

Package leaflet: Information for the user

Methenamine hippurate Pfleger 1 g tablets

Methenamine hippurate

Read all of this leaflet carefully before you start taking 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <Invented name> is and what it is used for
2. What you need to know before you take <Invented name>
3. How to take <Invented name>
4. Possible side effects
5. How to store <Invented name>
6. Contents of the pack and other information

1. What <Invented name> is and what it is used for

<Invented name> is a urinary tract anti-bacterial agent (bactericidal) that is used to prevent relapsing urinary tract infections.

<Invented name> is also used during urinary examinations and urinary treatments to reduce the risk of infections.

<Invented name> 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.

2. What you need to know before you take <Invented name>

Do not take <Invented name>

- 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 <Invented name>

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 <Invented name> by making your urine less acidic
- Medicines called sulphonamides, also known as “sulpha” as they can increase the risk of crystal formation in the urine (so-called crystalluria)

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

<Invented name> with food and drink

<Invented name> can be taken with and 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 <Invented name> during the pregnancy.

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

Driving and using machines

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

<Invented name> contains sodium

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

3. How to take <Invented name>

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

The 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

Recommended dose for children older than 12 years: 1 tablet twice daily.

Recommended dose for children 6-12 years: ½ 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 <Invented name> 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 <Invented name>

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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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, rash, bladder irritation

Rare: may affect up to 1 in 1000 people

Blood in the urine

Not known (cannot be estimated from the available data)

Diarrhoea, abdominal pain, 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 **national reporting system** listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

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 <Invented name> contains**

- The active substance is Methenamine hippurate, 1 gram per tablet.
- The other ingredients are silica colloidal anhydrous, povidone K29/32, magnesium stearate and croscarmellose sodium.

What <Invented name> looks like and contents of the pack

White to off-white, capsule shaped tablets with dimension 19 mm x 8 mm and with breaklines on both sides. The tablets can be divided into equal doses. Pack size:

Bottle pack - 20, 60 and 100 (glass bottle).

Alu-Alu Blister pack - 20, 60, 100, 180 and 200 tablets in a cardboard outer box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

<To be completed nationally>

Manufacturer

EQL Pharma AB

Stortorget 1

222 23 Lund

Sweden

This medicine is authorised in the Member States of the European Economic Area under the following names:

<To be completed nationally>

This leaflet was last revised in 2025-01-16.