NHS Somerset

PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY OF

RETAPAMULIN 1% OINTMENT

BY PHARMACISTS TO PATIENTS FOR THE TOPICAL TREATMENT OF MINOR LOCALISED IMPETIGO

Version:	1.3
Name of Originator/Author:	Ana Alves, Practicing Professional LPN-Pharmacy, NHS Somerset
Acknowledgments:	Stephen Du Bois, Chair Pharmacy-LPN, NHS Somerset
Approved by:	Lucy Watson, Director of Nursing and Patient Safety
Date issued:	14 December 2012
Review date:	31 December 2014 or in light of significant changes in best practice

SOMERSET PRIMARY CARE TRUST

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RETAPAMULIN 1% OINTMENT

FOR THE TOPICAL TREATMENT OF MINOR LOCALISED IMPETIGO

VERSION CONTROL

Document Status:	Final
Version:	1.3

DOCUMENT CHANGE HISTORY		
Version	**Date**	**Comments**
1.0	December 2012	Drafted by Ana Alves, Pharmacist
1.1	December 2012	Reviewed by Stephen Du Bois, Locality Medicines Manager
1.2	December 2012	Reviewed by Dr Lindsay Smith, General Practitioner, Patient Safety Lead
1.3	December 2012	Reviewed by Dr Robert Baker, Lead for Antimicrobial Prescribing

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Acknowledgments:	Stephen DuBois, Chair Pharmacy-LPN, NHS Somerset
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PATIENT GROUP DIRECTION (PGD) FOR:

DRUG: Retapamulin 1% ointment
CONDITION: ADULTS and CHILDREN aged 9 months and older requiring topical treatment for minor localised impetigo
PROFESSIONAL GROUP: Registered Pharmacists

You must be Authorised by Name, Under the Current Version of this PGD before you attempt to work according to it

Clinical Condition		
1.	**Defined condition / indication**	Adults and Children aged nine months and older requiring topical treatment for minor localised impetigo.
2.	**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.

3.	**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 100cm^2 (adults) or lesion length <10cm or <2% body surface area (children)
4.	**Cautions / Need for further advice**	• Impetigo close to eyes (avoid ointment near eyes); • Retapamulin was shown to be 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.
5.	**Action if patient declines or is 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.

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Drug Details		
6.	**Name, form and strength of medicine**	Retapamulin 1% ointment
	Legal Category	Prescription Only Medicine (POM)
	Black Triangle Status	None.
	Route / method of administration	Topical.
	Dosage and frequency	A thin layer of ointment to be applied to the affected area twice daily.
	Duration of treatment	Five days.
	Total dose number to supply / administer	• 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.
7.	**Additional facilities**	This patient group direction should be available in the clinical setting.
8.	**Adverse reactions**	• 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.

9.	**Reporting procedure of Adverse Reactions**	• Any serious adverse reaction to Nitrofurantoin, or any of the excipients of the capsules should be documented in the patient's medication record. The patient's GP must also be informed. Discuss with the GP the need to report the reaction to CSM/MHRA using the "Yellow Card" system; • All significant events/incidents/near misses occurring in relation to the supply of Nitrofurantoin capsules under this PGD must be reported to the PCT in a timely manner (see the current version of the Somerset PCT policy on incident reporting).
10.	**Advice to patient / 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. • Do not mix other preparations with the ointment (e.g. antiseptic creams, cosmetics etc.) as this risks dilution, resulting in a reduction of antibacterial activity and potential loss of stability of the active ingredient; • 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.
11.	**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; • If the ointment accidently gets on to the eyes, nasal mucosa, mouth or lips rinse and caused discomfort after wiping and rinsing it off. • In the event of a sensitisation reaction or 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 medical attention if they develop symptoms of hypersensitivity reactions; • Patients should be advised to seek urgent medical attention if they develop early symptoms of anaphylaxis such as breathlessness, swelling, and rash.

