Chief Medical Officer Directorate Pharmacy and Medicines Division



16 October 2023

# Medicine Supply Alert Notice

# Bumetanide 1mg and 5mg tablets

# Priority: Level 3<sup>\*</sup> Valid until: March 2024

#### Issue

- 1. Bumetanide 5mg tablets are out of stock until early March 2024.
- 2. Bumetanide 1mg tablets remain available until the end of October and will be out of stock until January 2024.
- 3. Bumetanide 1mg/5ml SF oral solution remains available but is unable to support increased demand.
- 4. Furosemide 20mg and 40mg tablets remain available and can support increased demand.
- 5. Where these are not suitable, unlicensed supplies of bumetanide 1mg and 5mg tablets may be sourced, lead times vary.

## Advice and Actions

- 6. Healthcare professionals in primary and secondary care should not initiate any new patients on bumetanide 1mg and 5mg tablets until the supply issue has resolved.
- 7. Where existing patients have insufficient supplies of bumetanide tablets to last until the resupply date, clinicians should:
  - review patients to determine if this is still the most suitable therapy;
  - reserve any remaining stock of bumetanide 1mg tablets for patients using this strength who are unsuitable for a switch to furosemide.
  - consider prescribing furosemide tablets which are able to support the market during this time, ensuring that the patient is not intolerant to any of the excipients and is counselled on the appropriate dose to take (see Supporting information below);
  - only consider prescribing unlicensed products 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 Additional Information below); and
  - if the above options are not considered appropriate or symptoms are not controlled on furosemide, advice should be sought from specialists on management options.
- 8. A switch should be made before patients run out of tablets to avoid a break in therapy that could increase the risk of decompensation and unintentional fluid retention.

# **Additional Information**

#### **Clinical Information**

- 9. Bumetanide is a loop diuretic licensed for the treatment of oedema associated with e.g., congestive heart failure, renal dysfunction including nephrotic syndrome and cirrhosis of the liver in adults. In oedema of renal or cardiac origin where high doses of a potent short-acting diuretic are required, a 5mg dose of bumetanide may be used in adults.
- 10. Furosemide is a loop diuretic licensed for use in all indications where a prompt and effective diuresis is required. It is similar in activity to bumetanide; both act within 1 hour of oral administration and diuresis is complete within 6 hours. The diuresis associated with these drugs is dose related.
- 11. Loop diuretics produce the same response if given at equipotent doses. When kidney function is normal, a 40mg dose of furosemide is approximately equal to 1mg of bumetanide. Selecting an equivalent dose is determined on a case-by-case basis as effects will differ based on clinical status and stability of patient, fluid status, and renal function. Patients switched from a stable dose of bumetanide to furosemide may require follow up to assess response, with dose titration if required, to ensure fluid balance remains stable.

#### Please refer to the links below:

- SmPCs: Bumetanide 1mg and 5mg tablets
- SmPCs: Furosemide 20mg and 40mg tablets
- BNF: Loop diuretics
- <u>CKS: Chronic heart failure managing diuretics</u>

## Guidance on ordering and prescribing unlicensed imports

- 12. The following specialist importers have confirmed they can source unlicensed bumetanide 1mg and 5mg tablets (please note there may be other companies that can also source supplies):
  - Alium
  - Mawdsleys
- 13. Any decision to prescribe an unlicensed medicine must consider the relevant regulatory, professional and Board guidance and 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)

## DHSC medicines supply tool (hosted on Specialist Pharmacy Service (SPS) website)

14. 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 <u>SPS website</u>.

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.

15. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool in order 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

 Enquiries from Health Boards or healthcare professionals should be directed in the first instance to <u>PharmacyTeam@gov.scot</u> (primary care) or <u>NSS.NHSSMedicineShortages@nhs.scot</u> (secondary care).