NHS Circular:
MSAN (2019) 8

Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
Riaghaltas na h-Alba
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28 October 2019

Dear Colleague

MEDICINE SUPPLY ALERT NOTICE

Medicine in short supply: Ongentys® (opicapone) 50mg capsules

Priority: **Level 3**
Valid until: **Mid-January 2020**

Issue

1. This Medicine Supply Alert Notice provides information regarding the current supply issues for **Ongentys® (opicapone) 50mg capsules.** Bial Pharma are the sole suppliers of Ongentys®.

2. Production of Ongentys® has been affected by a production incident at the Active Pharmaceutical Ingredient (API) manufacturer site. The supply issue affects the global supply of opicapone.

Advice and actions

3. The following actions should be considered by the appropriate healthcare professionals:

- Defer initiating new patients on opicapone until the supply disruption is resolved in mid-January 2020.
- For patients who do not have sufficient supplies of Ongentys® 50mg capsules, early contact should be made with secondary/tertiary care specialists for advice on management options or referral to specialist. There is further advice in **Annex A** of this alert for prescribers when switching patients to alternative products.
- There may be very limited supplies of unlicensed opicapone capsules available from specialist importers. This should be reserved for those patients in whom alternatives are not clinically appropriate.

Addressees:

For action
NHS Directors of Pharmacy
NHS Medical Directors
Pharmacy Primary Care Leads
Medicines Information Pharmacists
Community Pharmacy Scotland
NHS National Procurement
Scottish Prescribing Advisor Network

For information
Director Practitioner Services, NHS NSS
NHS Scotland Chief Executives
NHS Director of Finance

General Enquiries to:

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St Andrew's House
EDINBURGH, EH1 3DG

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- For patient with sufficient supplies to last them until mid-January 2020, then no further action is required. These patients should **not** be issued with a further prescription during this period

Further background

4. It is anticipated that current stock will be depleted by mid-November 2019. Further deliveries are currently anticipated mid-January 2020, however exact dates are still to be confirmed.

5. Ongentys® (opicapone) is used as adjunctive therapy to preparations of levodopa/ DOPA decarboxylase inhibitors (DDCI) in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations.

6. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and Health Board governance procedures. Please see the links below for further information:

- Prescribing unlicensed medicines, General Medical Council (GMC);
- The supply of unlicensed medicinal products, Medicines and Healthcare products Regulatory Agency (MHRA);
- Professional Guidance for the Procurement and Supply of Specials, Royal Pharmaceutical Society (RPS).

Action

7. Health Board Medical Directors and Directors of Pharmacy are asked to cascade this Medicines Supply Alert Notice to general practices, community pharmacies, and other relevant professionals in their Health Board area.

8. Healthcare professionals are asked to note the content and actions outlined in this circular and Annexes.

Yours sincerely,

Rose Marie Parr
Chief Pharmaceutical Officer/
Deputy Director Pharmacy & Medicines Division

ANNEX A

Advice on Switching Patients from Ongentys® (opicapone) 50mg capsules

Patients who require switching from Ongentys® (opicapone) 50mg capsules during this time should do so under the supervision of their secondary/tertiary specialist.

It is advised that these patients are considered for switching to alternative catechol-O-methyltransferase inhibitors (COMT inhibitors) – entacapone & tolcapone. Switching patients to an alternative COMT inhibitor is only advised following clinical evaluation by the specialist. The following alternative treatments are available:

Drug	Strength	Formulation	Dose	Manufacturers
Levodopa with Carbidopa and Entacapone	50mg/12.5mg/200mg 75mg/18.75mg/200mg 100mg/25mg/200mg 125mg/31.25mg/200mg 150mg/37.5mg/200mg 175mg/43.75mg/200mg 200mg/50mg/200mg	Tablets	One tablet per each dose	Teva Actavis Orion Pharma
Entacapone	200mg	Tablets	200mg, dose to be given with each dose of levodopa with dopa-decarboxylase inhibitor; maximum 2g per day	Wockhardt Mylan Teva
Tolcapone*	100mg	Tablets	100mg 3 times a day (max. per dose 200mg 3 times a day) continuing beyond 3 weeks only if substantial improvement	Mylan

*** Caution: increased risk of hepatotoxicity; discontinue if abnormal liver function tests or symptoms of liver disorder; do not re-introduce tolcapone once discontinued.**

ANNEX B

CLASSIFICATION OF MEDICINE SHORTAGES

LEVEL	DESCRIPTION	POTENTIAL RESPONSES
Level one (low impact)	Supply problem with a short duration **(up to one month**) where immediately available measures are expected to be sufficient and there is minimal additional management requirement.	Business as usual. Response likely to involve using the same medicine. • Alternative strength/formulation available to meet demand, potentially from other suppliers.
Level two (medium impact)	Supply problem where alternatives in the same therapeutic class are available but which may require some management such as switching to those alternatives, which may include unlicensed medicines.	Business as usual. Response not likely to require a change in the class of medicine. • Alternative strength/formulation available but clinical advice is required to help manage the switch. • Alternative medicine in the same therapeutic class. • Unlicensed alternatives may be used. • Issuing a Medicine Supply Alert Notice.
Level three (high impact)	Supply problems where there are limited or no alternatives in the same therapeutic class and which require significant management, potentially including changes in clinical practice or operational direction or that have patient safety implications. Level three shortages also include level two shortages for medicines used in life saving conditions such as anaphylaxis or involving patient groups considered as vulnerable, such as neonates, paediatrics or people with learning disabilities.	Serious shortage situation. Response likely to require a change in the class of medicine. • Alternative therapeutic class of medicine available. • The use of a 'serious shortage protocol'. • Additional clinical advice. • Exceptional MHRA regulatory measures. • Issuing a Medicine Supply Alert Notice.
Level four (critical impact)	Supply problems where there is no viable therapeutic alternative and where responses may also require support from outside the health system and / or which trigger the use of national resilience structures.	Very serious shortage situation. Wider burden on NHS and public sector. • Non-medicine support provided to patients. • National Resilience procedures potentially activated – including links with agencies outside NHS. Additional project management or communications support may be required. • Issuing a Medicine Supply Alert Notice.