedure of adverse reactions | • Any serious adverse reaction should be documented e.g. in the consent forms, patient’s medical record and the GP should also be informed.  
  • Any serious adverse events that may be attributable to retapamulin ointment should be reported to the MHRA using the yellow card system (www.yellowcard.gov.uk) and also follow the local incident reporting procedure. |
| Additional facilities               | • Consultation room available for discussion |
Records to be kept

It is a legal requirement to keep auditable records of administration and supply of medication via a PGD.

Information entered into a patient clinical record should include:

- Patient’s name, address and date of birth
- Consent given
- Indication
- Name strength form and pack size of medication supplied
- Date supplied
- Information and advice given to the patient.
- Signature/name and GPhC number of pharmacist who supplied the medication, and name and address of pharmacy
- Details of any drug interactions experienced
- Details of any adverse reactions experienced
- Any patient decline or reason for exclusion
- Record that medicine supplied via Patient Group Direction

The GP practice should be informed of the consultation and supply of medication.

Data must be stored in accordance with Caldicott guidance and the Data Protection Act.

A computer or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes within each practice. Check with employer which method of recording is to be used.

Follow up

- Adverse effects: Any adverse effects should be documented in the patient’s record, the patient’s GP practice informed and unusual /persistent side effects should be followed up with a medical practitioner

When further Medical Advice should be sought

- If the patient fulfils any of the criteria listed under the “Cautions” section and pharmacist supplying medication considers it appropriate;

Patient information

Information to be given to patient or carer

- Advise patient/carer on self-management strategies for impetigo;
- Advise the patient/carer on the importance of regular application and course completion (five days);
- The patient/carer should contact a GP or relevant specialist if there is no improvement or a worsening in the affected area after 2-3 days of treatment;
- If impetigo has not resolved after 5 days further medical advice should be sought;
- The bacteria that cause the infection live under the crusts so it is important to remove the crusts with warm soapy water before each application;
- When retapamulin 1% ointment is used on face, take care to avoid the eyes, nasal mucosa, mouth or lips; if the ointment accidently gets on to the eyes, nasal mucosa, mouth or lips, wipe and rinse off;

Information to be given to patient or carer (continued)
• In the event of local irritation occurring with retapamulin 1% ointment, treatment should be discontinued and the product should be rinsed off. The patient should seek further medical advice regarding a possible alternative therapy;

• Patients should be advised to seek urgent medical attention if they develop early symptoms of anaphylaxis such as breathlessness, swelling, and rash;

• Concurrent application of retapamulin and other topical medicinal products to the same area of skin has not been studied, and is not recommended;

• Children with impetigo should not go to school or nursery until the ointment has been used for at least 48 hours and there are no new blisters or crusts appearing;

• Individuals with impetigo who prepare food as part of their job should stay off work for at least one week and until all spots, blisters, and crusts have disappeared and completely healed;

• Inform the patient of the possible side-effects and their management (see SPC, current BNF and “Adverse reactions” section above);

• Advice the patient or carer of person to read the Patient Information Leaflet (PIL) before using the medicine and that the pharmacy can be contacted if any queries arise;

• The retapamulin 1% ointment supplied is for use of the patient only. It should not be shared with anyone else;

• Patients must dispose of open tubes 5 days after opening even if they are not empty;

• All medicines should be disposed of in an appropriate manner i.e. unwanted and out of date medicines should be returned to a pharmacy for appropriate disposal.
This medication listed below must be supplied under the relevant Patient Group Directions. Pharmacists must be authorised by name to use the relevant Patient Group Directions (Pharmacists must have signed the authorisation sheet of the PGDs, which must also have been signed-off by the relevant authorising manager in their company).

The summary of the condition and its treatment with the medicine under the relevant Patient Group Direction is included in this document (above) for reference only. Please refer to the relevant PGDs for the detailed conditions of treatment and supply.

<table>
<thead>
<tr>
<th>Patient Group Direction</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloramphenicol eye drops 0.5% and Chloramphenicol eye ointment 1.0%</td>
<td>ADULTS and CHILDREN aged one month and older requiring topical treatment for acute bacterial eye infections.</td>
</tr>
<tr>
<td>Nitrofurantoin capsules 50mg</td>
<td>FEMALE ADULTS and CHILDREN aged between 16 years and 65 years with symptoms of uncomplicated acute urinary tract infection (UTI)</td>
</tr>
<tr>
<td>Retapamulin 1% ointment</td>
<td>ADULTS and CHILDREN aged nine months and older requiring topical treatment for minor localised impetigo</td>
</tr>
</tbody>
</table>

For detailed information and guidance please refer to relevant PGD separately.
REFERENCES TO NATIONAL / LOCAL POLICIES OR GUIDELINES:

All references given are current at the time of authorisation of these Protocols. Guidance and/or best practice may change before these Protocols are revised – pharmacists should be responsible for checking they are referring to most up to date sources of information and best practice.

