

# Shortage of Carbagen® 200 and 400mg immediate release (IR) and 200 and 400mg prolonged release (PR) tablets

**Updated: 13<sup>th</sup> December 2019**

## **Description of product affected**

Carbagen tablets are licensed for the treatment of epilepsy (generalised tonic-clonic and partial seizures), paroxysmal pain of trigeminal neuralgia, and prophylaxis of manic-depressive psychosis in patients unresponsive to lithium therapy.<sup>1</sup>

## **Background**

There is a shortage 200 and 400mg immediate release (IR) and 200 and 400 mg prolonged release (PR) tablets (the 100mg IR tablets are no longer marketed).

Mylan (manufacturer of Carbagen) are expected to be out of stock of these products until March 2020.

It is anticipated that all patients are Carbagen will need to be switched to the alternative, Tegretol formulation.

## **Alternative agents and management options**

The only other brand of carbamazepine tablets available is Tegretol (100, 200 and 400mg IR and 200 and 400mg PR).<sup>2</sup> Novartis, the manufacturer of Tegretol tablets, have confirmed that all presentations are currently available and they are able to support additional demand during this time for all affected strengths and formulations.

The MHRA has classified carbamazepine as a Category 1 antiepileptic drug, which means there are clear indications that clinically relevant differences between different manufacturers' products might occur, even when the pharmaceutical forms are the same and bioequivalence has been shown. Therefore the patient should be maintained on a specific manufacturer's product.<sup>3</sup> However, in the event of a shortage of a product, it is not possible to maintain the patient on their previous preparation; all product switches must be carried out with care and close monitoring, and where possible, patients should be maintained from then onwards on a single manufacturer's product.<sup>4</sup>

## Managing existing stock

In order to preserve any stock of this brand for patients already on it for epilepsy:

- No new patients should be started on Carbagen until the shortage has resolved.
- Remaining stock should not be used for prescriptions written generically without confirmation patient is already on this brand for epilepsy.
- Patients with optimal seizure control (i.e. seizure-free or their seizure frequency has been markedly reduced) should be prioritised, particularly

where there is a history of good seizure control and where the recurrence of a seizure could lead to socio-economic harm (e.g. loss of a driving license).

- People with epilepsy who are most anxious/vulnerable to change may also need to be prioritised.
- Non-epilepsy users of antiepileptic drugs do not generally have significant consequences following minor changes in dose so switching is unlikely to cause problems.<sup>5</sup>

#### Switching patients with epilepsy to Tegretol

- It is important the transition is carefully discussed with the patient so that they are aware of the change and the potential risk, without creating excess anxiety or alarm.
- Patients should be switched to the same dose and release profile of Tegretol.
- Patient/carers should be advised to report any problems with seizure control after a switch; seizure diaries may be helpful to identify any change in seizure patterns, particularly in complex cases (who may have diaries already).
- Patient/carers should be reminded of the signs of toxicity and advised to report any concerns (e.g. drowsiness, slurred speech, ataxia, hallucinations, nausea, vomiting, tremors, seizures, oliguria, blurred vision, bullous skin formations).<sup>6</sup>.

**Advice should be sought from specialist pharmacists/neurologists if there are concerns about switching in complex cases or if any problems arise after switching. Carbamazepine dosing is primarily guided by clinical response, plasma levels are not part of routine practice, and should not be undertaken without specialist advice to enable appropriate interpretation and management recommendations to be made.**

#### **References**

1. Carbagen SPCs accessed via emc, 04 Jan 2019:  
<https://www.medicines.org.uk/emc/search?q=carbagen%23>
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<https://www.medicines.org.uk/emc/search?q=%22carbamazepine%22>
3. MHRA. Antiepileptic drugs: updated advice on switching between different manufacturers' products, Published 24 November 2017:  
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4. The NEWT Guidelines. Carbamazepine monograph, updated November 2018
5. UKCPA Neurosciences Group/ Pharmaceutical Market Support Group (PMSG): Generics Sub-Group. The Use of Generic Anti-Epileptics Drugs in Patients with Epilepsy: consensus view; November 2012
6. Kapoor N. Carbamazepine Toxicity Clinical Presentation. Medscape Updated: 16 Dec 2017: <https://emedicine.medscape.com/article/813654-clinical>

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