

22 January 2019



RE: Shortage of DBL MORPHINE SULFATE 30mg/1mL injection BP ampoule and alternative supply arrangement under Section 19A of the Therapeutic Goods Act

PO Box 718
Mona Vale
NSW 1660
Australia

www.clinigengroup.com

+61 2 8401 9777

+61 2 8401 9788

info@linkhealthcare.com.au

Dear Healthcare Professional,

This notification is sent by LINK to inform your organisation that due to a shortage of the Australian registered **DBL MORPHINE SULFATE 30mg/1mL injection BP ampoule** (AUST R 121755), LINK has arranged the supply of an alternative product. LINK can supply **Morphine Sulfate Injection BP 30mg in 1mL ampoules**, registered and marketed in the United Kingdom.

Morphine Sulfate Injection BP 30mg in 1mL ampoules are NOT registered in Australia and supply is granted under an exemption granted by the Therapeutic Goods Administration (TGA) under Section 19A of the Therapeutic Goods Act, 1989 until **30 June 2019**.

Morphine Sulfate Injection BP 30mg in 1mL ampoules are approved for use under Section 19A for the following indication(s):

For the relief of severe pain not responsive to non-opioid analgesics.

NOTE: **Morphine Sulfate Injection BP 30mg in 1mL ampoules** is **not** indicated for use as a pre-operative medication or as an analgesic adjunct in general anaesthesia. **Morphine Sulfate Injection BP 30mg in 1mL ampoules** is **not** recommended for children under 6 years.

Note: The formulation of the **Morphine Sulfate Injection BP 30mg in 1mL ampoules** from the UK, contains a preservative and consequently must **NOT** be administered via the epidural or intrathecal route. It is approved for intravenous (IV), intramuscular (IM) and subcutaneous (SC) routes of administration only. The Australian registered **DBL MORPHINE SULFATE 30mg/1mL injection BP ampoule** formulation is preservative free.

WARNING

UK registered Morphine Sulfate Injection BP 30mg in 1mL ampoules

CONTAINS PRESERVATIVE

NOT FOR EPIDURAL or INTRATHECAL USE.

The UK registered **Morphine Sulfate Injection BP 30mg in 1mL ampoules** will have an over-stick on the front of the outer packaging, warning clinicians that this product can be used for SC, IV and IM use only. Please refer to the adjacent image for an illustration of the front panel of the packaging with the over-sticker.



Morphine Sulfate Injection BP 30mg in 1mL ampoules are registered in the United Kingdom and are packaged in English language. Please refer to the package leaflet within the carton and the SmPC (UK prescribing information) attached to this letter for more information.

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are **Morphine Sulfate Injection BP 30mg in 1mL ampoules** should be reported by healthcare professionals and patients to Link Healthcare Medical Information. This information can also be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

Link Healthcare Medical Information can be contacted by phone on **1800 181 060** or via email at medinfo@linkhealthcare.com.au.

For further information please contact Link Healthcare Customer Service on **1800 181 060** or via email at customerservice@linkhealthcare.com.au.

We would appreciate if you could distribute this information to those in your organisation who would be affected by the shortage of morphine sulfate ampoules.

Senior Regulatory Affairs Associate