



ProPharmaceuticalsGroup

Pro Pharmaceuticals Group Pty LTD

ABN: 20 605 457 430

www.propg.com.au

Dear Healthcare Professional,

Shortage of Bleomycin sulphate powder for injection

IMPORTANT NOTE:

Each vial of the Section 19A Bleomycin for Injection (Meitheal Pharmaceuticals Inc) product contains 15 USP Units of Bleomycin Sulfate Powder for solution which is equivalent to Bleomycin Sulfate 15,000 IU (1 USP unit is equivalent to 1,000 IU). Prescribers and Pharmacists must be alerted to this difference in labelled units in order to prevent medication errors.

Pro Pharmaceuticals Group recognises the importance of supplying essential medicines in Australia and would like to advise you the change in supply status of **Bleomycin sulphate powder for injection** in Australia.

The Australian registered medicine, CIPLA BLEOMYCIN 15K bleomycin sulfate 15000 IU powder for injection vial AUST R: 220440 sponsored by Cipla Australia Pty Ltd, is currently in shortage due to manufacturing issues. Other sponsors of **Bleomycin sulphate powder for injection** are also in shortage.

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **Bleomycin for Injection, USP 15 units per vial (Meitheal Pharmaceuticals Inc)**. This product is NOT registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under section 19A of the Therapeutic Goods Act 1989 until **31st January 2020** for the following indication(s):

Palliation and treatment adjuvant to surgery and radiation therapy of the following neoplasms:

- *Squamous cell carcinoma of the skin, head and neck, and oesophagus (primary indication).*
- *Squamous cell carcinoma of the larynx, penis and uterine cervix.*
- *Squamous cell carcinoma of the bronchus (response infrequent).*
- *Choriocarcinoma and embryonal cell carcinoma of the testis.*
- *Advanced Hodgkin's disease and other lymphomas.*

Note. Use of bleomycin after radiation therapy is less successful than use before radiation therapy. Bleomycin is bone marrow sparing and may be used when other cytotoxic agents are contraindicated.

Bleomycin for Injection, USP 15 units per vial is only to be used for the following routes of administration: intramuscular, intravenous and subcutaneous.

Bleomycin for Injection, USP 15 units per vial is registered and marketed in the USA by Meitheal Pharmaceuticals Inc.

Pro Pharmaceuticals Group recommends that healthcare professionals refer to the Australian approved Product Information for recommended dosing for various indications.

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **Bleomycin for Injection, USP 15 units per vial (Meitheal Pharmaceuticals Inc)** must be reported by healthcare professionals, pharmacists and patients to the TGA at <https://www.tga.gov.au/reporting-problems> or to Pro Pharmaceuticals Group on 1300077674 or email regulatory@propg.com.au

Any product complaints with **Bleomycin for Injection, USP 15 units per vial (Meitheal Pharmaceuticals Inc)** should be reported to Pro Pharmaceuticals Group on 1300077674 or email regulatory@propg.com.au

For any orders please contact Pro Pharmaceuticals Group on 1300077674 or email info@propg.com.au

Please forward this information to relevant staff members in your organisation.

For further information, please contact Pro Pharmaceuticals Group on 1300077674 or email info@propg.com.au

Sincerely,

Sandip Manku – Director, Pro Pharmaceuticals Group Pty Ltd

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