

CARINOX CAPSULE®

Pseudoephedrine Sulphate/Loratadine (120mg/5mg)

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What Carinox is used for

Carinox is a medicine which is used to relieve the symptoms of hay fever including sneezing, runny nose, watery eyes, itching and nose blocked.

How Carinox works

Loratadine belongs to a class of medications called antihistamines. It works by blocking the action of histamine, a substance produced in the body that causes allergic symptoms.

Pseudoephedrine is a decongestant which helps to relieve nose and sinus congestion. It works by causing the blood vessels in the sinuses to tighten, decreasing the swelling of the sinuses and making it easier to breathe.

Before you use Carinox

- When you must not use it

Do not take Carinox if you:

- Are allergic to pseudoephedrine or any of the ingredients listed in the leaflet
- are taking similar medicines
- have an overactive thyroid gland.
- Have increased pressure in the eye
- have difficulty with passing urine
- have very high blood pressure or severe heart disease
- are taking, or have taken in the last two weeks, medicines for depression known as Monoamine Oxidase Inhibitors (MAOIs).

- Before you start to use it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Pregnancy and breastfeeding

- Tell your doctor or pharmacist if you

are pregnant or plan to become pregnant or are breastfeeding.

- Your doctor or pharmacist can discuss with you the risks and benefits involved.
- Safe use of Carinox capsules during pregnancy has not been established. Therefore, the product should be used only if potential benefit justifies the potential risk to the foetus. Since loratadine and pseudoephedrine sulphate are secreted in breast milk, a decision should be made whether to discontinue nursing or discontinue the use of this product.

Talk to your doctor or pharmacist if you have:

- bladder neck obstruction
- severe liver problems
- stenosing peptic ulcer (scarring and swelling due to ulcers causes narrowing in the duodenum and gastric outlet obstruction)
- gastric outflow obstruction
- blood vessels or heart disease
- diabetes
- enlarged prostate

Elderly people 60 years of age or older may be more likely to experience confusion, hallucination (hearing voices or seeing things which are not there), fits or central nervous system (CNS) depression. Use this product with caution.

Safety and efficacy of Carinox in children younger than 12 years of age have not been established

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist if you are taking any other medicines, including:

- ketoconazole for antifungal
- erythromycin as antibiotic
- cimetidine for stomach ulcers
- antacids (to relieve heartburn or indigestion) and kaolin (for diarrhoea)

- medicines used to treat high blood pressure such as methyldopa and beta blockers
- Monoamine oxidase inhibitors (MAOIs) (used to treat depression).
- digitalis (to treat heart problems)

How to use Carinox

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor, pharmacist or nurse to explain it to you.

- How much to use

For oral use only.

Adults and children 12 years of age and over: One capsule to be taken.

- When to use it

To be taken 2 times daily or ask your doctor or pharmacist on when you should use Carinox.

- How long to use it

Consult your doctor or pharmacist on how long you should use Carinox.

If symptoms persist, consult your doctor.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of the nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of overdoses include:

- Central Nervous System (CNS) depression (sedation, interrupted breathing during sleep), diminished mental alertness, blue or purple colour to the skin, coma, sudden loss of blood flow to the brain and other organs
- CNS stimulation (sleeping difficulty, hallucination, tremors or fits).
- Extreme happiness, rapid heart rate, feeling strong pounding of heartbeat, thirst, perspiration, nausea, dizziness, ringing or buzzing in ears, the loss of full control of bodily movements, blurred vision and high blood pressure or low blood pressure.
- Stimulation (increased activity) is particularly likely in children, as are atropine-like signs and symptoms (dry mouth, dilated pupils, flushing, increased body temperature and bowel symptoms).

While you are using Carinox

- Things you must do

Talk to your pharmacist or doctor if your symptoms do not improve. Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

Tell all the doctors, dentists and pharmacists treating you that you are taking Carinox.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Carinox to anyone else, even if they have the same symptoms or condition as you.

Do not take more than the recommended dose unless your pharmacist or doctor tells you to.

- Things to be careful of

Avoid alcoholic drink.

Antihistamines should be discontinued approximately 48 hours before skin testing procedure since antihistamines may affect the test results.

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

This medicine helps most people, but like all medicines, Carinox can also cause unwanted side effects, although not everybody gets them. Sometimes they are serious, most of the time they are not.

You may need medical attention if you get some of the side effects. Do not be alarmed by the following list of side effects. You may not experience any of them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Ask your pharmacist or doctor to answer any questions you may have.

Get emergency medical help immediately if you have any of these signs of an allergic reaction while taking Carinox: hives; difficult breathing; swelling of your faces, lips, tongue, or throat.

- Common side effects:

- Difficulty sleeping
- Dry mouth

- Serious side effects:

- Drowsiness
- Rash
- Fast or strong pounding of heartbeat
- Unusual weakness
- Feeling short of breath
- High blood pressure

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Carinox

- Storage

Keep the medicines in a cool dry place where the temperature stays below 30°C. Keep it where children cannot reach it.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Carinox is a capsule which has an ivory (opaque) body and a rich yellow (opaque) cap with "CARINOX" printed on both sides the cap and the body of the cap contains a 6mm round yellow coated capsule and white to off-white granules.

- Ingredients

- Active ingredient

Each Carinox capsule contains 5mg Loratadine and 120mg of Pseudoephedrine Sulphate.

- Inactive ingredients

- Surelease Clear E-7-19010
- Lactose Monohydrate
- Quinolone Yellow Lake
- Glyceryl Behenate
- Magnesium Stearate
- Talcum
- Croscarmellose Sodium
- Microcrystalline Cellulose 102
- Eudragit RSPO

- MAL number:

MAL05032545AZ

Manufacturer

Duopharma Manufacturing (Bangi) Sdn Bhd (53667-M)
Lot 2&4, Jalan P/7, Section 13, Bangi Industrial Estate, 43650, Selangor Darul Ehsan

Product Registration Holder

Duopharma Manufacturing (Bangi) Sdn Bhd (53667-M)
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