Date: 23rd August 2024

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Mydrane 0.2 mg/ml + 3.1 mg/ml + 10 mg/ml solution for injection (Tropicamide, Phenylephrine hydrochloride, Lidocaine hydrochloride monohydrate): Interim Supply of Polish Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: THEA PHARMACEUTICALS LTD is currently experiencing supply disruption with Mydrane 0.2 mg/ml + 3.1 mg/ml + 10 mg/ml solution for injection in the UK.

To ensure continuity in supply, THEA PHARMACEUTICALS LTD has obtained approval from the MHRA to supply Polish product (batch number MY068 (400 packs) and batch number MY070 (1140 packs)), which is expected to be on the UK market from beginning of September 2024.

Please note the following:

- This product is licensed in the UK.
- The product from Poland has the same formulation as the UK product.
- The product from Poland is manufactured according to the same manufacturing process and quality controls as the UK product.
- The ampoules are identical in appearance, except with Polish labelling.
- There only difference between the Polish and UK product information is the packaging (the ampoule and blister), see the Background section below for more information
- Please refer to the UK Patient Information Leaflet (PIL) supplied in the pack.
- Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.
- For additional copies of the leaflet, please refer to Hreferralspccleanen (medicines.org.uk) or contact the company contact point (see below).
- The MHRA has approved this product under a batch specific variation to the marketing authorisation.

Background

THEA Pharmaceuticals Ltd is currently experiencing supply disruption with Mydrane 0.2 mg/ml + 3.1 mg/ml + 10 mg/ml solution for injection in the UK.

Polish product has been re-packed into standard UK cartons and with standard UK PILs. The inner packaging (ampoule and blister) carries Polish labelling which is identical (in Polish) to the UK wording, except that the names of the active ingredients are not stated on the ampoule.

It is not possible to overlabel with UK wording as the ampoule is sealed within a sterilised blister and the blister has a peel-off traceability label. Copies of standard UK wording for the ampoule and blister are appended to the end of this letter.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

Thea Pharmaceuticals Ltd
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Keele, Newcastle Under Lyme, ST5 5NT
T. 0345 521 1290
www.thea-pharmaceuticals.co.uk
Registration No: 6505496 VAT No: GB 927 7952 73

Images of Polish imported product labelling which differs from standard UK product ***(ampoule and blister):***

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.

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Company contact point
If you have any questions about this letter or require any information or support, please contact Théa Pharmaceuticals Ltd on 0345 521 1290.

Yours faithfully,

Amy Marsh
Surgical Product Manager

Thea Pharmaceuticals Ltd

UK approved wording for the ampoule and blister

BLISTER LABELLING

MYDRANE 0.2 mg/ml +3.1 mg/ml +10 mg/ml injection

tropicamide / phenylephrine hydrochloride / lidocaine hydrochloride monohydrate

Intracameral use

Laboratoires THEA

EXP

Lot

0.6 ml sterile ampoule and 5 µm filter sterile needle

POM

PL 20162/0022

FLAG LABEL

MYDRANE

EXP

Lot

AMPOULE LABELLING

MYDRANE, 0.2+3.1+10 mg/ml injection

tropicamide / phenylephrine HCl / lidocaine HCl monohydrate

Intracameral use only.

EXP

Lot

0.6 ml

Do not swallow.

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