

All you need to know about: Pregabalin and gabapentin reclassification

Here we explain the prescribing and dispensing changes that will need to take place when pregabalin and gabapentin become Schedule 3 Controlled Drugs.

How these medicines becoming Controlled Drugs will affect your patients' prescriptions



From 1st April 2019, amendments to the Misuse of Drugs Regulations 2001 and the Safe Custody Regulations 1973 come into force which mean that pregabalin and gabapentin will be reclassified as Schedule 3 Controlled Drugs (CDs). But how will this affect prescriptions?

Prescription requirements

From 1st April 2019, all gabapentin and pregabalin prescriptions will be subject to the following prescription writing requirements for Schedule 3 CDs:

- Patient name and address
- Prescriber's address
- Prescriber's signature
- Date of prescriber's signature
- Drug name, strength and formulation
- Dose (Note: 'as directed' is NOT acceptable; 'one as directed' is acceptable)
- Total quantity (in both words and figures)

Validity: Prescriptions for Schedule 3 CDs are valid for 28 days after the appropriate date on the prescription.

Repeat dispensing: Following the change, it will be illegal to supply pregabalin and gabapentin through repeat dispensing.

EPS: Some GP practices are piloting EPS CDs, so you may receive and dispense a mix of EPS/paper prescriptions for gabapentin and pregabalin.

Emergency supplies: Schedule 3 CDs cannot be supplied in an emergency without a valid prescription, except for phenobarbitone or phenobarbitone sodium for epilepsy.

Storage and record-keeping requirements

Pregabalin and gabapentin will be included in the list of "exempted drugs" in the safe custody regulations which means that they will not be required to be kept in the CD cabinet.

Schedule 3 CDs are also exempt from record-keeping requirements.

Changes to prescribing systems

GP clinical systems will be updated ahead of 1st April 2019, when pregabalin and gabapentin will be classified as CDs. NHS England has informed PSNC that EMIS has already implemented updates, meaning paper prescriptions will replace those previously sent by EPS.

If a patient's other prescription items are issued via EPS, there is a risk that the paper script for pregabalin or gabapentin may not be collected from the GP practice; pharmacy teams should be alert to this risk.

Advice for pharmacy teams

Prescriptions and owings awaiting collection from before 1st April 2019

should be checked, assessed for clinical appropriateness (taking into account the length of time that the prescription or owing has been awaiting collection), and where necessary, the prescriber should be contacted for a replacement prescription.

Community pharmacy teams should also check all NHS repeat dispensing prescriptions that they currently hold for gabapentin and pregabalin, ensuring that all batch issues dispensed prior to the 1st April are claimed for no later than the 5th April. Any remaining issues from the batch which have not been dispensed should be returned to the prescriber/spine and a replacement prescription requested as repeat dispensing prescriptions will not be valid after 1st April 2019.

Further information

PSNC has issued a briefing on gabapentin and pregabalin's reclassification as Controlled Drugs, which includes a set of FAQs to outline what to do in certain scenarios: ow.ly/2oD030nKQpy

NHS England has issued a briefing note on *Rescheduling of Gabapentin and Pregabalin as Schedule 3 Controlled Drugs*: ow.ly/wywp30nKQqQ

Summary

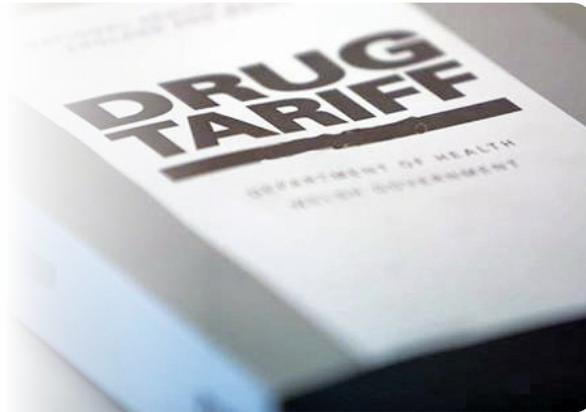
Requirements for gabapentin and pregabalin from 1st April 2019 are as follows:

Controlled Drug	Prescription requirements	Prescription validity	Safe custody requirements	Entry in CD register	Emergency supplies	Repeat dispensing
Gabapentin	✓	28 days	✗	✗	✗	✗
Pregabalin	✓	28 days	✗	✗	✗	✗

Book now for PSNC's Price Concessions Webinar

Upcoming PSNC webinar will guide viewers through process of negotiating price concessions and describe what we are doing to try to improve it.

