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22nd April 2020

Information about
Esmeron® (rocuronium bromide) 10 mg/ml solution for injection

Dear Healthcare Professional

On behalf of Merck Sharp & Dohme Ltd (MSD), I am writing to inform you that, as an interim measure during the COVID 19 crisis, to help with the supply of the muscle relaxant rocuronium bromide, the company will be supplying some packs of Esmeron which were packed for Australia. The details of the two batches that will be supplied initially are detailed below and some of the most important differences in packaging are highlighted below.

Batch number	Expiry date
T011923	Feb 2023
T011924	Feb 2023

Summary

- **In relation to the COVID 19 crisis, we are experiencing a substantial increase in demand for our product Esmeron globally and the Company is actively engaged in increasing supply.**
- **To help the supply of rocuronium bromide to the UK market, a quantity of Esmeron which was packaged for Australia has been made available to the UK, as an interim measure.**
- **The Medicines and Healthcare Regulatory Agency (MHRA) have approved the use of this supply for the UK under the existing UK Product Licence for Esmeron.**
- **We would like to make you aware of the differences in the packaging and that a PIL is not included in the pack (see details below).**

Further information

- The Australian product is manufactured to the same formulation and it meets the same quality release specifications as the product that is usually distributed by MSD in the UK.

- The Australian carton lacks the following important UK information
    - Product Licence Number: PL 05003/0041
    - Marketing Authorisation Holder: NV Organon
Kloosterstraat 6
PO Box 20
5340 BH Oss
The Netherlands
- While the Australian pack does not include a combined patient information leaflet (PIL) and technical information leaflet (TIL) like the UK pack, it does include the Australian Datasheet (see below)
- The UK technical information leaflet is based on the current UK SmPC. Both the current UK SmPC and PIL can be accessed at https://www.medicines.org.uk/emc/
- There are some important omissions from/differences between the Australian Datasheet and the UK technical information leaflet. These are as follows:

Section 1 Name of the Medicinal Product

- In the UK TIL the product strength is described as follows:

  Each ml Esmeron contains 10 mg rocuronium bromide.

- In the Australian datasheet the product strength is described as follows:

  Esmeron 25mg = 2.5mL, Esmeron 50mg = 5mL and Esmeron 100mg = 10mL contain rocuronium bromide 10mg/mL

Section 4.1 Indication

- In the UK the product can be used from birth whilst in Australia it is from >1month and during surgery.

- In the UK the product can be used first line but in Australia it is used second line as an adjunct to general anaesthesia to facilitate endotracheal intubation during rapid sequence induction when suxamethonium is contraindicated.

Section 4.4 Special warnings and precautions for use

- The following warning statement about malignant hyperthermia is omitted from Australian datasheet:

  Because rocuronium bromide is always used with other drugs and because of the risk of malignant hyperthermia during anaesthesia, even in the absence of known triggering factors, physicians should be aware of the early symptoms, confirmatory diagnosis and treatment of malignant hyperthermia prior to the start of anaesthesia. Animal studies have shown that rocuronium bromide is not a triggering factor for malignant hyperthermia. Rare cases of malignant hyperthermia with ESMERON have been observed through post-marketing surveillance; however, the causal association has not been proven.

Section 4.5 interactions

- Potential interactions with calcium chloride, potassium chloride and protease inhibitors are omitted from the Australian Datasheet

Section 4.6 pregnancy and lactation

- Use in C-section is omitted from the Australian Datasheet

Section 4.8 Reporting of suspected adverse reactions

- The following important information is omitted from the Australian datasheet:

  Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

It is possible that other batches of Australian packs will be supplied to the UK market in the future during the COVID pandemic. Details of these batches will be made available on the Company website [https://www.msd-uk.com/products/supply.xhtml].

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason

- all suspected ADRs associated with new drugs and vaccines identified by the black triangle▼

It is easiest and quickest to report ADRs online via the Yellow Cards website - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store.

Alternatively, prepaid Yellow Cards for reporting are available by writing to FREEPOST YELLOW CARD (no other address details necessary); by emailing yellowcard@mhra.gov.uk; at the back of the British National Formulary (BNF); by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789; or by downloading and printing a form from the Yellow Card website.

Adverse reaction should also be reported to the relevant company [see below for company contact details]

Company Contact Point
For medical information enquires please contact:
Medical Information Department: Telephone +44(0) 1992 467272

Yours faithfully

Phil Berry

Dr Phil Berry
Director of Medical Affairs, MSD UK