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Referral Arrangements and Audit Trail		

12.	**Record specific information for the supply/administration of medicines to include details for audit trail and significant events**	• In all cases manual records and/or computerised records should include:
		  ○ Patient's name, current address, and date of birth;
		  ○ Name, strength, form, and pack-size of medication supplied;
		  ○ Dose, and route of administration;
		  ○ Date supplied and by whom;
		• Additionally the following is to be noted in the patient's medication records:
		  ○ For children: Name and relationship to patient of person with parental responsibility giving consent for supply and treatment.
		  ○ Details of all significant events / incidents / adverse reactions relating to the supply of Retapamulin 1% ointment under this PGD;
		• The patient's GP should be notified that Retapamulin 1% ointment has been supplied under this PGD (including dose, quantity supplied, reason for supply, and date) 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.

		• All significant events/incidents/near misses occurring in relation to the administration of Retapamulin 1% ointment under this PGD must be reported to the PCT on the relevant PCT incident form in a timely manner.

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Staff Characteristics	
Professional qualifications	• Pharmacist currently registered with the General Pharmaceutical Council.
Specialist competencies or qualifications	• Approved training (if any) as defined in the Service Level Agreement; • Competent to assess the person's capacity to understand the nature and purpose of the treatment in order to give or refuse consent.
Continued education & training	• Maintenance of own level of updating with evidence of continued professional development: ○ GPhC CPD requirements for pharmacists.
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 Summary of Product Characteristics (SPC) for a more complete overview of the medicine supplied/administered under this PGD; • Must be authorised by name under the current version of this PGD before working under it; • Must be able to access this PGD when needed; • 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 this PGD.

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References / Resources and comments	• Current edition of *British National Formulary* (BNF); • Current edition of the *BNF for children*; • General Pharmaceutical Council. *Standards of conduct, ethics and performance* (Current version. Available at www.pharmacyregulation.org.uk); • General Pharmaceutical Council. *Standards for continuing professional development* (Current version. Available at www.pharmacyregulation.org.uk); • General Pharmaceutical Council. *Guidance: Consent* (Current version. Available at www.pharmacyregulation.org.uk); • General Pharmaceutical Council. *Guidance: Patient Confidentiality* (Current version. Available at www.pharmacyregulation.org.uk); • General Pharmaceutical Council. *Guidance: Raising concerns* (Current version. Available at www.pharmacyregulation.org.uk); • General Pharmaceutical Council. *Guidance: Responding to complaints and concerns* (Current version. Available at www.pharmacyregulation.org.uk); • Medicines Act 1968 as amended • NHS Executive (2000) *Patient Group Directions [England only].* Health Service Circular HSC 2000/026. (Available at www.dh.gov.uk); • Royal Pharmaceutical Society of Great Britain (2005) *The Safe & Secure Handling of Medicines: A Team Approach*. London, RPSGB. (A revision of the Duthie Report 1988) • Somerset PCT Incident Reporting Policy;

	• Summary of Product Characteristics (SPC) (Available at www.medicines.org.uk); • Somerset PCT Incident Reporting Policy; • Somerset PCT Safe and Secure Handling of Medicines policy • Somerset PCT Consent Policy.

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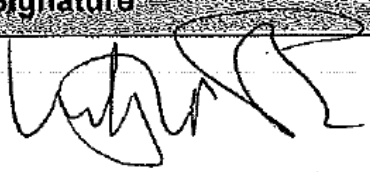
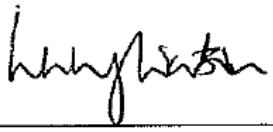
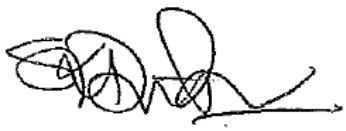
This patient group direction must be agreed to and signed by all health care professionals involved in its use. The NHS Trust should hold the original signed copy. The PGD must be easily accessible in the clinical setting	
Organisation	**SOMERSET PCT**

Authorisation	Signature	Date
Nominated GP		14/12/12
Director of Nursing and Patient Safety		14.12.12.
Senior Pharmaceutical Advisor		14.12.12
Microbiologist review		13/12/12

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Individual Authorisation

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.

Note to pharmacists: authorised staff should retain an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction and agree to supply / administer this medicine only in accordance with this PGD.

Name of Professional	Professional registration no.	Signature	Authorising Manager[1]	Date

Please return one copy of pages 12 and 13 only to:

Primary Care Commissioning Support Officer - Pharmacy, Wynford House, Lufton Way, Lufton, Yeovil, Somerset, BA22 8HR.

[1] Pharmacists – please leave blank. For pharmacists the 'Authorising Manager' will be a member of the PCT.