

# AQUA MARIS®



## PRESCRIBING INFORMATION FOR PATIENTS

### Product for washing and irrigating nasal cavity «Aqua Maris® Intensive Rinsing»

#### Design variants:

- Product for washing and irrigating nasal cavity «Aqua Maris® Baby. Intensive Rinsing» 50 mL;
- Product for washing and irrigating nasal cavity «Aqua Maris® Baby. Intensive Rinsing» 150 mL;
- Product for washing and irrigating nasal cavity «Aqua Maris® Norm. Intensive Rinsing» 50 mL;
- Product for washing and irrigating nasal cavity «Aqua Maris® Norm. Intensive Rinsing» 125 mL;
- Product for washing and irrigating nasal cavity «Aqua Maris® Norm. Intensive Rinsing» 150 mL.

**REGISTRATION CERTIFICATE NO:** № P3H 2018/7549 or 31.08.2018 r.

**NACL CONTENT NOT LESS THAN 9 G/L.**

#### CONTENT PER 100 ML:

Seawater – 27.1 ± 3.0 mL;

Purified water – up to 100 mL.

Product is based on the natural water of the Adriatic Sea, which contains ions **Cl<sup>-</sup>, Na<sup>+</sup>, SO<sub>4</sub><sup>2-</sup>, Mg<sup>2+</sup>, Ca<sup>2+</sup>, K<sup>+</sup>, HCO<sub>3</sub><sup>-</sup>, Br<sup>-</sup>**, as well as microelements such as: **zinc, selenium, iodine, iron, manganese, etc.**

Does not contain chemical additives and preservatives.

#### APPEARANCE:

Clear colorless odorless solution with salty taste.

#### PRESCRIPTION:

The product is prescribed for application to the nasal mucous membrane for effective washing and removal of nasal discharge.

#### DESCRIPTION:

Isotonic seawater solution administered on nasal mucosa ensures its normal physiological state, it facilitates thinning of mucus, stabilizes its secretion in beaker cells of nasal mucosa.

A stream of solution under pressure thoroughly washes all parts of the nasal and pharyngonasal cavities, actively cleansing them from excess mucus, viruses, bacteria, foreign particles, including allergens, dense exudates (crusts).

- Microelements in the drug substance composition improve the ciliated epithelium function, have anti-inflammatory, -cleansing, stimulating, restorative effect on the nasal mucosa. The combined action of seawater healthful microelements causes a therapeutic effect;
- Reduces the oedema of nasal and pharyngonasal mucosa;
- Reduces the risk of local complications and accelerates the healing process after operations in the nasal cavity and paranasal sinuses (removal of adenoids, polyps, septoplasty, etc.);
- Increases the therapeutic efficacy of drugs applied to the nasal mucosa (vasoconstrictors, hormones, inhaled corticosteroids, antiallergic drugs, etc.);
- Reduces the need for the use of local nasal drugs.

When pressing the tip solution distributes in the form of an aerosol.

The special "anatomical" tip with a rounded applicator promotes convenient use in infants, children and adults. A special grooved surface with a limiter makes it possible to carry out a uniform intensive spraying of the «shower» type, and the tight connection with the tip prevents solution leakage. The spraying system is specifically designed to ensure the most effective washing, while the procedure itself is comfortable for the patient.

Modern packaging technology lets to avoid the contact of the propellant and the seawater solution. In addition, the bottle design provides reliable protection of the product from a microbiological point of view; makes it possible to use all the amount of solution available in the bottle; provides a convenient application, as the Product can be used in all positions.

The pressure in the «Aqua Maris® Norm. Intensive Rinsing» bottle reaches a value of 8.0·105 Pa, which contributes to the efficient washing of the nasal passages along the entire length. The pressure in the «Aqua Maris® Baby. Intensive Rinsing» bottle does not exceed 7.2·105 Pa, providing a delicate washing of the baby's nose with the help of a «soft shower».

#### INDICATIONS FOR USE:

— Complex treatment of acute and chronic inflammatory diseases of nasal, paranasal cavities and pharyngonasal (infectious, allergic):

- acute and chronic rhinitis;
- acute and chronic sinusitis;
- acute and chronic adenoiditis;
- allergic and vasomotor rhinitis;

— Complex treatment of acute respiratory infections.

— Daily use during acute respiratory infections and influenza epidemics.

— Hygiene of nasal cavity:

- after surgery of nasal cavity;
- removal of microorganisms, foreign particles, allergens, dust, pollen;
- preparation of nasal mucosa to the use of drug substances;
- Long-term therapy with topical corticosteroids.

#### ADMINISTRATION:

Intranasal route of administration.

1-2 injections into each nasal passage several times a day (2-6 times a day) and more if necessary. Duration of application is not limited.

#### DIRECTIONS FOR USE:

**Product for washing and irrigating nasal cavity «Aqua Maris®Baby. Intensive Rinsing» is used in infants from 3 months.**



In young children washing is carried out in prone position.



Turn child's head on one side.



Insert bottle tip in the upper nasal passage. Rinse nasal cavity for several seconds. Repeat the procedure if needed. Carry out the same for the other nasal passage.



Carry out the same for the other nasal passage.

**Product for washing and irrigating nasal cavity «Aqua Maris® Norm. Intensive Rinsing» is used in children from 6 months and adults.**



Incline head on one side.



Blow one's nose. Repeat the procedure if needed.



Insert bottle tip in the upper nasal passage. Rinse nasal cavity for several seconds.



Carry out the same for the other nasal passage.

The product is compatible with all products used to treat rhinitis.

#### CONTRAINDICATIONS:

Contraindications not identified.

#### THE ABILITY TO AFFECT THE REACTION RATE WHEN DRIVING VEHICLES OR WORKING WITH OTHER MECHANISMS:

Does not affect the reaction rate when driving vehicles and working with other mechanisms.

#### USE DURING PREGNANCY AND LACTATION:

Can be used during pregnancy and lactation.

#### ADVERSE REACTION:

If used according to instruction no adverse reactions are revealed.

#### SHELF-LIFE:

3 years. Do not use after expiry of shelf-life.

#### FORM OF PRESENTATION AND PACKAGING:

50 mL, 125 mL or 150 mL metal bottles under pressure. One bottle with a tip and a plastic cap is placed in a cardboard box along with the instructions for use.

#### SPECIAL INSTRUCTIONS:

Bottle content is under pressure: may explode when exposed to heat. Do not pierce or burn, even after use. Keep away from heat, hot surfaces, sparks, open flames or any other source of ignition. Do not smoke. Protect from sunlight. Do not heat above 50°C.

#### STORAGE CONDITIONS (OPERATION CONDITIONS):

Store in a dry place out of reach of children at a temperature of + 25±10°C, humidity 45-80%, pressure 84-106.7 kPa.

#### DISPOSAL:

Product for washing and irrigating nasal cavity «Aqua Maris®Intensive» does not adversely affect the environment, therefore no special measures are required for the disposal of the solution.

#### MANUFACTURER:

JADRAN – GALENSKI LABORATORIJ d.d., Svilno 20, 51000 Rijeka, Croatia.

#### Site of manufacture:

JADRAN – GALENSKI LABORATORIJ d.d., Svilno 20, 51000 Rijeka, Croatia.

#### Claims to the quality of the product should be sent to the Limited liability company «JADRAN»

119330, Moscow, Lomonosovsky pr-t, h. 38 of. VII tel./fax: +7(499)143-33-71.

[www.aquamaris.ru](http://www.aquamaris.ru)



Attention! This document contains only BASIC information, all additional parameters are contained in the Instructions for use for specialists with medical education and can also be provided on request.