

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What **salinose COLD DEFENCE** is and what it is used for
2. Before you use **salinose COLD DEFENCE**
3. How to use **salinose COLD DEFENCE**
4. Possible side effects
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1. What salinose COLD DEFENCE is and what it is used for

salinose COLD DEFENCE Nasal Spray (called '**salinose COLD DEFENCE**' in this leaflet) helps to stop a cold from progressing when used at the **1st signs of a cold**, **salinose COLD DEFENCE acts at the back of the nose directly where the cold virus takes hold and starts to develop. It traps, inactivates and helps your body naturally remove the cold viruses**, to reduce the risk of the initial infection developing into a full blown cold.

Mechanisms by which **salinose COLD DEFENCE** works:

- 1. TRAP:** The unique micro-gel formula traps the cold viruses that start to develop at the back of the nose and helps prevent them from developing and spreading.
- 2. INACTIVATE:** The micro-gel reduces the pH of the nasal cavity and inactivates the viruses, reducing their ability to multiply and further infect you.
- 3. REMOVE:** Then, it flushes the nose and stimulates natural secretion (one of the body's natural defences in the nose) to help naturally remove the inactivated virus (toward the stomach or by blowing one's nose).

2. Before you use salinose COLD DEFENCE

Do not use salinose COLD DEFENCE

- If you are allergic to any of the ingredients of this medicine (listed in section 6).
- See your doctor before using this product if you have nose, ear or throat sensitivities.
- Infection with a cold can also irritate the lining of your nose sometimes causing nose bleeding.

Not suitable for children under 12 years of age.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding or think you may be pregnant ask your doctor or pharmacist for advice before taking this medicine.

Using other medicines, herbal or dietary supplements:

Please tell your doctor or pharmacist if you are taking or have recently taken any other products, including products obtained without a prescription.

3. How to use salinose COLD DEFENCE

Always use **salinose COLD DEFENCE** exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. Start to use as soon as feeling the first cold symptoms (e.g. A tickle at the back of the throat or sneezing), before the cold has fully developed. You can even start using it when feeling at risk of catching a cold.

Adults and children (12 years & older): Apply 2-3 sprays per nostril up to 4 times a day. Allow 4 hours between applications, no more than 4 applications in 24 hours.

For best results continue to use for 2 days after symptoms subside.

Use only as directed: **Without tilting your head**, insert the nozzle into your nostril, aiming the nozzle outward in the direction of your ear. Then **fully depress the pump 2 or 3 times** with firm even strokes and **avoid inhaling deeply**. Repeat for the other nostril.

Before first usage, remove the protective cap from the nozzle, hold bottle upright and prime the pump (into a tissue) by depressing it firmly several times. Wipe nozzle clean after use and replace protective cap.

After periods of storage of greater than 1 week, prime again before use.

- Do not use this container for more than one person; it may spread infection.
- Don not use more than the recommended dose.
- **For nasal use only.**

Consult your pharmacist or doctor if:
• After 7 days your cold is still present

- Symptoms worsen or are accompanied by fever
- In the case of accidental contact with eyes, flush with water and seek medical advice straight away.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. When using **salinose COLD DEFENCE**, you may experience increased nasal discharge (runny nose), nasal discomfort or temporary stinging. These are normal signs that the product is working. They are not harmful to your health and will last for long. If the sensation persists, stop using the product.

In some occasions, temporary headache pain in the nose, eye and neck have been reported; these symptoms will subside if the product is discontinued.

salinose COLD DEFENCE, like other nasal preparation, can irritate the lining of the nose which can result in nose bleeding. Such bleeding is rare, usually minor and short duration. Should nose bleeding occur during a cold, avoid using **salinose COLD DEFENCE**. If nose-bleed occurs whilst using (or soon after using) the product, discontinue use. If nosebleed for any reason is heavy or persistent consult your doctor.

Stop use immediately if you experience an allergic reaction or side effect and contact a healthcare professional.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store salinose COLD DEFENCE

- Keep this medicine out of the sight and reach of children.
- Store below 25°C.
- Keep out of direct sunlight.
- Do not use **salinose COLD DEFENCE** after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines if you no longer use. These measures will help to protect the environment.

6. Further information

What salinose COLD DEFENCE contains

salinose COLD DEFENCE contains: Purified Water, Hydroxypropyl Methylcellulose, Succinic Acid, Disodium Succinate Anhydrous, Pyridone Carboxylic Acid – PCA, Phenylethyl Alcohol, Zinc EDTA, Zinc Acetate Dihydrate, Polysorbate 80, Menthol, Camphor, Eucalyptus Oil and Saccharin Sodium.

What salinose COLD DEFENCE looks like and contents of the pack

Bottle with Snap-On Spray pump with nasal head and protection cap
Pack size: 20 ml

Manufacturer & Marketing Authorisation Holder:

Middle East Pharmaceutical Industries Co Ltd (Avalon Pharma)
P.O.Box 4180 Riyadh 11491
2nd Industrial City, Riyadh, Kingdom of Saudi Arabia
Tel: +966 (11) 2653948 - 2653427
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To report any side effect(s):

- **Saudi Arabia:**

The National Pharmacovigilance and Drug Safety Centre (NPC)
• Fax: +966-11-205-7662 • SFDA call centre: 19999 • Toll free phone: 800240000 • E-mail: npc.drug@sfdagov.sa • Website: https://ade.sfdagov.sa
• Other GCC States:
Please contact the relevant competent authority.
THIS IS A MEDICATION
- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. - Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication. - The doctor and the pharmacist are the experts in medicines, their benefits and risks. - Do not by yourself interrupt the period of treatment prescribed for you. - Do not repeat the same prescription without consulting your doctor. - Keep all medications out of reach of children.
Council of Arab Health Ministers, Union of Arab Pharmacists