

## PATIENT INFORMATION LEAFLET Information for the Patient about HYDROMIST

Read all of this leaflet carefully before you start using HYDROMIST, because it contains important information for you. This product is available without a doctor's prescription. Nevertheless you still need to use HYDROMIST carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- You must see a doctor if your symptoms worsen or do not improve.

### PROPRIETARY NAME (AND DOSAGE FORM):

HYDROMIST (Nasal Spray).

### COMPOSITION:

HYDROMIST is an isotonic, sterilised, 100 % natural seawater solution (Diluted to physiological level (0,9 %) with Purified Water).

HYDROMIST contains natural seawater collected in the Atlantic Ocean off the coast of Sweden.

### PRODUCT DESCRIPTION:

HYDROMIST is a non-medicated, deeply penetrating nasal irrigation spray that can be used for infants, children, and adults.

HYDROMIST works by thinning nasal mucus and washing away foreign particles such as dust, pollen, and allergens.

HYDROMIST is non-habit forming and can be used together with other medicines.

HYDROMIST may alleviate symptoms of rhinitis and sinusitis, and decrease the use of medicated products if used regularly.

### BEFORE YOU USE HYDROMIST:

Do NOT use HYDROMIST:

- If you are allergic (hypersensitive) to any of the ingredients in the formulation.
- HYDROMIST should not be used to replace any medicines prescribed by your doctor.

### Pregnancy and breastfeeding:

HYDROMIST is non-medicated and may be used in pregnancy and while breastfeeding.

### WARNINGS:

1. The use of this device by more than one person may spread infections. Clean the nozzle in soapy water and rinse with hot water after each use.
2. Keep out of reach of children. The use in children under the age of 6 months should be strongly indicated and always be supervised by an adult.
3. Only use HYDROMIST For Little Noses, as recommended, for babies.
4. Never tilt your or your baby's head backwards, to prevent secretions running into the throat.
5. Do not expose to temperatures exceeding 50 °C.
6. Keep away from heat/sparks/open flames/hot surfaces.
7. Pressurised container: May burst if heated. Do not pierce or burn, even after use.

### RECOMMENDED USE:

## HydroMist™ for Little Noses

#### *Children between 0 – 6 months:*

1. Place baby on its back in a stable position.
2. Turn baby's head to the side.
3. Gently insert the nozzle into the nostril.
4. Press the nozzle briefly.
5. Repeat the action in the other nostril, with the baby's head turned to the other side.
6. Wipe baby's nose with a paper tissue.
7. Clean the nozzle in soapy water, rinse and dry.

#### *Children from 6 months:*

1. Tilt your child's head slightly forward, pushing his/her chin towards their chest.
2. Gently insert the nozzle into the nostril.
3. Press the nozzle for 1 – 2 seconds.
4. Repeat the action in the other nostril.
5. Wipe baby's nose with a paper tissue.
6. Clean the nozzle in soapy water, rinse and dry.

HYDROMIST can be used up to six times daily.

## HydroMist™ ADULT

1. Tilt your head slightly forward, pushing your chin towards your chest.
2. Gently insert the nozzle into the nostril.
3. Press the nozzle for 1 – 2 seconds.
4. Repeat the action in the other nostril.
5. Clean the nozzle in soapy water, rinse and dry.

HYDROMIST can be used up to six times daily.

Consult your doctor or healthcare professional should symptoms persist for longer than 7 days or return after the use of HYDROMIST.

### STORAGE INSTRUCTIONS:

Store at or below 25 °C.  
Protect from sunlight.

### PRESENTATION:

50 ml pressurised aluminium canister, containing sterile isotonic (0,9 %) seawater, packed in an outer carton.

### NAME AND BUSINESS ADDRESS OF THE APPLICANT:

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CE 0413 STERILE R  
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REF 1010

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