From the Chief Medical Officer
Dr Michael McBride

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

HSS(MD) 27/2019

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Our Ref: HSS(MD) 27/2019
Date: 30 October 2019

For Action:
Chief Executives of HSC Trusts
GP Medical Advisers, Health and Social Care Board
All General Practitioners and GP Locums (for onward distribution to practice staff)
Director of Integrated Care, Health and Social Care Board
Chief Executive RQIA (for onward transmission to all independent providers including independent hospitals)
Assistant Director of Pharmacy and Medicines Management, Health and Social Care Board (for onward distribution to Community Pharmacies)

PLEASE SEE ATTACHED FULL CIRCULATION LIST

Dear Colleague

OPICAPONE 50MG CAPSULES - SUPPLY DISRUPTION ALERT

ACTIONS FOR ALL HEALTHCARE PROFESSIONALS WHO PRESCRIBE, DISPENSE OR ADMINISTER OPICAPONE 50MG CAPSULES

This letter is to inform you of a current global supply issue affecting Ongentys (opicapone) 50mg capsules. This supply issue is due to a production incident at the manufacturing site of the Active Pharmaceutical Ingredient (API), affecting the global supply of opicapone. Bial Pharmaceuticals are the sole licensed UK supplier.

It is anticipated that current stock will be depleted by mid-November 2019. Further deliveries are currently anticipated mid-January 2020, however exact dates have not been confirmed.

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. Patients who require switching during this time should do so under the direction of their specialist.

Actions for healthcare professionals

All healthcare organisations in primary, secondary or specialist healthcare services should work with clinicians including pharmacists to ensure the following actions are undertaken where relevant:

- Defer initiating new patients on opicapone until the supply disruption is resolved in mid-January 2020.

- GPs to identify all patients currently prescribed opicapone. Early contact should be made with the patient or patient's parent/carer to determine if the stocks at home will last until mid-January 2020, or if any switches are likely to be required between mid-November 2019 and mid-January 2020.

- If the patient has 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

- If the patient does not have sufficient supplies of opicapone, make early contact with secondary/tertiary care specialists for advice on management options or referral to specialist.

- Ensure prescribers are aware of the advice in the attached DHSC Supply Disruption Alert 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.

The limited supplies from specialist unlicensed importers should be reserved, for patients in whom alternatives are not clinically appropriate. Pharmacies will be familiar with sourcing unlicensed products and "specials" and should be able to advise further. Prescribers should liaise with local pharmacy team to clarify availability before prescribing.

When prescribing and dispensing unlicensed preparations, prescribers and pharmacists should always ensure the following:

- Use of unlicensed products should be in line with agreed local policies and guidance.

- Any decision to prescribe an unlicensed medicine must take into account the relevant GMC guidance and Trust / Local governance procedures. Please see link to GMC guidance:

  https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines

Please refer to the attached DHSC Supply Disruption Alert for further information. This alert can also be accessed at https://www.cas.mhra.gov.uk/ViewAndAcknowledgment/viewAttachment.aspx?Attachment_id=103311

Yours sincerely

DR MICHAEL McBRIDE
Chief Medical Officer

MRS CATHY HARRISON
Acting Chief Pharmaceutical Officer

Circulation List

Executive Medical Director/Director of Public Health, Public Health Agency (for onward distribution to all relevant staff)
Director of Nursing, Public Health Agency
Directors of Pharmacy HSC Trusts
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This letter is available on the Department of Health website at https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications

Department of Health & Social Care

NHS

Supply Disruption Alert

SDA/2019/007 Issued: 25 October 2019 Valid until: 31 January 2020

Opicapone 50mg capsules – Supply Disruption Alert

Summary

- Ongentys (opicapone) 50mg capsules, manufactured by Bial Pharmaceuticals will be out of stock from mid-November 2019 to mid-January 2020.
- The supply issue is due to a production incident at the manufacturing site of the Active Pharmaceutical Ingredient (API), affecting the global supply of opicapone.

Action

All healthcare organisations in primary, secondary or specialist healthcare services should work with clinicians including pharmacists to ensure the following actions are undertaken where relevant:

- Defer initiating new patients on opicapone until the supply disruption is resolved in mid-January 2020.
- GPs to identify all patients currently prescribed opicapone. Early contact should be made with the patient or patient's parent/carer to determine if the stocks at home will last until mid-January 2020, or if any switches are likely to be required between mid-November 2019 and mid-January 2020.
- If the patient has 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
- If the patient does not have sufficient supplies of opicapone, make early contact with secondary/tertiary care specialists for advice on management options or referral to specialist.
- Ensure prescribers are aware of the advice in later sections of this alert 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.

Action, to be taken by

- General Practices
- Neurologists
- Acute Trusts
- Community Trusts
- Geriatricians
- Pharmacy Departments
- Community Pharmacists

Deadlines for actions

Actions initiated: 01 November 2019
Actions completed: 31January 2020

Product details

Ongentys (opicapone) 50mg capsules

Background

There is a global short-term supply issue affecting Ongentys (opicapone) 50mg capsules due to a production incident at the manufacturing site of the API. Bial Pharmaceuticals are the sole licensed UK supplier.

It is anticipated that current stock will be depleted by mid-November 2019. Further deliveries are currently anticipated mid-January 2020, however exact dates have not been confirmed.

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.

Advice on switching patients

Patients who require switching 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	1 tablet per each dose	Teva Actavis Orion Pharma
Entacapone	200mg	Tablets	200 mg, dose to be given with each dose of levodopa with dopa-decarboxylase inhibitor; maximum 2 g per day.	Wockhardt Mylan Teva
Tolcapone*	100mg	Tablets	100 mg 3 times a day (max. per dose 200 mg 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.

Clinicians are advised to review patient's treatments when opicapone becomes available in mid-January 2020.

The limited supplies from specialist unlicensed importers should be reserved, for patients in whom alternatives are not clinically appropriate.

Pharmacies will be familiar with sourcing unlicensed products and "specials" and should be able to advise further. Before prescribing, you should liaise with your pharmacy team to clarify availability. When prescribing and dispensing unlicensed preparations, prescribers and pharmacists should always ensure the following:

- Use of unlicensed products should be in line with agreed local policies and guidance.
- Any decision to prescribe an unlicensed medicine must take into account the relevant GMC guidance and NHS Trust / Local governance procedures. Please see link to GMC guidance: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines