

Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

ISOKEAN 2.16 g powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ISOKEAN: Each 1 sachet contains Sodium Chloride 2.16 g

3. PHARMACEUTICAL FORM

A white crystalline powder

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

For nasal cleansing and removal of dust, mucus or pus from nasal cavity and sinus in patient with

1. allergic rhinitis (Hay fever) to wash away pollens and cleanse nasal and sinus tissue.
2. Acute sinusitis to help the body remove infected mucus from the sinus cavities or with post operation to cleanse mucus and dry blood from nose and sinuses and help the healing process.
3. Chronic Rhinosinusitis to remove excess mucus and bacteria from sinus cavities.
4. For oral irrigation.
5. For cleansing the non-wounded skin by soaking in gauze pad to clean the area of face.

4.2 Posology and method of administration

For Topical use only

Use ISOKEAN 1 bottle (240 ml) at least 2 times daily in the morning and at bedtime or presence of plenty of viscous mucus or nasal congestion.

Using ISOKEAN by follow this step

1. Fill the soft squeeze bottle with a little distilled water, purified or clean tap water for clean the bottle, then up to the 240 ml mark.
2. Cut or tear open a sachet of ISOKEAN, then empty the entire contents into the bottle filled with water.
3. screw the cap and shake gently until all the powder has dissolved.
4. Lean far over sink with your head down.
5. The bottle is placed against the nostril. Open mouth deep inhale and stop breathing for a while. After the bottle is squeeze, saltwater comes out.
6. The opposite nostril and may come out the mouth. The nose is then blown gently.

7. The procedure is then repeated with the other nostril.
8. Gently blow your nose to clear any remaining fluid and mucus.

4.3 Contraindications

Do not use in <2 years children or children who cannot stop breathing or blow the nose.

4.4 Special warnings and precautions

Whenever the soft squeeze bottle needs to "breathe": i.e., fill with air, remove it from the nose before releasing the hand pressure. This prevents "suck back" and helps to keep the remaining solution clean. If the patient has recently had nasal or sinus surgery, do not blow the nose before checking with the physician. Any remaining solution in the bottle should be discarded. Fresh solution must be made for each treatment.

4.5 Interaction with other medicinal products and other forms of interactions

ISOKEAN may be used whilst taking any other medicine.

4.6 Fertility, pregnancy and lactation

ISOKEAN may be used during pregnancy or whilst breastfeeding.

4.7 Effects on ability to drive and use machines

Not relevant

4.8 Undesirable effects

Earache may be experienced if applying too much pressure when squeezing the bottle. If this occurs, try to apply less pressure. If the earache persists, contact the physician.

4.9 Overdose Excessive

Not applicable

5. Pharmacological properties

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Each one sachet contains Sodium Bicarbonate 0.02 g

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at temperature below 30°C. Protect from light.

6.5 Nature and contents of container

Paper box with 20, 30, 50 and 100 Aluminum sachets.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

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9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10. DATE OF REVISION OF THE TEXT

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