- Current edition of *British National Formulary* (BNF);
- Current edition of the *BNF for children*;
- Medicines Act 1968 (as amended)
- Summaries of Product Characteristics (SPCs) (Available at [www.medicines.org.uk](http://www.medicines.org.uk));
# PROFESSIONAL CONSIDERATIONS

You must be authorised by Name, under the Current Version of these Protocols before you attempt to work according to it

| A. Target audience and Scope | • Community Pharmacists currently registered with the GPhC authorised by name, under the current version of these Protocols before working under it;  
• MAS Protocols are not a form of prescribing: consist of an authorisation to supply a specific medicine for a specific condition in specific circumstances. |
| B. Additional requirements | • The health professional is professionally accountable for this work and should be working within his/her competence;  
• Should always refer to the manufacturers Summaries of Product Characteristics (SPCs) for a more complete overview of the medicine supplied/administered under these Protocols;  
• Must be able to access these Protocols when needed; therefore should make a copy of this guidance available in the clinical setting.  
• He / she must have undertaken appropriate training to carry out clinical assessment of a patient leading to diagnosis that requires treatment according to the indications listed in these Protocols. |
| C. Additional information | • The product supplied to the patient under these Protocols must be licensed for the intended uses under the Protocols.  
• Any written Patient Information Leaflet (PIL) not produced by the manufacturer must not to be confused with the manufacturer’s PIL for legal and consent purposes.  
• All professionals supplying the drug authorised by these Protocols should first check the BNF section on drug interactions if the patient is taking existing medication and decide to supply or not according to their professional judgement. |
| D. Continued education and training | • Maintenance of own level of updating with evidence of continued professional development (GPhC CPD requirements for pharmacists). |
## MINOR AILMENTS SCHEMES PROTOCOLS 2014-2015

### Protocol Authorisation for Registered Pharmacists

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aciclovir 5.0% cream</td>
<td>2g</td>
</tr>
<tr>
<td>Clotrimazole 500mg pessary</td>
<td>1</td>
</tr>
<tr>
<td>Clotrimazole 1% cream</td>
<td>20g</td>
</tr>
<tr>
<td>Fluconazole 150mg capsule</td>
<td>1</td>
</tr>
<tr>
<td>Loratadine 10mg tablets</td>
<td>30</td>
</tr>
<tr>
<td>Miconazole nitrate 2.0% cream</td>
<td>30g</td>
</tr>
<tr>
<td>Sodium Cromoglicate 2.0% eye drops</td>
<td>10ml</td>
</tr>
</tbody>
</table>

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

*I have read and understood the protocols and agree to supply / administer this medicine only in accordance with these protocols.*

**IMPORTANT:** Completion of this Protocol Authorisation sheet does not authorise the individual named below to supply the Prescription-only medicines\(^1\) that are included in the Minor Ailments Scheme.

### Protocol authorisation for Registered Pharmacists

<table>
<thead>
<tr>
<th>Details</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Pharmacist</td>
<td></td>
</tr>
<tr>
<td>GPhC registration no.</td>
<td></td>
</tr>
<tr>
<td>Signature</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td></td>
</tr>
<tr>
<td>Authorising Manager (company pharmacy manager, area manager or superintendent pharmacist)</td>
<td></td>
</tr>
<tr>
<td>Date:</td>
<td></td>
</tr>
</tbody>
</table>

The Authorising Manager should keep this completed authorisation sheet safely (it does **not** need to be sent to the Area Team but should be made available on request).

Individual pharmacists should also retain an individual copy of this document and this completed authorisation sheet.

\(^1\) Prescription-only medicines to be supplied under the Minor Ailments Scheme must be supplied under the relevant Patient Group Directions. Pharmacists must be authorised by name to use the relevant Patient Group Directions by signing the authorisation sheet of the PGDs, which must also have been signed-off by the relevant authorising manager in their company.