SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Methenamine hippurate Zentiva 1 g tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1 g methenamine hippurate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.

White to off white, capsule shaped tablets with dimensions approx. 19 mm x 8 mm, debossed with 'L` '59' on one side and score line on the other side. The tablet can be divided into equal doses.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Long-term prophylaxis after an initial treatment with a suitable chemotherapeutic agent in case of recurrent urinary tract infections.
Short-term prophylaxis for short-term catheterisation and instrumental interventions in the urinary tract.
Prophylaxis in case of asymptomatic bacteriuria in long-term care patients caused by catheter, uridome, etc.

4.2 Posology and method of administration

Posology
Adults: 1 g 2 times daily.
In patients with catheters the dosage may be increased to 1g 3 times daily.
Children 6-12 years: 0.5 g twice daily.
Adolescents over 12 years: 1 g twice daily.

In cases where pH of urine is alkaline, administration of acidifying agent may be required.

Special population
Renal impairment
[Invented name] is contraindicated with renal insufficiency, see section 4.3.

Hepatic impairment
[Invented name] is contraindicated in patients with hepatic impairment, see section 4.3.

Method of administration
For oral administration.

A tablet-cutter can be used to split the tablet into halves, if the patient is unable to break the tablet by hand. The tablets can be halved or crushed and taken with some water if the patient is unable to swallow the whole tablet.

4.3 Contraindications

[Invented name] is contraindicated in patients with:
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Severe renal failure (creatinine clearance or GFR<10 ml/min.)
- Severe dehydration and gout.
- Renal parenchymal infection.
- Intolerance or allergic reactions to formalin.
- Hepatic dysfunction.
- Metabolic acidosis.

[Invented name] should not be administered concomitantly with:
- Sulphonamides due to the risk of crystalluria.
- Alkaline substances, such as a mixture of potassium citrate (see section 4.5).

4.4 Special warnings and precautions for use

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

4.5 Interaction with other medicinal products and other forms of interaction

Alkaline agents reduce the effect of methenamine and should be avoided, antacids might cause an increase of urine pH and hence decrease the effect of [Invented name].

Co-administration of methenamine and sulphonamides should be avoided as this may increase the risk of crystalluria.

Depending on analytical procedure, methenamine might affect the determination of steroid, catecholamine and 5-hydroxyindoleacetic acid leading to incorrect results.

4.6 Fertility, pregnancy and lactation

Pregnancy
A moderate amount of data on pregnant women (between 300-1000 pregnancies) has not shown signs of malformations or foetal/neonatal toxicity. Animal studies do not indicate reproductive toxicity (see section 5.3). The use of [Invented name] may be considered during pregnancy, if necessary.

Breast-feeding
Methenamine hippurate is excreted in human milk, but at therapeutic doses of [Invented name] no effects on the breastfed newborns/infants are anticipated.

Fertility
There are no human studies regarding fertility and methenamine hippurate. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

4.7 Effects on ability to drive and use machines

[Invented name] has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Tabulated list of adverse reactions
Frequencies are defined as: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1 000 to < 1/100); rare (≥ 1/10 000 to < 1/1 000); very rare (< 1/10 000); not known (cannot be estimated from the available data).

System organ class	Frequency	Adverse reaction
Gastrointestinal disorders	Common	Nausea, vomiting
	Not known	Diarrhoea, abdominal pain
Skin and subcutaneous tissue disorders	Common	Rash
	Not known	Pruritus
Renal and urinary disorders	Common	Bladder irritation
	Rare	Haematuria

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Toxicity
8 g to a 2½-year old child resulted in moderate intoxication.

Symptoms
Nausea, vomiting, vertigo, tinnitus and metabolic acidosis may occur. Irritating effect on the urinary tract with albuminuria and haematuria.

Measurement
The treatment is symptomatic and supportive, the use of an anti-emetic and drinking plenty of water. Bladder symptoms can be treated by taking plenty of water and 2-3 teaspoonfuls of sodium bicarbonate.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antibacterials for systemic use, other antibacterials; ATC code: J01XX05

Mechanism of action
[Invented name] contains methenamine hippurate, a salt of methenamine and hippuric acid, which is absorbed and excreted rapidly. In acidic environment, methenamine is hydrolyzed to formaldehyde,

which, together with hippuric acid mediates the antibacterial effect in urine. The studies have shown that the urine has antibacterial effect already in 30 minutes after the administration.

Clinical efficacy and safety
[Invented name] is active against microorganisms, which usually causes urinary tract infection, e.g. *Escherichia coli* and *Aerobacter aerogenes*, *Pseudomonas* and some strains of *Proteus*.

5.2 Pharmacokinetic properties

Absorption
[Invented name] is readily absorbed from the gastro-intestinal tract. Plasma concentrations of methenamine hippurate reach maximum 1-2 hours after a single dose.

Elimination
The half-life is about 4 hours. Methenamine is excreted via the kidneys; methenamine recovered in the urine corresponds to about 80% of the administered dose.

5.3 Preclinical safety data

Preclinical studies did not show any special risk for humans.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Silica, colloidal anhydrous
Povidone
Sodium starch glycolate (type A)
Cellulose, microcrystalline
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Packed into HDPE bottle with polypropylene child resistant cap and two silica gel desiccants.

Pack size: 100 tablets

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

2025-09-17