“We will explain how the system operates and outline our work in this area”



Mike Dent (Director of Pharmacy Funding) and Suraj Shah (Drug Tariff and Reimbursement Manager) will be hosting a PSNC webinar about price concessions on **Tuesday 5th March at 7.30pm.**

The webinar will address the following questions:

- How are price concessions negotiated?
- What is the impact of price concessions on overall funding?
- What are the current challenges in setting price concessions?
- How is PSNC working to improve the price concession system?

During the webinar viewers will be guided through the price concession process; from applying for a price concession to how prices are finalised and then communicated to pharmacy contractors and their teams.

Mike and Suraj will also explain how price concessions are measured in the Margin Survey and the impact this has on the overall funding envelope. Finally, they will explore the challenges of the current price concession system and discuss the principles of a fair system agreed by the PSNC Committee. There will also be an opportunity for viewers to ask questions.

So if you want to better understand how the price concession system works and PSNC's work in this area, attending this webinar will provide some useful insights.

Join us for the webinar

Book your place now: psnc.org.uk/webinar

Even if you are unable to attend the webinar live, it is still worth registering for the event so that you will be sent a link to the recorded version of the webinar as soon as it becomes available.

You may wish to read *PSNC Briefing 067/18: How the price concession system operates* in advance of the webinar, which can be found at: psnc.org.uk/concessionsbriefing

Changes to proof of exemption

As part of the NHS Business Services Authority (NHSBSA) service improvement programme, paper certificates are replacing plastic cards.

NHSBSA envisage it taking up to five years for the plastic cards to be fully phased out. During this transition period pharmacy teams may be presented with plastic, paper and digital certificates as proof of exemption from NHS charges.

Find out more at: ow.ly/EVi130nGGya

Phasing out paper certificates

As part of work to phase out paper prescription prepayment certificates (PPCs), the NHSBSA is encouraging pharmacy teams to register to sell PPCs or direct patients on how to obtain a PPC.

Pharmacy teams can register to sell PPCs by complete the form at: <https://apps.nhsbsa.nhs.uk/pharmacy-ppc/login>

Or they can direct patients to obtain a PPC from www.nhsbsa.nhs.uk/ppc or by calling 0300 330 1341.

Part VIII B Drug Tariff changes

From February 2019, the following unlicensed (special) products have been deleted from Part VIII B of the Drug Tariff:

- Clobetasone 0.05%/Oxtetracycline 3%/Nystatin 100,000units/g cream
- Clonidine 50micrograms/5ml oral solution
- Clonidine 50micrograms/5ml oral suspension

Licensed alternatives for these products have been added to Part VIII A:

- Clobetasone 0.05%/Oxytetracycline 3%/Nystatin 100,000units/g cream (*Trimovate Cream*)
- Clonidine 50micrograms/5ml oral solution sugar free (*Thame Laboratories Ltd*)

Find out more at: ow.ly/2bcl30nzGjE

Carbagen tablets

There is currently a shortage of Carbagen 200mg and 400mg immediate release (IR) tablets and 200mg and 400mg prolonged release (PR) tablets. As stocks might not return to normal until late 2019, patients may need to be switched to Tegretol.

Drug Tariff Watch

Below is a quick summary of the changes due to take place from **1st March 2019**.

Part VIIIA additions

Category A:

- *Danazol 100mg capsules (28)
- *Danazol 200mg capsules (56)
- Valganciclovir 450mg tablets (60)

Category C:

- Adefovir 10mg tablets ■ (30) – *Hepsera*
- Benzocaine 1.5mg/dose oromucosal spray sugar free ■ (60 dose) – *AAA*
- Colistimethate 1,662,500unit inhalation powder capsules (56) – *Colobreathe*
- Dexpantenol 5% ointment ■ (100g) – *Bepanthen Nappy Care*
- Dimethyl fumarate 120mg gastro-resistant tablets (90 & 180) – *Skilarence*
- Dimethyl fumarate 30mg gastro-resistant tablets (42) – *Skilarence*
- Diphenhydramine 10mg/5ml oral solution (150ml) – *Histergan*
- Ephedrine hydrochloride 15mg / Chlorphenamine 10mg tablets (10) – *Haymine*
- Gentamicin 80mg/2ml solution for injection vials (5) – *Cidomycin Adult Injectable*
- Ketorolac 30mg/1ml solution for injection ampoules (5) – *Toradol*
- Lidocaine 0.05% / Chlorhexidine 0.2% oromucosal spray sugar free ■ (30ml) – *Covonia Sore Throat*
- Loperamide 2mg / Simeticone 125mg tablets (6) – *Imodium Plus Comfort*

