

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Distribute to Pharmacy/Wholesaler Level

Dear Healthcare Professional

Sevredol 10 mg tablets

PL 16950/0063

Batch Number	Expiry Date	Pack Size	First Distributed
243406	29-Feb-2024	56s	27-May-2021
244570	29-Feb-2024	56s	not yet distributed

Sevredol 20 mg tablets

PL 16950/0064

Batch Number	Expiry Date	Pack Size	First Distributed
244573	31-Mar-2024	56s	18-Jun-2021

Active Pharmaceutical Ingredient: Morphine Sulfate

Brief description of the problem

Napp Pharmaceuticals Limited would like to notify you of an error regarding specific batches of Sevredol 10 mg Tablets and Sevredol 20 mg Tablets, sold and distributed in the UK. The error identified relates to approved safety-related variations to the PIL that were not implemented, resulting in an older version of artwork being used and packed within finished batches.

Below are listed the differences in the PIL text:

- *Section 2. What you need to know before taking Sevredol tablets* – the addition of “severe asthma”
- *Section 2. Warnings and Precautions* – the addition of “constipation”.



- *Section 2. Warnings and Precautions* – the addition of “This medicine may cause breathing problems or worsen already existing problems while sleeping. These problems may include pauses in breathing during sleep, being awoken by shortness of breath, difficulty staying asleep or excessive daytime drowsiness. If you or someone else observes these symptoms contact your doctor. Your doctor may want to lower your dose.”
- *Section 2. Other medicines and Sevredol tablets* – re-wording of an existing paragraph (no change in the overall meaning)
- *Section 4. Possible side effects* – the addition of “Problems with breathing during sleep (sleep apnoea syndrome)”

Advice for healthcare professionals

Healthcare professionals are advised to exercise caution when dispensing the product and where possible, provide an updated PIL. There is no risk to product quality as a result of this issue, therefore the affected batches are not being recalled. Where available, Napp will be providing the updated PIL with all future deliveries for the affected batches.

Please see link to updated PIL available from the MHRA.

Further Information

For more information, medical information queries or replacement PIL enquiries, please contact: medicalinformationuk@napp.co.uk

For stock control queries, please contact: supplies.uk@napp.co.uk

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this notice

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

TO ALL CHEMISTS, DOCTORS ON THE LISTS

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12th July 2021

Pharmaceutical website: <http://www.hscbusiness.hscni.net>