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Lumeblue (*methylthioninium chloride*)[1]

An overview of Lumeblue and why it is authorised in the EU

What is Lumeblue and what is it used for?

Lumeblue is used in adults as a dye to help doctors see the lining of the colon (large bowel) more clearly and improve detection of lesions (abnormalities) during colonoscopy, a procedure to examine the colon through a tube with a camera.

Lumeblue contains the active substance methylthioninium chloride.

Lumeblue is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance, but the authorised use, strength, pharmaceutical form and route of administration are different. The reference medicine for Lumeblue is Metilénkék Pharmamagist, a medicine authorised in Hungary.

How is Lumeblue used?

Lumeblue can only be obtained with a prescription.

It is available as 25 mg tablets. The recommended total dose is 200 mg methylthioninium chloride (8 tablets) by mouth taken the day before the colonoscopy together with a bowel cleansing preparation (a medicine that clears all solid matter from the colon) of 4 litres in total. The first 3 tablets should be taken after drinking at least 1 litre of the bowel cleansing preparation; the next 3 tablets should be taken 1 hour after the first dose and the last 2 tablets should be taken 1 hour after the second dose.

For more information about using Lumeblue, see the package leaflet or contact your doctor or pharmacist.

How does Lumeblue work?

The active substance in Lumeblue, methylthioninium chloride (also called methylene blue), has been widely used for medical purposes. Methylthioninium chloride enters cells such as those in the small intestine and colon and temporarily stains the lining of these organs. Because the amount of methylthioninium chloride taken up by different types of cells varies, the medicine helps doctors identify any abnormalities in the makeup of the lining.

[1] Previously known as Methylthioninium chloride Cosmo

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The tablets have a special coating which allows the medicine to reach the colon before methylthioninium chloride is slowly released to stain the lining evenly.

What benefits of Lumeblue have been shown in studies?

Lumeblue improved detection of adenoma (a type of tumour linked to increased risk of cancer) or carcinoma (a type of cancer) during colonoscopy.

At least one adenoma or carcinoma was detected in 56% of patients (273 out of 485) who received Lumeblue compared with 48% of patients (229 out of 479) who did not receive it. The presence of adenoma and carcinoma was later confirmed by examining tissue after removing it from the colon. Using Lumeblue did not lead to a higher number of 'false positive' results.

What are the risks associated with Lumeblue?

The most common side effects with Lumeblue (which may affect more than 1 in 10 people) are discoloration of the urine and faeces, which disappears after a few days. Short-lived nausea and vomiting are also common (they can affect up to 1 in 10 people).

Lumeblue must not be used in patients who are hypersensitive (allergic) to peanuts, soya or any ingredients in the medicine. It must also not be used in patients in whom the enzyme glucose-6-phosphate dehydrogenase (G6PD) is not working (G6PD deficiency). It must not be taken during pregnancy and when breastfeeding.

Why is Lumeblue authorised in the EU?

Lumeblue improves detection of adenoma and carcinoma in the colon during colonoscopy, which may lead to a reduction in the risk of colorectal cancer if removed. The safety profile of Lumeblue is well known from other medicines and products containing the same active substance; the side effects are mainly mild or moderate and of short duration. The European Medicines Agency therefore decided that Lumeblue's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Lumeblue?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Lumeblue have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Lumeblue are continuously monitored. Side effects reported with Lumeblue are carefully evaluated and any necessary action taken to protect patients.

Other information about Lumeblue

Methylthioninium chloride Cosmo received a marketing authorisation valid throughout the EU on 19 August 2020.

The name of the medicine was changed to Lumeblue on 15 December 2020.

Further information on Lumeblue can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/lumeblue.

This overview was last updated in 05-2021.