- Loperamide 2mg / Simeticone 125mg tablets (12) – *Imodium Plus*
- Menotrophin 1,200unit powder and solvent for solution for injection vials ■ (1) – *Menopur*
- Menotrophin 150unit powder and solvent for solution for injection vials (10) – *Menopur*
- Menotrophin 600unit powder and solvent for solution for injection vials ■ (1) – *Menopur*
- Menotrophin 75unit powder and solvent for solution for injection vials (10) – *Menopur*
- Miconazole 2% vaginal cream ■ (78g) - *Gyno-Daktarin*
- Pitolisant 18mg tablets (30) – *Wakix*
- BPitolisant 4.5mg tablets (30) – *Wakix*
- Pseudoephedrine 60mg Acrivastine 8mg capsules (12) – *Benadryl Allergy Relief Plus Decongestant*
- Ruxolitinib 10mg tablets (56) – *Jakavi*
- Ruxolitinib 15mg tablets (56) – *Jakavi*
- Ruxolitinib 20mg tablets (56) – *Jakavi*
- Ruxolitinib 5mg tablets (56) – *Jakavi*
- Selenium 100micrograms/2ml oral solution unit dose ampoules (20) – *Selenase*
- Water for infusion polyethylene bottles ■ (1) – *Polyfusor W*

Part VIIIA deletions

- *Danazol 100mg capsules (60) – *Danol*

KEY:

- Special container
- * This pack only (others already available)
- SLS Selected List Scheme

- *Danazol 200mg capsules (60) – *Danol*
- Emedastine 0.5mg/ml eye drops (5ml) – *Emadine*
- Glycerol 40% cream (100ml) - Neutrogena Norwegian Formula
- Oxprenolol 20mg tablets (56) - Advanz Pharma
- Oxprenolol 40mg tablets (56) - Advanz Pharma
- Terbutaline 500micrograms/dose dry powder inhaler (100 dose) - Bricanyl Turbohaler
- Timolol 0.25% eye drops 0.2ml unit dose preservative free (30) - Timoptol Unit Dose
- Verapamil 120mg modified-release capsules (28) - Univer
- Verapamil 180mg modified-release capsules (56) - Univer
- Verapamil 240mg modified-release capsules (28) - Univer

Part VIIIB deletions

- Clobetasone 0.05% / Oxytetracycline 3% / Nystatin 100,000units/g cream
- Clonidine 50micrograms/5ml oral solution and Clonidine 50micrograms/5ml oral suspension

For a full list of the upcoming Drug Tariff changes, including amendments, please visit: ow.ly/2dl130nKCJp

Part IX deletions

Product	Size, Type, Product Code
MelMax dressing, Rectangular	All sizes
Spirit 2mm Silicone Adhesive Non Border Hydro Foam dressing	10cm x 10cm
Spirit 5mm Silicone Adhesive Non Border Hydro Foam dressing	All sizes
Spirit Silicone Adhesive Border Hydro Foam dressing	All sizes
TRACHEOSTOMY AND LARYNGECTOMY APPLIANCES - Blom-Singer HME Cartridge	BE1055
DEODORANTS - Peak Medical Ltd - Auricare Odour Eliminator	All sizes
ILEOSTOMY (DRAINABLE) BAGS - Hollister Ltd - Compact Drainable Pouch, Clear	13-64mm (3250)
ILEOSTOMY (DRAINABLE) BAGS - Hollister Ltd - Impression "C" with convex wafer, Beige	35mm (3265)
TWO PIECE OSTOMY SYSTEMS - ConvaTec Ltd - Combihesive Natura with filter	All sizes
TWO PIECE OSTOMY SYSTEMS - ConvaTec Ltd - Combihesive Natura no filter, Standard size - Opaque	All sizes
TWO PIECE OSTOMY SYSTEMS - ConvaTec Ltd - Esteem Synergy with InvisiClose outlet, small right, Opaque	13-48mm (S1236N)
TWO PIECE OSTOMY SYSTEMS - ConvaTec Ltd - Natura+ no filter, Standard Size - Opaque	All sizes
UROSTOMY BAGS - ProSys International Ltd - Apuro 1 piece urostomy activity pouch	UP10