



# MEDICINES NOTIFICATION

## CLASS 4 MEDICINES DEFECT INFORMATION

### Caution in Use Distribute to Pharmacy/Wholesaler Level

Date: 12 July 2021

EL (21)A/17

Our Ref: MDR 074-07/21

Dear Healthcare Professional,

## Napp Pharmaceuticals Limited

### 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

Active Pharmaceutical Ingredient: Morphine Sulfate

### 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](mailto:medicalinformationuk@napp.co.uk)

For stock control queries, please contact: [supplies.uk@napp.co.uk](mailto:supplies.uk@napp.co.uk)

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice.

NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

**Defective Medicines Report Centre**  
**10 South Colonnade**  
**Canary Wharf**  
**London**  
**E14 4PU**  
**Telephone +44 (0)20 3080 6574**