

Re: DBL™ MORPHINE SULFATE INJECTION BP 10mg/1mL

14th December 2012

Dear Healthcare Professional,

As previously communicated, due to manufacturing issues, Hospira is currently experiencing a supply shortage of DBL™ **MORPHINE SULFATE INJECTION BP 10mg/1mL** (AUST R 101240, Product code: 618191BAU). Although stock will still be available throughout December, supplies are constrained and have been placed on reserve. We anticipate that regular supply is expected to resume during the second quarter of 2013.

In the interim, Hospira proposes to supply Australia, via Section 19A of the *Therapeutic Goods Act 1989*, with an alternate presentation of Morphine Sulfate Injection 10mg/1mL (pack of 10 ampoules) which is registered and supplied in the United Kingdom by Wockhardt UK Ltd. This alternative product is not currently registered in Australia. The package leaflet included with this product is the approved information in the United Kingdom.

Availability of the Wockhardt product is expected in mid January 2013.

Note: The **WOCKHARDT** formulation of Morphine Sulphate Injection 10mg/1mL product contains 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.

WARNING

WOCKHARDT Morphine Sulphate Injection 10mg/1mL

CONTAINS PRESERVATIVE

NOT FOR EPIDURAL or INTRATHECAL USE.

WE LISTEN.

WE THINK.

WE DISCOVER.

WE CREATE.

WE ADVOCATE.

WE INVEST.

The **WOCKHARDT** Morphine sulphate injection 10mg/1mL will have an over-sticker on the front, outer packaging, warning clinicians that this product can be used for SC, IV and IM use only. Refer to **Figure 1** for an illustration of the packaging's front panel with the over-sticker.

Furthermore, a poster highlighting the differences in clinical use between **DBL™ Morphine sulfate injection BP 10mg/1mL** injection and the **WOCKHARDT** morphine product accompany this letter. Please ensure this poster is printed out in colour and displayed prominently in areas where morphine ampoules are stored or administered throughout your institution e.g. on controlled drug safes/ cabinets, on pages within the controlled drugs register where morphine 10mg ampoule entries are made. The Wockardt morphine product will also have its own unique Catalog number for ordering purposes



Figure 1

Once the **WOCKHARDT** Morphine sulphate injection 10mg/1mL becomes available for sale in January 2013, we will provide further communication confirming its release to the market as well as all relevant details to set this up in your systems for ordering.

For further information on this product please contact:

| | | |
|---------------------------------|--|---|
| Hospira Customer Service | 1300 046 774 – Option 1 Customerservice.au@hospira.com | Customer Support including product availability and order related enquiries |
| Medical Information Team | 1300 046 774 – Option 2 or medicalinformationAUS@hospira.com . | Medical enquiries |

Hospira apologise for any inconvenience as a result of this situation and are working to reduce the likelihood of further supply shortages in the future. We are working closely with the TGA to ensure your patient's receive the best possible healthcare.

Yours Sincerely,



Alex Pedrana

Customer Service Manager

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