Chief Medical Officer Directorate Pharmacy and Medicines Division



19 July 2022

Medicine Supply Alert Notice

Alendronic acid 70mg tablets

Priority: Level 2 Valid until: late-August 2022.

Issue

- 1. Alendronic acid 70mg tablets are out of stock until late-August 2022.
- Risedronate sodium 35mg tablets (weekly) and ibandronic acid 150mg tablets (monthly) remain available. Where these are not suitable, unlicensed supplies of alendronic acid 70mg tablets may be sourced, lead times vary.

Advice and Actions

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

- consider reviewing the need for bisphosphonate treatment based on national guidance (see additional information*);
- consider prescribing risedronate 35mg once weekly tablets, check that the patient is not intolerant to any of the excipients and is counselled on dose and administration (see additional information below);
- if the above is unsuitable consider prescribing ibandronic acid 150mg once **monthly** tablets, ensuring that this is a suitable dose regimen for the patient, no intolerance to any of the excipients and ensure the patient understands the counselling provided on the once monthly dose regimen and administration (see additional information); and
- if none of the above is appropriate consider prescribing unlicensed weekly alendronic acid 70mg. Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see supporting information below).

Additional Information

Clinical Information

Licensed indication and dosing

4. Alendronic acid 70mg tablets are licensed in adults for the treatment of postmenopausal osteoporosis. The recommended dosage is one 70mg tablet swallowed whole once weekly taken at least 30 minutes before the first food, beverage, or medicinal product of the day with plain water only and patient should stand or sit upright for at least 30 minutes after administration. The only other licensed weekly formulation of a bisphosphonate is risedronate 35 mg tablets, which also needs to be administered as recommended for alendronate.

- 5. A monthly bisphosphonate formulation is also available: ibandronic acid, which is recommended to be taken after an overnight fast (at least 6 hours) and 1 hour before the first food or drink (other than water) of the day or any other oral medicinal products or supplementation (including calcium) and the patient should stand or sit upright for at least 1 hour after taking tablet.
- 6. If considering switching patients from a weekly to a monthly oral bisphosphonate, ensure that adherence will not be affected, as some patients may find it more difficult to remember to take a monthly tablet, when accustomed to a weekly regimen of alendronic acid.

<u>Guidance</u>

- 7. <u>The National Osteoporosis Guidance Group (NOGG)</u>* recommends that after 5 years of bisphosphonate treatment, re-assess fracture risk. Longer durations of treatment, for at least 10 years, are recommended in certain high risk groups. After 10 years of treatment, the decision regarding ongoing management must be made on an individual basis, in careful consultation with the patient, and specialist advice may need to be sought. Refer to guidance for further information on risk assessment.
- 8. Please click on the following links for further information:
 - BNF alendronic acid
 - <u>NICE guidance: Osteoporosis</u>
 - <u>SmPC risedronate acid 35mg</u> tablets

- BNF bisphosphonate
- SmPC alendronic acid
- SmPC Ibandronic acid 150mg

Guidance on ordering and prescribing unlicensed imports

The following specialist importers have confirmed they can source unlicensed alendronic acid 70mg tablets (please note there may be other companies that can also source supplies):

- Smartway Pharmaceuticals Limited
- Target Healthcare
- 9. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Board 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)

Specialist Pharmacy Service (SPS) website

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

- 11. To access the online Medicines Supply Tool it is required 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 Planning tab and then click on Medicines Supply option.
- 12. 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 with regards to medicines supply disruptions.
- 13. Please be aware that while medicines supply issues will appear on the SPS website, some of the recommended actions may not be appropriate / relevant within the Scottish context.

Enquiries

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