

## **Instruction for use AQUA MARIS**

### **Registration number:**

Nasal dosage spray - IIN013831/01

Nasal drops for children – IIN013831/02

**Trade name** AQUA MARIS

### **Pharmaceutical form**

Nasal dosage spray

Nasal drops for children

### **Content**

100 ml of solution contain 30 ml of Adriatic Sea water with natural microelements and 70 mL of purified water.

Preservatives free.

Content of ions:

Na<sup>+</sup> - min. 2.50 mg/mL;

Ca<sup>2+</sup> - min. 0.08 mg/mL;

Mg<sup>2+</sup> - min. 0.35 mg/mL;

Cl<sup>-</sup> - min. 5.50 mg/mL;

SO<sub>4</sub><sup>2-</sup> - min. 0.60 mg/mL;

HCO<sub>3</sub><sup>-</sup> - min. 0.03 mg/mL.

### **Description**

Colorless clear odorless solution.

### **Pharmacotherapeutic group**

Product for treatment of nasal diseases.

**ATC-code:** R01AX10

### **Pharmacological properties:**

Sterilized isotonic sea water helps to maintain normal physiological state of nasal mucosa.

The drug product facilitates thinning of mucus, stabilizes its secretion in beaker cells of nasal mucosa.

Microelements contained in the product improve ciliate epithelium function and provide anti-inflammatory, cleansing, stimulating, reducing effect on nasal mucosa.

In allergic and vasculomotor rhinitis the drug facilitates removal of allergens and haptens from nasal mucosa and reducing local inflammatory process. Used for hygiene convenience, Aqua Maris facilitates cleansing of nasal mucosa from street and room dust.

### **Indications for use:**

- acute and chronic inflammatory diseases of nasal, sinus and pharyngonasal cavities;
- adenoids;
- post-operative period (after operations on nasal cavity);
- allergic and vasculomotor rhinitis (especially in patients predisposed to or suffering from hypersensitivity to drugs, including pregnant and lactating women);
- for preventing nasal cavity infections during autumn and winter period (including in pregnant and lactating women);
- extreme dryness of nasal mucous membrane and patients residing or working at premises with

conditioned air and/or central heating; patients with upper respiratory tract mucosa permanently exposed to detrimental effects (smokers, drivers, workers of heat- and dust-loaded workshops, and people staying at regions with tough climatic conditions);

### **Contraindications**

Hypersensitivity to drug components.

Children younger than 1 year (for nasal dosage spray).

### **Dosage and administration**

#### ***For treatment :***

Aqua Maris nasal drops for kids:

- children from the first days of life: 4 times a day 2 drops into each nostril;

Aqua Maris nasal dosage spray:

- children aged 1 to 7: 4 times a day two injections into each nostril;
- children aged 7 to 16: 4 -6 times a day two injections into each nostril;
- adults: 4 - 8 times a day two-three injections into each nostril.

Treatment course in all cases is 2-4 weeks (to doctor's discretion). It is recommended to repeat the course in a month.

#### ***For prevention:***

Aqua Maris nasal drops for kids:

- children from the first days of life: instill 1-2 drops 2 times a day into each nostril;

Aqua Maris nasal dosage spray:

- children aged 1 to 7: 1 - 3 times a day one-two injections into each nostril;
- children aged 7 to 16: 2 -6 times a day two injections into each nostril;
- adults: 3 - 6 times a day two-three injections into each nostril.

#### ***For thinning and removing dirty collections and nasal secretion:***

- Aqua Maris sprinkle or instill into each nostril as many times as needed, removing excess of liquid with absorbent cotton or handkerchief. The procedure can be repeated many times until dirty collections are removed.

### **Adverse reactions**

Hypersensitivity reactions are possible.

### **Overdose**

No overdose events are registered.

### **Drug-to-drug interactions**

The drug product does not provide systemic exposure on organism, so there are no drug-to-drug interactions registered. It is possible to use the drug product along with the other medicines for treating rhinorrhea.

### **Special instructions**

To the newborn instill the solution into nasal cavity with caution to avoid middle ear infecting. It is recommended to press the bottle slightly.

### **Effects on ability to drive and use machines**

No data available

### **Form of presentation**

*Nasal dosage spray*

Each neutral brown-glass bottle with spraying device and propylene safety cap contains 30 mL

(30.36 g) of medicine. Each carton box contains one bottle with instruction for use.

*Nasal drops for kids.*

Each polyethylene dropper bottle with thread contains 10 mL of the drug. Each dropper bottle contains one bottle with instruction for use.

### **Storage conditions**

Store under temperature less than 25 °C out of reach of children.

### **Shelf-life**

*Nasal dosage spray*

3 years

Do not use after expiry of shelf-life.

Use within 45 days after opening.

*Nasal drops for kids*

2 years

Do not use after expiry of shelf-life.

Use within 45 days after opening.

### **Dispensing rules**

No prescription required.

### **Manufacturer**

JADRAN - GALENSKI LABORATORIJ d.d.

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