Package leaflet: Information for the user

Methenamine hippurate 1 g Tablets

methenamine hippurate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- 1. What Methenamine Tablets is and what it is used for
- 2. What you need to know before you use Methenamine Tablets
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1. What Methenamine Tablets is and what it is used for

Methenamine Tablets is an urinary tract anti-bacterial agent (bactericidal) that is used to prevent relapsing urinary tract infections.

Methenamine Tablets is also used during urinary examinations and urinary treatments to reduce the risk of infections.

Methenamine Tablets is also given to people who carry urinary tract catheter for a long time.

The prophylactic treatment in accordance with these instructions diminishes the risks for new urinary tract infections with repeated painful mictions and bad smelling urine.

2. What you need to know before you use Methenamine Tablets

Do not use Methenamine Tablets

- if you are allergic to methenamine hippurate or any of the other ingredients of this medicine (listed in section 6)
- if you are hypersensitive to formalin
- if you suffer from renal impairment, are severely dehydrated or have gout
- if you suffer from liver impairment
- if you have a condition called metabolic acidosis (high amount of acidic substances in the body which causes symptoms such as increased heart rate, headache and nausea)
- if you have kidney infection

Other medicines and Methenamine Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Especially tell your doctor if you take any of the following medicines:

- Medicines used for heartburn, since these decrease the effect of Methenamine Tablets by making your urine less acidic
- Medicines called sulphonamides, also known as "sulpha" as they can increase the risk of crystals in the urine (so-called crystalluria)

If you are collecting a urine sample, tell the doctor or nurse that you are using Methenamine Tablets, since methenamine hippurate might cause misleading results for some substances, e.g. steroids

Methenamine Tablets with food and drink

Methenamine Tablets can be taken with or without food and drink.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

No known risks when used during pregnancy. Ask your doctor if you can use Methenamine Tablets during the pregnancy.

Methenamine hippurate is excreted in breast milk but is not likely to influence the child. Discuss with your doctor in case of more than temporary use of Methenamine Tablets during breast-feeding.

There is no data available regarding fertility in humans and Methenamine Tablets.

Driving and using machines

Using this product is not known to affect your ability to drive or to use machines.

Methenamine Tablets contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to use Methenamine Tablets

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Recommended dose for adults is 1 tablet 2 times a day. In patients with catheters the dosage may be increased to 1 tablet 3 times a day.

Use in children and adolescents

Recommeded dose for children 6-12 years: ½ tablet twice daily Recommended dose for children older than 12 years: 1 tablet twice daily The tablet can be divided into two equal doses. The tablets may be halved or crushed and taken with water if the patient is unable to swallow whole tablets or other formulations with methenamine hippurate can be used if available.

If you take more Methenamine Tablets than you should

The most common symptoms of an overdose are nausea, vomiting and possibly blood in the urine, dizziness and tinnitus. Drink plenty of water.

If you forget to take Methenamine Tablets

Continue with the treatment according to your doctor's prescription, take your next dose as planned. Do not take a double dose to make up for a forgotten dose.

4. **Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common: may affect up to 1 in 10 people

• nausea, vomiting, rashes, irritation of the bladder

Rare: may affect up to 1 in 1,000 people

• blood in the urine

Not known: frequency cannot be estimated from the available data

• diarrhoea, abdominal pains, pruritus

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card System website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Methenamine Tablets

Keep this medicine out of the sight and reach of children.

Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton or label after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Methenamine Tablets contains

- The active substance is Methenamine hippurate, 1 gram per tablet.
- The other ingredients are silica colloidal, povidone, magnesium stearate and croscarmellose sodium.

What Methenamine Tablets looks like and contents of the pack

White, capsule shaped tablet, break line on both sides.

Pack size: 20, 21, 60, 100 and 105 tablets (glass bottle). Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

Mercury Pharmaceuticals Ltd. Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

Manufacturer

EQL Pharma AB Stortorget 1 222 23 Lund Sweden

This medicinal product is authorized in the Member States of the EEA under the following names:

Denmark: Methenamine hippurate EQL Pharma Norway: Methenamine hippurate EQL Pharma Sweden: Methenamine hippurate EQL Pharma United Kingdom: Methenamine hippurate

This leaflet was last revised in January 2024

Other sources of information

Detailed information on this medicine is available on the website of MHRA (www.gov.uk/government/organisations/medicines-andhealthcare-products-regulatory-agency)