



11 June 2024

## **Medicine Supply Alert Notice**

### **Clomethiazole 192mg capsules**

**Priority: Level 2\***

**Valid until: mid-July 2024**

#### **Issue**

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

#### **Advice and Actions**

5. Prescribers should not initiate new patients on clomethiazole 192mg capsules until the shortage has resolved.
6. Where people have insufficient supplies to last until the re-supply date, prescribers should:
  - review individuals to determine reason for being on this treatment;
  - if treatment is no longer considered necessary, **abrupt withdrawal must be avoided**, and people should be withdrawn by slow dose reduction or switching to an approximately equivalent dose of diazepam, which is then tapered down: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 a person's needs.
  - for people 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 people 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;

\*<https://www.nss.nhs.scot/media/1842/medicine-supply-alert-notices-definitions-of-classifications-21-october-2019.pdf>

- if the above options are not considered appropriate, advice should be sought from specialists on alternative management options.
7. GPs and other prescribers working in the community should refer to local protocols for information on drug regimens for medically assisted withdrawal from alcohol.

## Additional Information

### Clinical Information

8. Clomethiazole is a short acting sedative and muscle relaxant with anticonvulsant effect, which is pharmacologically distinct from both benzodiazepines and 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.
9. 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.
10. **Abrupt withdrawal of clomethiazole should be avoided as it could have serious consequences for some people.**
11. Please refer to the links for further information:
- [SmPC Clomethiazole 192mg capsules](#)
  - [BNF Hypnotics and anxiolytics](#)
  - [BNF Clomethiazole](#)

### Guidance on ordering and prescribing unlicensed medicines

12. 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
13. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and Health Board 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.
14. 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).

## Specialist Pharmacy Service (SPS) website

15. The UK Department of Health and Social Care (DHSC) in conjunction with SPS have launched an online Medicines Supply Tool, which provides up to date information about medicine supply

issues. To access the online Medicines Supply Tool you need to register with the [SPS website](#). Registration for access to the website is available to UK healthcare professionals and organisations providing NHS healthcare. The tool is located under the Tools tab and then click on the Medicines Supply option.

16. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool to stay up to date concerning medicines supply disruptions. Please be aware that while medicines supply issues will appear on the SPS website, some of the recommended actions may not always be appropriate / relevant within the Scottish context.

## **Enquiries**

17. Enquiries from Health Boards or healthcare professionals should be directed in the first instance to [PharmacyTeam@gov.scot](mailto:PharmacyTeam@gov.scot) (primary care) or [NSS.NHSSMedicineShortages@nhs.scot](mailto:NSS.NHSSMedicineShortages@nhs.scot) (secondary care).