Package leaflet

Aspecton® Nasenspray

Nasal spray with sea salt solution for spraying into the nose

Dear Patient,

Please read this leaflet carefully because it contains important information you should consider when using this medical device. If you have any questions, please contact your doctor or pharmacist.

Composition:

Hypertonic sea salt solution (corresponding to 1.5 % saline), hypromellose, dexpanthenol, camphor, menthol, thyme oil, eucalyptus oil, mint oil, macrogolglycerol hydroxystearate (Ph. Eur.), sodium hydroxide, citric acid, aqua demineralised

Free of preservatives, free of propellant gas

Pharmaceutical form and contents:

Aspecton[®] Nasenspray with sea salt solution for spraying into the nose is available in packs of 20 ml.

Therapeutic indications:

For supportive treatment of rhinitis and blocked nose.

Nasal spray as complementary therapy of rhinitis and/or blocked nose.

Contraindications:

Aspecton[®] Nasenspray is contraindicated in patients with known hypersensitivity to any of the ingredients. It is furthermore contraindicated in subjects with respiratory disorders associated with significant airway reactivity such as bronchial asthma. The device should not be used after a nasal operation, accidents affecting the nose.

Use in children:

Aspecton® Nasenspray should not be used in children below 8 years of age.

Pregnancy and breast-feeding:

Due to a lack of experience, administration during pregnancy and breast-feeding should only be done after consultation with a doctor.

Interactions with other medicinal products and other forms of interaction:

To date there are no known interactions.

Side effects:

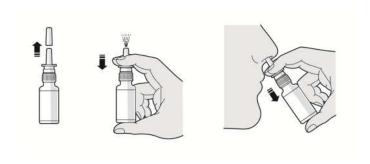
Hypersensitivity reactions may occur. Increased bronchospasms cannot be excluded.

Note:

If you suffer from disorders during treatment talk to a doctor or pharmacist.

Posology and route of administration:

- 1. Remove protective cap from the nozzle.
- 2. Pump several times before first use, until an even spray mist is produced. For all other applications the metered spray is ready for use.
- 3. Introduce the nasal applicator gently into one nostril and press the pump to apply the product. Repeat the process in the other nostril.



For hygienic reasons, it is recommended that the spray nozzle be wiped dry and the protective cap replaced after each use.

Dosage for adults and children aged 8 years and older:

Apply 1-2 sprays of Aspecton[®] Nasenspray into each nostril, several times per day as needed.

Aspecton[®] Nasenspray may be used to accompany the treatment of rhinitis and/or blocked nose for up to 14 days. If the symptoms do not improve or get worse after a treatment period of 7-14 days please consult a doctor.

For more severe symptoms requiring the use of a local decongestant over a limited period of time, it is recommended to continue treatment with Aspecton[®] Nasenspray for another few days after treatment with the decongestant nasal spray has ended, until symptoms resolve.

When Aspecton® Nasenspray is used with a decongestant nasal spray, Aspecton® Nasenspray should be used first.

Notes and information on shelf life:

The expiry date of this pack is printed on the carton and label. Do not use the medical device after the expiry date (\boxtimes) .

After opening, Aspecton® Nasenspray has a shelf life of 6 months.

Notes on storage:

Keep Aspecton® Nasenspray out of the reach and sight of children.

Do not store above 25 °C.

Manufacturer ():

Krewel Meuselbach GmbH, Krewelstraße 2, D-53783 Eitorf

Tel.: +49 (0)2243 / 87-0, fax: +49 (0)2243 / 87-175

E-Mail: info@krewelmeuselbach.de

Only available from pharmacies

Date of revision of the text

November 2018

[CE mark]

General user information:

Aspecton® Nasenspray brings relief from rhinitis and blocked nose.

Especially during the head-cold season, we are regularly exposed to a large number of head-cold viruses, without being able to defend ourselves from them. In head colds, the nasal mucous membrane swells up and secretes thick, viscous mucus. The nose becomes blocked. Additionally pollen or dust in the breathing air can lead to a blockage of the nose. We can no longer breathe freely. Especially at this time, proper care of the sensitive nasal mucous membrane is particularly important.

The sea salt solution contained in Aspecton® Nasenspray cleanses and moistens your blocked nose and gently reduces the swelling of the nasal mucosa for improved nasal breathing.

The product contains essential oils as odorants.

Aspecton[®] Nasenspray is free from preservatives and from propellant gas.