



14/10/2024

Important information for healthcare professionals

Summary:

New contraindication for Ilvico administration with MAOIs concomitantly or within last 14 days.

Product details:

Ilvico® Cold and Flu film-coated tablets

Paracetamol 325 mg, Caffeine 30 mg, Brompheniramine maleate 3 mg

PA22703/001/001

Dear Healthcare Professional:

P&G Health Germany GmbH, as Marketing Authorisation Holder of Ilvico® Cold and Flu, would like to inform you that a contraindication has been added to Section 4.3 of the SmPC, and subsequently on the Package Leaflet as follows:

Administration of monoamine oxidase inhibitors (MAOIs) concomitantly or in the last 14 days.

This contraindication replaces the warning and precaution in Section 4.4, following a review of the potential pharmacological interaction. MAOIs inhibit the activity of the enzyme monoamine oxidase which breaks down serotonin. Brompheniramine increases the levels of serotonin by inhibiting its reuptake. Because of this dual action, concomitant MAOI therapy increases the risk of serotonin syndrome. Furthermore, monoamine oxidase inhibitors enhance the anticholinergic effects of antihistamines such as brompheniramine. For these reasons, a contraindication has been added.

The communication of this information has been agreed with the Health Products Regulatory Authority (HPRA). Please ensure that all relevant staff are made aware of the content of this letter. The updated SmPC is also available on the HPRA official website.

Reporting of suspected adverse reactions

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 to HPRA Pharmacovigilance using the report form on the HPRA website, www.hpra.ie.

Adverse events should also be reported to P&G Health Germany GmbH, which can be contacted via the following call numbers in Ireland: 1800509242 and 1800509529, or by E-Mail: consumerrelation.im@pg.com.

If you have any questions, please kindly contact us using the above details.

Yours faithfully,

Oliver Matthews

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