Chief Medical Officer Directorate Pharmacy and Medicines Division



8 March 2021

Medicine Supply Alert Notice

Sancuso[®] (granisetron) 3.1mg/24 hours transdermal

Priority: Level 2^{*} Valid until: until late March 2021

Issue

- 1. Sancuso[®] (granisetron) 3.1mg/24 hours transdermal patches are out of stock until late March 2021 (other formulations of granisetron (tablets and injection) are not affected).
- 2. The patches are licensed for the prevention of nausea and vomiting associated with moderately or highly emetogenic chemotherapy, for a planned duration of 3 to 5 consecutive days, where oral antiemetic administration is complicated by factors making swallowing difficult.
- 3. An alternative 5HT3 antagonist, ondansetron, is available in formulations suitable for patients with swallowing difficulties.
- 4. Specialist importer companies have indicated that unlicensed imports of granisetron 3.1mg/24hours transdermal patches can be sourced.

Advice and Actions

- 5. Where patients have insufficient supplies of Sancuso[®] (granisetron) 3.1mg/24hours transdermal patches to last until the re-supply date, clinicians should consider:
 - reviewing if patients can swallow tablets and if so, prescribing granisetron tablets.
 - prescribing ondansetron melts/lyophillisates/orodispersible film/oral solution/oral syrup (see additional information below) for patients unable to swallow tablets.
 - prescribing unlicensed imports of granisetron transdermal patches if the licensed alternatives listed above are not suitable to meet individual patient need (see additional information below).

Additional Information

6. Please note, manufacturers and preparations listed below can support an increase in demand.

| Drug name, Strength | Strength | Formulation | Manufacturer |
|------------------------|----------|------------------------|--|
| Granisetron | 1mg | Tablets | Atnahs (Kytril®) |
| Granisetron | 2mg | Tablets | Atnahs (Kytril®) |
| Ondansetron | 4mg | Orodispersible tablets | Bluefish Pharma Healthcare Pharma Morningside Healthcare Teva |
| | | Orodispersible film | Norgine (Setofilm [®]) |
| | | Oral lyophillisates | Novartis (Zofran [®]) |

| Ondansetron | 8mg | Orodispersible tablet | Bluefish Pharma Healthcare Pharma Morningside Healthcare Teva |
|-------------|---------|-----------------------|--|
| | | Orodispersible film | Norgine (Setofilm [®]) |
| | | Oral lyophillisates | Novartis (Zofran®) |
| Ondansetron | 4mg/5ml | Syrup | Advanz Pharma ParaPharm Development Crescent |

Table 1: Summary of licensed alternative preparations of Sancuso[®] (granisetron) 3.1mg/24hours transdermal patches

Guidance on ordering and prescribing unlicensed imports:

- 7. The following specialist importers have currently confirmed they can source unlicensed imports of granisetron 3.1mg/24hours transdermal patches, lead times vary (please note, there may be other companies that can also source supplies):
 - Alium Medical
 - Durbin PLC
 - Mawdsley's Unlicensed
 - Target Healthcare
 - Waymade PLC
- 8. 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 (RPS)
 - Prescribing unlicensed medicines, General Medical Council (GMC)
- 9. Please refer to the BNF and SPCs for further information on alternative preparations:
 - Granisetron preparations BNF
 - Granisetron preparations SmPC
 - Ondansetron preparations BNF
 - Ondansetron preparations SmPC

Enquiries

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

NSS.NHSSMedicineShortages@nhs.scot (secondary care).