

NOZOIL® 10 ML NASAL SPRAY

Sesamum Indicum (Sesame seed oil)

Read all of this leaflet carefully because it contains important information for you.

NOZOIL is available without a doctor's prescription. Nevertheless, you still need to use NOZOIL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share NOZOIL with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.
- Avoid contact with eyes.
- Do not use the product if the bottle or spray part is not intact.
- Do not try to enlarge the tip of the spray pump.

WHAT NOZOIL CONTAINS

NOZOIL is a medical device.

NOZOIL contains 100 % pure sesame seed oil.

NOZOIL does not contain any preservatives.

Sesame oil forms a protective, water-resistant (hydrophobic) coating on the mucous membrane in the nose and keeps the mucosa moist.

WHAT NOZOIL IS USED FOR

NOZOIL is recommended for the relief of nasal dryness and crusting. NOZOIL protects, lubricates, softens and moisturises the nasal mucosa, providing relief from nasal dryness and discomfort; and prevents recurring dryness and crusting. A dry nose may result from:

- Inhaling dry air (in air-conditioned buildings, dry hot climates, airplanes)
- Polluted environments and inhaling foreign particles such as dust and smoke
- Ageing (in particular menopausal women)
- Patients who undergo radiation therapy to the head or throat
- People who suffer from nosebleeds
- Use of certain medications - e.g. the treatment of acne, nasally administered allergy or steroid medicines
- During and after a common cold
- The optimal results are noticeable after continuous use for 10 days

BEFORE YOU USE NOZOIL

Do not use NOZOIL:

Not for children under 2 years of age.

Do not use NOZOIL if you are hypersensitive (allergic) to sesame oil.

In case the product causes an allergic reaction, stop using the product and contact a doctor.

Take special care with NOZOIL:

Consult your doctor or pharmacist if symptoms of nasal dryness and crusting do not improve after using NOZOIL.

Pregnancy and breastfeeding:

No known risks. If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using NOZOIL.

Driving and using machinery:

NOZOIL is not known to have any influence on driving and using machinery.

Using other medicines with NOZOIL:

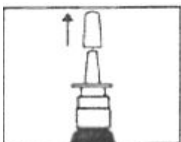
There are no known interactions with other medicines. Always tell your healthcare professional if you are taking any other medicine. This includes complementary or traditional medicines.

HOW TO USE NOZOIL

Always use NOZOIL as described in this leaflet, or as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adults and children over 2 years:
daily.

1 to 3 sprays in each nostril three times



Blow your nose well.
Remove the plastic cap from the bottle.



Let the bottle rest on your thumb and place your middle finger and index finger on the platform which is pushed down towards the bottle.
Before you use the spray for the first time, or if you have not used it for a long period, **you** will need to prime the spray by spraying several times until the oil is delivered in the form of a fine squirt.

NOZOIL is an oil based product. In order to avoid stains on walls and clothes etc., spray onto a tissue.



Insert the tip of the pump into the nostril. Hold the bottle upright and spray 1 to 3 times. Change the direction of the spray so that the oil reaches different parts of the mucosa. At the same time inhale air through the nose. After use, wipe the tip of the pump and replace the cap.

If you use more NOZOIL than you should:

Sesame oil is not expected to cause adverse effects. However, should adverse effects develop in the event of over-dosage consult your doctor or pharmacist.

POSSIBLE SIDE EFFECTS

When used as recommended, no adverse effects are to be expected.

Should your general health worsen or if you experience any unwanted effects while using NOZOIL, please consult your doctor, pharmacist or other healthcare professional for advice.

STORING AND DISPOSING OF NOZOIL

Store between 15 °C to 25 ° C and protect from light. Replace the cap after use. Do not use after the expiry date stated on the label and carton. KEEP OUT OF REACH OF CHILDREN. The opened product is stable for 6 months.

PRESENTATION OF NOZOIL

10 ml Brown spray glass bottle with white (plastic) cap.

IDENTIFICATION OF NOZOIL

Clear/colourless to light yellow solution.

NAME AND ADDRESS OF APPLICANT:

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

Manufacturer:

Pharmia Oy
Kalliotie 2
04360 Tuusula
Finland

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¹ Company registration number: 2008/008787/07