

 **12 June 2025**

**SUMMARY OF PRODUCT CHARACTERISTICS**

**for**

**Altaromin, tabletter**

**0. D.SP.NO.**

33933

**1. NAME OF THE MEDICINAL PRODUCT**

Altaromin

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

One tablet contains 1 gram of methenamine hippurate.

For the full list of excipients, see section 6.1.

**3. PHARMACEUTICAL FORM**

Tablets

White to off-white, capsule shaped uncoated tablets with a break line on both the sides.

Dimension 18.9 x 7.9 mm.

The tablet can be divided into equal halves.

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic indications**

Altaromin is indicated in the prophylaxis of uncomplicated lower urinary tract infections (see section 5.1):

* Prophylaxis of recurrent cystitis after initial treatment with appropriate antibacterial agent of recurrent urinary infection.
* Prophylaxis of infections for short-term catheterization or instrumental interventions in the urinary tract.
* Asymptomatic bacteriuria.

Consideration should be given to therapeutic guidance on the appropriate use of antimicrobial agents.

**4.2 Posology and method of administration**

Posology

Therapeutic guidance should be taken into consideration.

*Adults*: 1 g two times a day.

In patients with catheters the dosage may be increased to 1 g three times a day.

*Children 6-12 years*: 0,5 g two times a day .

*Children over 12 years*: 1 g two times a day .

Since the antimicrobial activity of methenamine hippurate is greater in acidic urinary conditions, alkalinizing food or drink should be avoided (see section 4.5). If necessary in cases of alkaline urinary pH, supply of acidifying agent could be needed.

Method of administration

For oral administration.

The tablets may be halved or crushed and taken with water if the patient is unable to swallow whole tablets.

**4.3 Contraindications**

Altaromin is contraindicated in patients with:

* Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
* Hypersensitivity to formaldehyde.
* Renal insufficiency, severe dehydration and gout.
* Hepatic impairment.
* Metabolic acidosis.
* Infection of the kidney.

The concomittant use of Altaromin is not recommended with sulphonamides because of the possibility of crystalluria (see section 4.5).

The concomittant use of Altaromin with alkaline agents and antacids should be avoided because of the possibility of reduced effect (see section 4.5).

**4.4 Special warnings and precautions for use**

When antibiotic treatment of bacteriuria or urinary tract infection is indicated, prophylaxis with methenamine hippurate should be stopped. Therefore patients should be encouraged to consult their doctor at the onset of signs and symptoms of infection.

The use of alkaline agents and antacids, alkalinizing food and drink should be avoided during the treatment (see section 4.5).

Effects on laboratory tests

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

Sodium

This medicine 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 and antacids

Methenamine hippurate hydrolyses into the therapeutically active formaldehyde under acidic urinary conditions (see section 5.1). Therefore alkaline agents reduce the effect of methenamine hippurate and should be avoided.

Antacids that make urine alkaline might cause an increase in urinary pH, reduce the effect of methenamine hippurate and should be avoided.

Alkalinizing food and drink might cause an increase in urinary pH, reduce the effect of methenamine hippurate and should be avoided.

Sulphonamides

Sulphonamides may form an insoluble crystalline precipitate with formaldehyde in the urinary tract (favoured by the acidification of urine). Therefore concomitant use of methenamine hippurate with sulphonamides increases the risk of crystalluria and is not recommended.

**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 fetal/neonatal toxicity. Animal studies do not indicate reproductive toxicity (see section 5.3). The use of Altaromin may be considered during pregnancy, if necessary.

Breast-feeding

Methenamine hippurate is excreted in human milk, but at therapeutic doses of Altaromin 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**

No traffic warning.

Altaromin has no or negligible influence on the ability to drive and use machines.

**4.8 Undesirable effects**

Adverse events frequencies are defined as:

Very common (≥1/l0)

Common (≥1/100 to <1/10)

Uncommon (≥1/1000 to <1/100)

Rare (≥ 1/10 000 to <1/1000)

Very rare (<1/10 000)

Not known (cannot be estimated from the available data).

|  |  |
| --- | --- |
| **System Organ Class** | **Frequency** |
| *Common* | *Rare* | *Not known* |
| *Gastrointestinal disorders* | Nauesa, vomiting |  | Diarrhoea, abdominal pains |
| *Skin and subcutaneous tissue disorders* | Rashes  |  | Pruritus |
| *Renal and urinary disorders* | Irritation of the bladder | Haematuria |  |

Occasionally superinfection with yeast may occur. At high dosage, chemical cystitis leading to dysuria may occur.

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:

Lægemiddelstyrelsen

Axel Heides Gade 1

DK-2300 København S

Website: www.meldenbivirkning.dk

**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.

*Treatment*: The treatment is symptomatic and supportive, the use of an anti-emetic and drinking copious quantities of water. Bladder symptoms can be treated by the consumption of copious quantities of water and 2-3 teaspoonfuls of bicarbonate of soda.

**4.10 Legal status**

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**5. PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Urinary antibacterial agent, ATC code: J01XX05.

Mechanism of action

Altaromin contains methenamine hippurate, a salt of methenamine and hippuric acid, which is absorbed and excreted rapidly. In acidic environment, methenamine is hydrolysed to formaldehyde, which, together with hippuric acid mediates the antibacterial effect in urine. Bacteriological studies have shown that the urine has antibacterial effect already 30 minutes after intake of the drug.

Pharmacodynamic effects

Altaromin is active against microorganisms, which usually causes urinary tract infection, e.g. *Eschericha coli* and *Aerobacter aerogenes*. The substance has decreased effect on urea-degrading bacteria, e.g. *Pseudomonas* and some strains of *Proteus*. Urea-degrading bacteria hydrolyse the urea to ammonium hydroxide which is basic and increase urinary pH.

This results in reduced hydrolysis of methenamine to formaldehyde.

**5.2 Pharmacokinetic properties**

Absorption

Altaromin is readily absorbed from the gastro-intestinal tract and excreted via the kidney.

Distribution

Plasma concentrations of methenamine hippurate reach maximum 1-2 hours after a single dose and decline with a half-life of about 4 hours. The antibacterial effect is noticed 30 minutes after administration of the medicinal product as mentioned in section 5.1. Methenamine recovered in the urine corresponds to about 80% of the dose given.

**5.3 Preclinical safety data**

Preclinical studies reveal no special hazard for humans.

**6. PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Colloidal silica

Povidone

Magnesium stearate

Croscarmellose sodium

**6.2 Incompatibilities**

Not applicable.

**6.3 Shelf life**

3 years.

**6.4 Special precautions for storage**

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

This medicinal product does not require any special temperature storage conditions.

**6.5 Nature and contents of container**

Amber coloured glass bottle with a white opaque high density polyethylene screw cap and polyester wad seal.

Pack sizes: 20, 60 and 100 tablets.

Not all pack sizes may be marketed.

**6.6 Special precautions for disposal and other handling**

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

**7. MARKETING AUTHORISATION HOLDER**

Laboratoires Majorelle

6 Rue Copernic

75116 Paris

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**8. MARKETING AUTHORISATION NUMBER(S)**

71516

**9. DATE OF FIRST AUTHORISATION**

12 June 2025

**10. DATE OF REVISION OF THE TEXT**

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