

SUDAFED® Sinus 12 Hour Relief Tablets

Pseudoephedrine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SUDAFED® Sinus 12 Hour Relief Tablets.

It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking SUDAFED® Sinus 12 Hour Relief against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What SUDAFED® Sinus 12 Hour Relief is used for

SUDAFED® Sinus 12 Hour Relief provides temporary relief from the symptoms of:

- sinus pain and congestion
- nasal congestion of allergic (seasonal) rhinitis and vasomotor (perennial) rhinitis
- nasal congestion from the common cold in adults and children over 12 years.

Pseudoephedrine belongs to a group of medicines called sympathomimetic decongestants.

It works by reducing congestion in the upper respiratory tract, including the nose, nasal passages and sinuses, and making it easier to breathe.

Ask your pharmacist or doctor if you have any questions about this medicine.

Your pharmacist or doctor may have given it for another reason.

This medicine is only available from your pharmacist.

Before you take SUDAFED® Sinus 12 Hour Relief

When you must not take it

Do not take SUDAFED® Sinus 12 Hour Relief if you have an allergy to:

- any medicine containing pseudoephedrine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you have:

- very high blood pressure
- severe coronary artery disease (heart disease caused by poor

blood flow or narrowing of the blood vessels of the heart)

- taken monoamine oxidase inhibitors, medicines used to treat depression, in the last 14 days.

Do not take this medicine if you are pregnant or plan to become pregnant.

It may affect your developing baby if you take it during pregnancy. Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

Do not take this medicine after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

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

Tell your pharmacist or doctor if you have or have had any of the following medical conditions:

- high blood pressure
- overactive thyroid gland
- diabetes
- heart disease and poor blood flow in the blood vessels of the heart
- glaucoma (high pressure in the eyes)

- prostate problems
- liver or kidney disease.

Ask your pharmacist or doctor about taking pseudoephedrine if you are breastfeeding.

Small amounts of pseudoephedrine pass into the breast milk. Your pharmacist or doctor will discuss the potential benefits and risks of taking the medicine if you are breastfeeding.

If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking SUDAFED® Sinus 12 Hour Relief.

Taking other medicines

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

Some medicines and SUDAFED® Sinus 12 Hour Relief may interfere with each other. These include:

- medicines used to treat depression
- medicines used to treat heart conditions
- medicines used to treat high blood pressure
- medicines used that make the urine more acidic or more alkaline
- medicines used to treat behavioural disorders
- phenylephrine, a medicine used to treat congestion
- appetite suppressants.

These medicines may be affected by SUDAFED® Sinus 12 Hour Relief or may affect how well it works.

You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist will have more information on medicines to be careful with or avoid while taking this medicine.

How to take SUDAFED® Sinus 12 Hour Relief

Follow all directions given to you by your pharmacist or doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your pharmacist or doctor for help.

How much to take

The recommended dose of SUDAFED® Sinus 12 Hour Relief for adults and children over 12 years is one prolonged-release tablet every 12 hours.

After initial improvement, one prolonged-release tablet every 24 hours may successfully control symptoms.

Do not take more than the recommended dose.

How to take it

Swallow SUDAFED® Sinus 12 Hour Relief prolonged-release tablets with a glass of water as required.

Do not divide, crush, chew or dissolve the tablet.

How long to take it

If symptoms do not improve within 7 days, consult a doctor before continuing use.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, you may take a dose as soon as you remember if you think you need it.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your pharmacist or doctor.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much SUDAFED® Sinus 12 Hour Relief. Do this even if there are no signs of discomfort or poisoning.

While you are using SUDAFED® Sinus 12 Hour Relief

Things you must do

Talk to your pharmacist or doctor if your symptoms persist, worsen, or if new symptoms appear.

Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

Things you must not do

Do not take SUDAFED® Sinus 12 Hour Relief to treat any other complaints unless your pharmacist or doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

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

Things to be careful of

Be careful driving or operating machinery until you know how SUDAFED® Sinus 12 Hour Relief affects you.

This medicine may cause dizziness in some people. If this happens, do not drive or operate machinery.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel

well while you are taking SUDAFED® Sinus 12 Hour Relief.

This medicine helps most people with sinus pain and nasal congestion, but it may have unwanted side effects in a few people. All medicines can have side effects. 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 lists of side effects. You may not experience any of them.

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

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

- headache
- drowsiness
- dizziness
- difficulty sleeping
- nervousness
- excitability
- feeling of extreme happiness
- restlessness
- fear or anxiety
- change in heart rate
- rapid or irregular heart beat
- raised blood pressure
- tremor
- hallucinations
- dry mouth
- nausea
- vomiting

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Children and people over 65 years of age may have an increased chance of getting side effects.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- pain when passing urine
- urine retention
- shortness of breath

- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin reddening, blisters, rash, itching or hives on the skin.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your pharmacist or doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using SUDAFED® Sinus 12 Hour Relief

Storage

Keep your medicine in the original pack until it is time to take.

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

Do not store SUDAFED® Sinus 12 Hour Relief 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 your 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

Ask your pharmacist what to do with any medicine that is left over, or if the expiry date has passed.

Product description

What it looks like

SUDAFED® Sinus 12 Hour Relief are white, capsule-shaped, film-

coated tablets. They are printed with 'Sudafed 12 Hour' in blue ink on one side, and the other side is plain.

SUDAFED® Sinus 12 Hour Relief is available in blister packs of 6 prolonged-release tablets.

Ingredients

SUDAFED® Sinus 12 Hour Relief prolonged-release tablets contain 120 mg of pseudoephedrine hydrochloride as the active ingredient.

SUDAFED® Sinus 12 Hour Relief prolonged-release tablets also contain the following inactive ingredients:

- candelilla wax
- microcrystalline cellulose
- hypromellose
- magnesium stearate
- povidone
- purified talc
- OPACODE monogramming ink S-1-4176 Blue
- OPADRY complete film coating system YS-1-18173-A White.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer

SUDAFED® Sinus 12 Hour Relief is made in Australia by:

Johnson & Johnson Pacific
45 Jones Street
Ultimo NSW 2007
Australia

SUDAFED is a registered trademark.

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