Date: 22 June 2021

Direct Healthcare Professional Communication

Iloprost 100 micrograms/ml concentrate for solution for infusion – Medication Error: Risk of Underdosing due to Ampoule Labelling

Dear Healthcare Professional,

Colonis Pharma Ltd. in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Summary:

- **Colonis Pharma Ltd, has received a product quality complaint regarding labelling of the ampoule which was considered to have contributed to cases of underdosing due to medication error.**
- **Iloprost 100 micrograms/ml concentrate for solution for infusion is available in a 0.5 ml ampoule containing 50 micrograms of the active ingredient, Iloprost.**
- **The strength of '100 micrograms/ml' on the current approved label may not be fully visible which could be a potential contributory factor leading to underdosing in patients.**
- **Vigilance is advised during preparation and administration of Iloprost 100 micrograms/ml concentrate for solution for infusion to patients to avoid medication errors.**

Background on the Safety Concern:

Iloprost 100 micrograms/ml Concentrate for solution for infusion is indicated in adults for:

- Treatment of severe chronic ischaemia of lower limbs in patients at risk of amputation, in whom surgical revascularisation or angioplasty has failed or is not indicated, following an interdisciplinary meeting of physicians, surgeons and radiologists.
- Treatment of severe Raynaud's phenomena in patients with progressive trophic disorders.

The strength of '100 micrograms/ml' on the current approved label wrapped around the ampoule is not fully visible without rotating the ampoule. The visible width only displays '100 micro' and not the 'grams/ml', along with the volume of '0.5ml'. This could be a contributory factor leading to underdosing in patients. There have been no adverse events or safety concerns associated with the incidents of underdosing reported to Colonis Pharma Ltd.

Colonis Pharma Ltd. has worked with the MHRA to improve visibility of the strength and total quantity per unit volume as per the Government Best practice in the Labelling and Packaging of Medicines. Packs with updated labels have been approved by the MHRA and will become available in the coming months.

This Direct Healthcare Professional Communication is being sent to draw attention to this issue and encourage vigilance during preparation and administration of Iloprost 100 micrograms/ml

concentrate for solution for infusion to patients in order to avoid medication error. Please see an example image of the fully rotated label for an ampoule below.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. It is easiest and quickest to report ADRs online via the Yellow Card website https://yellowcard.mhra.gov.uk/, via the Yellow Card app available from the Apple App Store or Google Play Store or 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. You can leave a message outside of these hours.

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

Company Contact Point

For further questions or additional information on the correct use of Iloprost 100 micrograms/ml concentrate for solution for infusion, please contact:

E-mail address: medinfo@colonis.co.uk; Telephone Number: +44 (0) 1892 739403

Address: Colonis Pharma Ltd, Quantum House, Hobson Industrial Estate, Burnopfield, County Durham, NE16 6EA United Kingdom

Yours Sincerely,

DR HE Welgemoed

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