LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Methenamine hippurate Pfleger (methenamine hippurate)

SE/H/2508/01/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Summary Public Assessment Report

Methenamine hippurate Pfleger
methenamine hippurate, methenamine

Tablet, 1 g

This is a summary of the public assessment report (PAR) for Methenamine hippurate Pfleger. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Methenamine hippurate Pfleger and what is it used for?
The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Hiprex.

Methenamine hippurate Pfleger is a urinary tract anti-bacterial agent (bactericidal) that is used to prevent relapsing urinary tract infections. It is also used during urinary examinations and urinary treatments to reduce the risk of infections. It is also given to people who carry urinary tract catheters for a long time.

The preventative treatment in accordance with these instructions diminishes the risk for new urinary tract infections with recurrent painful urination and unpleasant smelling urine.

How is Methenamine hippurate Pfleger used?
The pharmaceutical form is tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Methenamine hippurate Pfleger have been shown in studies?
Because the product is a generic medicine, studies have been limited to tests to determine that it is bioequivalent to the reference medicine, Hiprex. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Methenamine hippurate Pfleger?
Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of restrictions, see the package leaflet.

Why is Methenamine hippurate Pfleger approved?
It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Hiprex, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Methenamine hippurate Pfleger?
A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

For more details, please see the full PAR for Methenamine hippurate Pfleger on the following website: MRI - Home.>

Other information about Methenamine hippurate Pfleger
The full PAR for Methenamine hippurate Pfleger can be found on the following website: MRI - Home. For more information about treatment with Methenamine hippurate Pfleger, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-05.