

APOHEALTH Sinus Nasal Decongestant Tablets

Contains the active ingredient Pseudoephedrine hydrochloride

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about APOHEALTH Sinus Nasal Decongestant tablets. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist who has detailed information.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor and/or pharmacist has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this information with the medicine as you may want to read it again.

What this medicine is used for

The name of your medicine is APOHEALTH Sinus Nasal Decongestant tablets. It contains the active ingredient pseudoephedrine hydrochloride, a decongestant, which acts to clear nasal congestion and dry a runny nose, making breathing easier.

If you have any concerns about this medication, ask your doctor or pharmacist.

Use in children

This medicine should not be used in children below 12 years of age.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, pseudoephedrine or any of the ingredients listed at the end of this leaflet.**
 - Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like

symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- You are taking, or within 14 days after stopping, monoamine oxidase inhibitors (MAOIs), a type of medicine used to treat depression
- You have very high blood pressure or severe blood vessel disease
- Do not give to children under 12 years
- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

If you are not sure whether you should take this medicine, talk to your doctor or pharmacist.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - high blood pressure

- heart disease
 - depression
 - lung, liver or kidney disorders
 - over active thyroid gland
 - prostate problems such as enlarged prostate
 - bladder problems
 - diabetes mellitus (high blood sugar)
 - increased pressure in the eye (glaucoma)
 - any other medical problems
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved
 4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding. Small amounts of pseudoephedrine may be excreted in breast milk.
 5. You are planning to have surgery or an anaesthetic.
 6. You are currently receiving or are planning to receive dental treatment.
 7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with pseudoephedrine. These include:

- medicines for high blood pressure
- medicines used for arrhythmia (for e.g. digoxin, quinidine)
- medicines that suppress appetite and for slimming
- other nasal decongestants (e.g. medicines used to treat symptoms of colds and flu)
- medicines for depression
- medicines used to relieve the burning sensation associated with urinary tract infections
- levodopa (a medicine used to treat Parkinson's disease)

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with pseudoephedrine.

How to take this medicine

How much to take

Adults and children over 12 years of age: 1 tablet 3 to 4 times a day, when necessary. Do not exceed 4 tablets in 24 hours.

Not suitable for use in children under 12 years.

If you are unsure what dose to take, ask your pharmacist.

How long to take it for

This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. Prolonged use may be harmful. If symptoms persist, seek medical advice.

If you forget to take it

If you miss a dose, do not take a double dose to make up.

This medicine should only be used when necessary.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Take APOHEALTH Sinus Nasal Decongestant tablets as described on the label and in this leaflet. If your symptoms do not improve within 7 days, you should contact your doctor for further advice.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to.
- Change the dosage, without first checking with your doctor or pharmacist.

Things to be careful of

This product may cause sleeplessness if it is taken up to several hours before going to bed.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking APOHEALTH Sinus Nasal Decongestant tablets or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All

medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor or pharmacist if you notice any of the following:

- raised blood pressure
- difficulty sleeping,
- nervousness,
- tremor (shaking),
- dizziness,
- headache,
- fast or irregular heartbeat,
- palpitations,
- sweating,
- flushing,
- anxiety,
- restlessness,
- skin rash
- hallucinations
- dry mouth or loss of appetite.

Children and the elderly may have an increased chance of getting side effects.

If you experience any of the following, contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation

- difficulty passing urine
- **If you develop sudden abdominal pain or rectal bleeding this could be due to inflammation of the colon (ischemic colitis). If you experience these symptoms stop taking this medicine and contact your doctor or seek medical attention immediately.**

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to APOHEALTH Sinus Nasal Decongestant tablets, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APOHEALTH Sinus Nasal Decongestant tablets looks like

APOHEALTH Sinus Nasal Decongestant tablets come as white round-shaped tablets.

Blister pack of 12 tablets

Active Ingredients

Each tablet contains:

Pseudoephedrine hydrochloride 60mg

It also contains the following inactive ingredients:

- microcrystalline cellulose
- magnesium stearate
- calcium hydrogen phosphate dihydrate

This medicine contains no lactose, sugar, gluten, yeast, artificial colouring, preservatives, starch, dairy products, glucose or alcohol.

Sponsor

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne, VIC 3121

Australian Registration Numbers

APOHEALTH Sinus Nasal Decongestant tablets: AUST R 265772

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