Package leaflet: Information for the patient

Methenamine hippurate 1 g tablets

Methenamine hippurate

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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

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

Methenamine hippurate belongs to a group of medicines called anti-bacterials. These work by killing many different types of bacteria which cause infections. Methenamine hippurate is used to treat infections of the urinary tract and stop them from coming back. The urinary tract is a collective name for the parts of the body that produce, store and transport urine. These include the kidney, bladder and tubes called the ureter and urethra. It is also used to avoid urinary tract infections in patients with catheters from their bladders (a tube that helps with incontinence) and in people undergoing certain medical procedures.

As maintenance therapy after successful initial treatment of acute infections with antibiotics.

As long-term therapy in the prevention of recurrent cystitis.

To suppress urinary infection in patients with indwelling catheters and to reduce the incidence of catheter blockage.

To provide prophylaxis against the introduction of infection into the urinary tract during instrumental procedures.

Asymptomatic bacteriuria.

2. What you need to know before you take Methenamine hippurate

Do not use Methenamine hippurate:

- If you have problems with your liver
- If you have serious problems with your kidneys

- If you are severely dehydrated
- If you have a condition called metabolic acidosis (a chemical imbalance in the blood).
- If you have gout
- If you are taking antibiotic medicines called sulphonamides. These can damage your kidneys when taken at the same time as methenamine hippurate
- If you are allergic to methenamine hippurate or any of the other ingredients of this medicine (listed in section 6)

If any of the above applies to you, talk to your doctor or pharmacist

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Methenamine hippurate if:

- You have any kinds of problems with your kidneys

Other medicines and methanamine Hippurate

Tell your doctor or pharmacist or nurse 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 called sulphonamides, as they can increase the risk of crystals in the urine (so-called crystalluria).
- Medicines to make your urine less acidic such as potassium citrate and acetazolamide.

These can stop Methenamine hippurate working properly.

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.

3. How to take Methenamine hippurate

Always take Methenamine hippurate exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Adults

The recommended dose is one tablet twice a day.

If you have a catheter your doctor may increase your dose to one tablet three times a day.

Use in children

Not for children aged under 6.

Children aged 6-12 years the recommended dose is 500 mg twice a day.

Method of administration

The tablets can be broken in half. If you find it particularly difficult to swallow them, the tablets may be crushed and taken with a drink of milk or fruit juice.

If you take more Methenamine hippurate than you should

If you accidentally take more Methenamine hippurate than you should you might be sick or see blood in your urine. Drink plenty of water and immediately go to the nearest hospital casualty department or your doctor. Your doctor may give you another medicine to stop you being sick.

If you forget to take Methenamine hippurate

Do not take a double dose to make up for a missed dose. Simply take your next dose as planned.

If you stop taking Methenamine hippurate

Your doctor will tell you how long to take your medicine for. Do not stop taking Methenamine hippurate without first talking to your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. You may experience the following:

Uncommon: may affect up to 1 in 100 people

- Rashes
- Stomach irritation
- Nausea
- Itching
- Bladder irritation usually seen as a burning sensation and pain on urinating.
- Vomiting

Not known (cannot be estimated from the available data)

• Diarrhoea, abdominal pain

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 hippurate

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

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

This medicine does not require any special storage conditions.

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 hippurate contains

The active substance is methenamine hippurate. Each tablet contains 1 g methenamine hippurate.

The other ingredients are colloidal silicon dioxide, povidone and magnesium stearate.

What Methenamine hippurate looks like and contents of the pack

White to off- white colored, capsule shaped, biconvex tablets, debossed with "H" and "1" on either side of breakline on one side and plain on other side with approximate length 20.00 mm & width 8.00 mm.

The tablet can be divided into equal doses.

Methenamine hippurate tablets are available in blister pack and HDPE bottle pack with a polypropylene screw cap.

Pack sizes:

Blister packs: 7, 8, 10, 20, 21, 60, 100 and 105 tablets.

HDPE packs: 60 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

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