



## STÉRIMAR™ Baby-Child Hypertonic Nasal Spray Solution



### SCHEDULING STATUS

Not Scheduled

### PROPRIETARY NAME AND DOSAGE FORM

**STÉRIMAR™ Baby-Child Hypertonic** (Nasal Spray Solution)

### COMPOSITION

**STÉRIMAR™ Baby-Child Hypertonic** is a filtered hypertonic sea water solution free from preservatives. It is enriched with copper and manganese mineral salts and marine trace elements.

Sea water: 60 ml

Purified water 40 ml

### PHARMACOLOGICAL CLASSIFICATION

16.5 Other (Sea Water)

### PHARMACOLOGICAL ACTION

**STÉRIMAR™ Baby-Child Hypertonic** is a filtered hypertonic sea water solution. It contains a moderately higher salt concentration than what is found in the body's cells, this causes "the osmotic effect" in the nasal passages.

### INDICATIONS

The "osmotic effect" of **STÉRIMAR™ Baby-Child Hypertonic** aids natural breathing and helps cleaning the nose.

**STÉRIMAR™ Baby-Child Hypertonic** is recommended for cleansing of the nasal passages to enhance the action of prescribed medicines in babies from 3 months and children.

### CONTRAINDICATIONS

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

### WARNINGS and SPECIAL PRECAUTIONS

**STÉRIMAR™ Baby-Child Hypertonic** 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.

### DOSAGE AND DIRECTIONS FOR USE

**STÉRIMAR™ Baby-Child Hypertonic** is recommended for short-term use only.

**Babies from 3 months and older:**

The spray should be primed by briefly pressing the nozzle. Lay baby on his/her side or sit up with baby's head tilted to one side.

1. Gently insert the nozzle into the nostril and press briefly.
2. Let any excess solution run out of the nose before wiping the nose.
3. Repeat the operation in the other nostril.
4. Clean the nozzle with soapy water, rinse and dry. Use 2 to 6 times a day in each nostril, as required.

### SIDE EFFECTS

Frequency unknown: Itching or tingling sensation in the nose caused by the high salt concentration of **STÉRIMAR™ Baby-Child Hypertonic**.  
**KNOWN SYMPTOMS OF OVERDOSE 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 Hypertonic** is available in 50 ml (Approximately 150 doses) aluminium containers.

### STORAGE INSTRUCTIONS

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

Do not pierce or burn, even after use. Do not use after expiry date stated on the label and carton. Keep out of the reach and sight of children.

### NAME AND ADDRESS OF APPLICANT

Medi Challenge (Pty) Ltd<sup>1</sup>  
Fancourt Office Park, Block 13 Loft Left, c/o Felstead Rd & Northumberland Ave  
North Riding, 2162

### MARKETED BY

Actor Pharma (Pty) Ltd<sup>2</sup>  
Unit 7, Royal Palm Business Estate  
646 Washington Street  
Halfway House, Midrand, 1685

### MANUFACTURER

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

<sup>1</sup> Company registration number: 1995/001589/07

<sup>2</sup> Company registration number: 2008/008787/07



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