25 June 2020
EMA/CHMP/313588/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Methylthioninium chloride Cosmo

methylthioninium chloride

On 25 June 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Methylthioninium chloride Cosmo, intended as a diagnostic agent to enhance visualisation of colorectal lesions. The applicant for this medicinal product is Cosmo Technologies Ltd.

Methylthioninium chloride Cosmo will be available as 25 mg prolonged-release tablets. The active substance of Methylthioninium chloride Cosmo is methylthioninium chloride, classified as an other diagnostic agent (ATC code: V04CX). It is taken up by the cell membrane and passes into the cytoplasm of actively absorbing cells such as those in the small intestine and colon, thereby staining the epithelia of those organs.

The benefit of Methylthioninium chloride Cosmo is its ability to improve the detection rate of adenomas. The most common side effects are chromaturia and discoloured faeces.

Methylthioninium chloride Cosmo is a hybrid medicine[2] of METILÉNKÉK PHARMAMAGIST 1% solution for injection, which has been authorised in the EU since 29 June 2006. Methylthioninium chloride Cosmo contains the same active substance as METILÉNKÉK PHARMAMAGIST 1% solution for injection, but it is for oral use.

The full indication is:

> Methylthioninium chloride Cosmo is indicated as a diagnostic agent enhancing visualisation of colorectal lesions in adult patients undergoing screening or surveillance colonoscopy.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

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