



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: 31 January 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>

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Chief pharmacists
- Clinical governance leads
- Clinical Procurement Specialists
- Community hospitals
- Community nurses
- District nurses
- Hospital pharmacies
- Hospital pharmacists
- Medical directors
- Outpatient clinics
- Pharmaceutical advisors
- Pharmacists

NHS England regional teams

CAS liaison officers for onward distribution to all relevant staff including:

- Community pharmacists
- General practitioners
- General practice managers
- General practice nurses

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Enquiries

England

Send enquiries about this notice to the DHSC Supply Resilience Team, quoting reference number **SDA/2019/007**.

Email: supplyresiliencemd@dhsc.gov.uk