

STÉRIMAR™ BABY-CHILD BLOCKED NOSE NASAL SPRAY SOLUTION

PROPRIETARY NAME AND DOSAGE FORM

STÉRIMAR™ Baby-Child Blocked Nose Nasal Spray Solution

COMPOSITION

STÉRIMAR™ Baby-Child Blocked Nose is a filtered, hypertonic, preservative-free sea water solution that benefits from the recognised properties of mineral salts and marine trace elements and is enriched with copper and manganese salts.

Each 100 ml contains:

Sea water: 60 ml; Copper salt: 0,0004037 g; Manganese salt: 0,000000632 g; Purified water qsp 100 ml.

INDICATIONS

STÉRIMAR™ Baby-Child Blocked Nose is a hypertonic sea water solution.

It has a slightly higher salt concentration than cells in the human body. This creates an osmotic effect that gently draws and drains excess fluid from the cells in the nasal lining.

STÉRIMAR™ Baby-Child Blocked Nose is recommended for short term use in babies and children from three months to 3 years of age.

- Provides **gentle relief** from a blocked nose.
- **Eliminates mucus** from the nasal passages.
- **Cleanses** the nasal passages and enhances the action of prescribed medicines.
- Washes out the nasal cavities to help **prevent colds and secondary infections**.

Nasal cleaning (if blocked) improves the effectiveness of local medicated treatments.

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients of **STÉRIMAR™ Baby-Child Blocked Nose**.

WARNINGS AND SPECIAL PRECAUTIONS

STÉRIMAR™ Baby-Child Blocked Nose is for short-term use only.

INTERACTIONS

There are no known interactions with other medicines.

PREGNANCY AND LACTATION

Safety in pregnancy and lactation has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using **STÉRIMAR™ Baby-Child Blocked Nose**.

DOSAGE AND DIRECTIONS FOR USE

STÉRIMAR™ Baby-Child Blocked Nose is recommended for short-term use only.

Babies and children from three months to 3 years of age:

On first use prime the spray by pressing the nozzle once.

Lay baby/child on his/her side or sit up with baby's/child's head tilted to one side.

Gently insert the nozzle into the nostril.

Spray briefly 1 to 2 times in each nostril.

Let any excess solution flow out of the nose and then wipe.

For a deeper cleansing of nasal cavities:

Gently insert the nozzle into the uppermost nostril.

Press the nozzle for approximately 2 seconds in each nostril.

Let any excess solution flow out of the nose and then wipe.

After each use clean the nozzle in hot water and dry.

Use 2 to 6 times a day in each nostril or more if required.

SIDE EFFECTS

Frequency unknown:

Itching or tingling sensation in the nose caused by the high salt concentration of **STÉRIMAR™ Baby-Child Blocked Nose**.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

There are no known symptoms of overdose. Treatment should be symptomatic and supportive.

IDENTIFICATION

Colourless solution.

PRESENTATION

Pressurised container with an inert gas (nitrogen).

STÉRIMAR™ Baby-Child Blocked Nose is available in 50 ml (Approximately 150 sprays) aluminum containers.

STORAGE INSTRUCTIONS

Store at or below 25° C.

Do not use after expiry date stated on the label and carton.

KEEP OUT OF REACH OF CHILDREN.

Warning: Pressurised container: May burst if heated. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not pierce or burn, even after use. Protect from sunlight.

Do not expose to temperatures exceeding 50 °C/122 °F.

DISTRIBUTED BY

Actor Pharma (Pty) Ltd¹
Unit 7, Royal Palm Business Estate
646 Washington Street
Halfway House, Midrand, 1685
Gauteng, South Africa

MANUFACTURER

Sofibel Laboratoires Fumouze,
110- 114,rue Victor Hugo,
92686 Levallois-Perret Cedex, France

¹Company Registration Number:2008/008787/07

STERBN/PI/01/06.2020