

Department of Health & Social Care



Medicine Supply Notification

MSN/2024/016

Oxcarbazepine 150mg and 300mg tablets Tier 2 – medium impact* Date of issue: 08/02/2024 Link: <u>Medicines Supply Tool</u>

Summary

- Oxcarbazepine 150mg tablets (Viatris) are out of stock until late March 2024.
- Oxcarbazepine 150mg tablets (Trileptal[®]) remain available, however, cannot support the full increase in demand.
- Oxcarbazepine 300mg tablets (Viatris) are out of stock until mid-February 2024.
- Oxcarbazepine 300mg tablets (Morningside) remain available and can support increased demand.
- Oxcarbazepine (Trileptal[®]) 60mg/ml oral suspension remains available, however, cannot support the increase in demand.
- Unlicensed supplies of oxcarbazepine 150mg tablets and 60mg/ml oral suspension may be sourced, lead times vary.

Actions Required

Prescribers should not initiate new patients on oxcarbazepine 150mg tablets until the shortage has been resolved.

Where patients have insufficient supplies to last until the re-supply date, clinicians should:

- for patients on a 300mg dose, prescribe generic oxcarbazepine 300mg tablets (Morningside);
- for patients on a 150mg dose, considering prescribing generic oxcarbazepine 300mg tablets (Morningside), halved to provide a 150mg dose (off-label), particularly in those patients on a twice daily dose where the other half is taken the same day, ensuring they are counselled on how to halve a tablet, and to use a tablet cutter;
- only prescribe Trileptal[®] 150mg tablets if the option to halve a tablet (off-label) is not appropriate, as there are insufficient supplies to support the full demand (see supporting information);
- reassure patients that whatever they are switched to, they are receiving the same drug at the same dose, and to report any side effects or loss of seizure control (or symptom control if being used off-label for trigeminal neuralgia), after the switch; and
- prescribe an unlicensed product only where licensed alternatives are not appropriate. Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see supporting information).

If the above options are not considered appropriate, advice should be sought from specialists on management options.

Supporting information

Clinical Information

Oxcarbazepine is licensed for the treatment of partial seizures with or without secondarily generalised tonicclonic seizures, as monotherapy or adjunctive therapy, in adults and in children of 6 years of age and above. The licensed starting dose is 600 mg/day given in 2 divided doses. Therapeutic effects are seen at doses between 600 mg/day and 2,400 mg/day.

It is a <u>category 2 antiepileptic drug</u> so the need for continued supply of a particular manufacturer's product should be based on clinical judgement and consultation with patient and/or carer, considering factors such as seizure frequency and treatment history, as well as patient/carer-related factors, including their negative perceptions about alternative products.

Oxcarbazepine 300mg tablets (Morningside) are scored on one side. The score line is licensed only to facilitate breaking for ease of swallowing and not to divide into equal doses. Halving the tablet is an off-label manipulation. The suggestion to halve generic oxcarbazepine 300mg tablets (Morningside) as a preferred action is to preserve the limited supplies of Trileptal[®] 150mg tablets for patients for whom halving a tablet is not appropriate.

Links to further information

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<u>SmPC oxcarbazepine</u> <u>BNF Oxcarbazepine</u> <u>BNF Treatment summary - Epilepsy</u> <u>CKS Epilepsy</u>

Guidance on ordering and prescribing unlicensed imports

The following specialist importers have confirmed they can source unlicensed oxcarbazepine 150mg tablets and/or 60mg/ml oral suspension (please note there may be other companies that can also source supplies):

- Alium Medical tablets and suspension
 - tablets and suspension
- Target Healthcare tablets

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information:

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

When prescribing a product that is not licensed in the UK due to a supply issue with the licensed alternative prescribers must indicate on the FP10 prescription that an unlicensed product is required. This can be done in one of the following two ways:

- Electronic prescriptions if the required unlicensed product is shown on electronic prescribing systems, GPs should select:
 - oxcarbazepine 150mg tablets (imported)
 - o oxcarbazepine 60mg/ml oral suspension (imported)
- Paper prescriptions where the unlicensed product is not shown on electronic prescribing systems, GPs should use a paper prescription and annotate with the following wording: "**special order**".

Enquiries

If you have any queries, please contact: DHSCmedicinesupplyteam@dhsc.gov.uk