Chief Medical Officer Directorate Pharmacy and Medicines Division



25 April 2024

Medicine Supply Alert Notice

Naloxegol (Moventig[®]) 12.5mg and 25mg tablets

Priority: Level 2^{*} Valid until: early August 2024

Issue

- 1. Naloxegol (Moventig[®]) 12.5mg tablets are out of stock until early August 2024.
- 2. Naloxegol (Moventig[®]) 25mg tablets are out of stock until the end of April 2024.
- 3. Naldemedine (Rizmoic[®]) 200 micrograms tablets remain available and can support increased demand.

Advice and Actions

- 4. Clinicians should not initiate new patients on naloxegol (Moventig[®]) tablets until the supply issues resolve.
- 5. Where patients have insufficient supply of either strength of naloxegol to last until the resupply date(s) consider:
 - prescribing naldemedine (Rizmoic®) 200 microgram tablets; or
 - when available, review if a 25mg dose of naloxegol may be appropriate for some patients; and
 - for patients requiring a 12.5mg dose of naloxegol, for whom a trial of naldemedine has not proven to be as effective or tolerated, consider off-label halving of naloxegol (Moventig[®]) 25mg tablets, to deliver a 12.5mg dose. Ensure a tablet cutter is provided and patients (or their carers) are counselled on dosing and the use of a tablet cutter (see Additional information).

Additional Information

- 6. Naloxegol is a peripheral opioid receptor antagonist licensed for the treatment of opioid-induced constipation in adults who have had an inadequate response to laxative(s). The recommended dose is 25mg once daily.
- 7. The starting dose for patients with moderate or severe renal insufficiency is 12.5mg daily. The dose can be increased to 25mg if 12.5mg is well tolerated by the patient. The 25mg tablets are film-coated and unscored; no data are available on halving them, and this manipulation would be considered off-label, although the product licence does allow for the tablets to be crushed to a powder and mixed in water for patients unable to swallow the tablet whole.

- 8. Naldemedine is another peripherally acting opioid receptor antagonist licensed for the treatment of opioid-induced constipation (OIC) in adult patients who have previously been treated with a laxative. The recommended dose is 200 micrograms daily. No dose adjustment is required in patients with renal impairment, but due to the limited therapeutic experience, patients with severe renal impairment should be clinically monitored when initiating therapy.
- 9. Both agents are accepted for use within NHS Scotland by the Scottish Medicines Consortium (SMC).

Links to further information

- <u>SmPC naloxegol (Moventig[®]) tablets</u>
- <u>SmPC naldemedine (Rizmoic[®]) tablets</u>
- BNF naloxegol
- BNF naldemedine

Guidance on prescribing off-label medicines

- 10. Any decision to prescribe an off-label medicine must consider the relevant guidance and NHS Health 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

- 11. 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.
- 12. 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

 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).