

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

BABYAF SALINE NASAL DROPS

(Sodium Chloride 0.9% w/v)

2. Qualitative and quantitative composition

Sodium Chloride 0.9% w/v

3. Pharmaceutical form

Nasal Drops.

Clear, colorless solution.

4. Clinical particulars

4.1 Therapeutic indications

This medicine is intended to relieve nasal congestion in infants and small children.

It moisturizes the nasal mucosa and thus eases mucous exudation and nose blowing.

4.2 Posology and method of administration

This medicine is dispensed without a doctor's prescription.

Use the medicine according to the instruction in this section.

Consult the doctor or pharmacist if you need further information.

Contact your doctor if disease symptoms worsen or do not improve after 3 days.

The recommended dosage is usually:

1-2 drops in each nostril 3-4 times daily.

Do not exceed the recommended dose.

If there is no improvement in the child's condition within 3 days, consult the doctor.

Attention:

Do not swallow.

This medicine is intended for external use only.

Ensure measuring the dose with a dropper.

Method of administration:

Blow the nose gently. Pull the child's head backwards, or lie him on the bed.

Drip the drop/s into each nostril and keep his head tilted back for a few minutes to enable dispersion of the medicine throughout the nasal area.

To avoid spreading of the infection, do not use the same bottle for more than one person.

Do not exceed the recommended dose.

Each plastic bottle with a dropper contains 10ml solution.

4.3 Contraindications

Allergy to the active ingredient or any of the other ingredients in this medicine.

The solution should not be administered orally or parenterally.

4.4 Special warnings and precautions for use

Before treatment with BABYAF SALINE NASAL DROPS, tell your doctor if you are suffering or have suffered in the past from impaired function of the heart and/or blood vessels, liver impairment or hypertension.

Do not use this medicine frequently or prolonged period without consulting a doctor. If you are sensitive to any food or medicine, inform your doctor before taking this medicine.

Do not use this medicine if there is a change in the color of the solution or when it becomes cloudy.

Do not use unless the product is clear and the pack intact.

4.5 Interaction with other medicinal products and other forms of interaction

Not known.

4.6 Pregnancy and lactation

As with most medicines, consult your doctor first if you are pregnant or breastfeeding.

4.7 Effects on ability to drive and use machines

Not known.

4.8 Undesirable effects

Requiring special attention:

Rare-Stop treatment and contact your doctor:

Hypertension (such as flushed face), rash or local inflammation (which did not exist before using the drug).

Additional undesirable effects:

Rash, Irritation or local burning.

Reporting of suspected adverse reactions

If you experience any undesirable effects, if any effects gets worse, or if you experience undesirable effect not mentioned in this leaflet, consult your doctor.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

4.9 Overdose

Substantial oral ingestion may require the use of a diuretic to remove excess sodium.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Isotonic (0.9% w/v) sodium chloride solution is widely used.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

There are no findings of relevance to the prescriber other than those already mentioned elsewhere in the SPC.

6. Pharmaceutical particulars

6.1 List of excipients

Benzalkonium chloride, purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

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After first opening, can be used for 12 months.

Use immediately after first opening of the ampoule. Discard any unused contents.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

The pack contains one plastic bottle with a dropper, containing 10ml solution.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorisation holder

Sam-On Ltd.

25 Ehud Kinnamon (haavoda) St.

Bat-Yam 59602

8. Marketing authorisation number(s)

58-90-27441

9. Date of first authorisation/renewal of the authorisation

NA

10. Date of revision of the text

1/2023