



Medicine Supply Notification

MSN/2024/067

Clomethiazole 192mg capsules

Tier 2 – medium impact*

Date of issue: 05/06/2024

Link: [Medicines Supply Tool](#)

Summary

- Clomethiazole 192mg capsules are out of stock until mid-June 2024.
- Clomethiazole 31.5mg/ml oral solution sugar free is currently out of stock until mid-July 2024.
- Alternative hypnotics/anxiolytics remain available.
- Unlicensed supplies of clomethiazole 192mg capsules can be sourced, lead times vary.

Actions Required

Prescribers should not initiate new patients on clomethiazole 192mg capsules until the shortage has resolved.

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

- review patients to determine reason for being on this treatment;
- if treatment is no longer considered necessary, **abrupt withdrawal must be avoided**, and patients should be withdrawn by slow dose reduction or switching to an approximately equivalent dose of diazepam, which is then tapered down:
 - local protocols for benzodiazepine withdrawal, where available, should be referred to and advice sought from mental health teams for a suitable withdrawal regimen tailored to patient needs.
- for patients unwilling/unable to stop treatment:
 - if receiving as an anxiolytic, consider appropriateness of switching to other short acting agents such as oxazepam and lorazepam, or
 - if receiving for insomnia, consider appropriateness of switching to a Z drug (zopiclone, zolpidem) or a sedating antihistamine (promethazine), in preference to a benzodiazepine.
- note dose conversions of clomethiazole to benzodiazepines should be approached with caution as there are limited data;
- consider whether high dose switches to alternative medicines or switches in patients with renal impairment can be safely done in primary care or if specialist advice should be sought from mental health teams or alcohol/drug dependency services;
- consider prescribing unlicensed clomethiazole capsules only where switching to a licensed alternative is not appropriate;
- if the above options are not considered appropriate, advice should be sought from specialists on alternative management options.

*Classification of Tiers can be found at the following link:

<https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/>

GPs and other prescribers working in the community should refer to local protocols for information on drug regimens for medically assisted withdrawal from alcohol.

Supporting information

Clinical Information

Clomethiazole is a short acting sedative and muscle relaxant with anticonvulsant effect, which is pharmacologically distinct from both the benzodiazepines and the barbiturates. It is licensed for the management of restlessness and agitation in the elderly, short term treatment of severe insomnia in the elderly and treatment of alcohol withdrawal symptoms where close hospital supervision is also provided.

Clomethiazole should not be used in community-based assisted withdrawal from alcohol because of the risk of overdose and misuse. Chlordiazepoxide or diazepam are the drugs of choice for alcohol detoxification.

Abrupt withdrawal of clomethiazole should be avoided as it could have serious consequences for some patients.

Please refer to the links below for further information:

[SmPC Clomethiazole 192mg capsules](#)
[BNF Hypnotics and anxiolytics](#)
[BNF Clomethiazole](#)

Guidance on ordering and prescribing unlicensed medicines

The following specialist importer has confirmed they can source clomethiazole 192mg capsules (please note there may be other companies that can also source supplies):

- Alium

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Unlicensed imports do not undergo any central quality assessment or suitability evaluation. Therefore, any import must be locally assessed in line with local unlicensed medicines processes.

Please see the links below for further information:

- [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
- [Prescribing unlicensed medicines](#), General Medical Council (GMC)

Enquiries

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