FULL PRESCRIBING INFORMATION

Hiprex 1 g Tablets

(methenamine hippurate)

Please refer to Summary of Product Characteristics (SmPC) before prescribing

Indication: Hiprex 1 g Tablets is indicated in the prophylaxis and treatment of urinary tract infections. It works 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 and for the treatment of asymptomatic bacteriuria.

Presentation: Hiprex 1 g Tablets is a white to creamy-white oblong shaped tablet coded HX with break line on one face and break line on the other face. Each Hiprex tablet contains methenamine hippurate 1 g.

Dosage and administration: *Adults*: For oral use, one tablet (1g) twice daily. In patients with catheters the dosage may be increased to one tablet (1g) three times daily. *Children under 6 years:* Not recommended. *Children 6-12 years*: half a tablet (500mg) twice daily. Older People: No special dosage recommendations. The tablets may be halved, or they can be crushed and taken with a drink of milk or fruit juice if the patient prefers.

Contraindications: Hypersensitivity to the active substance (methenamine hippurate) or to any of the excipients listed in section 6.1 of the SmPC. Other contraindications include hepatic dysfunction, renal parenchymal infection, severe dehydration, metabolic acidosis, severe renal failure (creatinine clearance or GFR<10 ml/min.) or gout. Hiprex may be used where mild (20-50 ml/min.) to moderate (10-20 ml/min.) renal insufficiency is present. (If the GFR is not available the serum creatinine concentration can be used as a guide.). Hiprex should not be administered concurrently with antibiotic medicines such as sulphonamides, due to the possibility of crystalluria (formation of crystals in the urine), or with alkalising agents, such as a mixture of potassium citrate.

Warning and precautions: No special warnings and precautions for use.

Interaction with other medicinal products: The active substance methenamine hippurate should not be administered concurrently with antibiotic medicines such as sulphonamides due to the possibility of crystalluria, or with alkalising agents such as potassium citrate. Concurrent use with acetazolamide should be avoided as the desired effect of hexamine will be lost.

Depending on the type of analysing method used, methenamine can affect the determination of steroids, catecholamines and 5 hydroxyindole acetic acid from urine and give false results.

Pregnancy and lactation: *Pregnancy:* There is inadequate evidence of safety of methenamine hippurate in human pregnancy, but it has been in wide use for many years without apparent ill consequence. As a precautionary measure, it is preferable to avoid the use of methenamine hippurate during pregnancy. *Breast feeding*: Methenamine is excreted in breast milk but the quantities will be insignificant to the infant. Mothers can therefore breast feed their infants. *Fertility:* There are no human data available on fertility.

Effects on ability to drive and use machines: No known effects on the ability to drive and use machines.

Undesirable effects: Uncommon: gastric irritation, irritation of the bladder, nausea, vomiting, rash and pruritus (itchiness). Not known: Diarrhoea and abdominal pain. Please refer to SmPC for a full list of adverse events.

Legal Category: POM **Marketing Authorisation Number**: PL 46302/0200 **MAH:** Mylan Products Ltd., Station Close, Potters Bar, Hertfordshire, EN6 1TL, UK **NHS Price**: £19.74 **Date of Revision of Prescribing Information**: July 2025 **Veeva reference:** UK-HIP-2025-00071

The SmPC for this product, including adverse reactions, precautions, contra-indications, and method of use can be found at: http://www.mhra.gov.uk/Safetyinformation/Medicinesinformation/SPCandPILs/index.htm and from Viatris Medical Information, Building 4, Trident Place, Hatfield Business Park, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, phone no. 01707 853000, Email: info.uk@viatris.com

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:
- the Yellow Card website www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report suspected adverse drug reactions to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting adverse drug reactions, you can help provide more information on the safety of this medicine.
You can also report directly to the manufacturer at pv.uk@viatris.com