Medisource Ireland Limited,
Unit 24-26 Bullford Business Campus,
Kilcoole, Co. Wicklow

P +353-1-2866 366
F +353-1-2866 288
info@medisource.ie
www.medisource.ie

IMPORTANT INFORMATION FOR HEALTHCARE PROFESSIONALS & PATIENTS

CAUTION IN USE NOTIFICATION

21st April 2022

Supply of Metaraminol 10 mg/ml Solution for Injection or Infusion (PA 22893/001/001)

Dear Hospital Chief Pharmacist,

I am writing to you in connection with supply of the above referenced product. We are unable to supply Irish licensed packs at the moment and have obtained approval from the Health Products Regulatory Authority (HPRA) to supply UK packs of Metaraminol 10 mg/ml for a limited period. These packs are labelled with batch number and expiry date in the below table Fig.1

Batch number	Expiry Date	MA Number	MA Holder
1E0111C29	5/31/2024	PL 41102/0001	GH Pharma (UK) Ltd

The pharmaceutical composition of the product (PL 41102/0001) is identical to the Irish licensed product (PA 22893/001/001) and it is manufactured and packaged under the same conditions. However, there are differences in the outer carton labelling and package leaflet which are summarized below:

- Outer carton
  - UK Product Licence (PL) Number (PL 41102/0001) instead of Irish Product Authorisation (PA) Number (PA 22893/001/001)
  - UK Marketing Authorisation Holder (GH Pharma (UK) Ltd) instead of Irish Marketing Authorisation Holder (Global Harvest Pharmaceuticals (Ireland) Limited
  - Absence of FMD/ serialisation information on the carton.
- Package Leaflet
  - Reporting details for side effects in the Patient Leaflet refer to the MHRA (UK). The correct reporting details for Ireland are stated in the Irish Patient Leaflet (attached to this email) and copied below:

You can also report side effects directly in Ireland via HPRA Pharmacovigilance, Earlsfort Terrace, Dublin 2, IRL. Tel: +353 1 6764971. Fax: +353 1 6762517. Website: www.hpra.ie, e-mail: medsafety@hpra.ie.

There are no differences in ampoule labelling.

For further details on the product please refer to the approved Irish summary of product characteristics (SmPC) and package leaflet, which are available on the HPRA website: www.hpra.ie
The Irish package leaflet is appended to this email for your information.

Please ensure that all relevant staff, particularly those who will be administering the product are made aware of the content of this letter and that the information is communicated to the patients.

If you have any questions, please contact Medisource Ireland Limited +353 1 2866366

Yours sincerely

Donal Cullinane

Digitally signed by Donal Cullinane
Date: 2022.04.21 15:13:34 +01'00'

Donal Cullinane MPSI
Group Pharmacist
donal.cullinane@dccvital.com