

Package Leaflet: Information for the patient

SNIP 325mg/15mg/1mg tablets

Paracetamol/pseudoephedrine hydrochloride/chlorphenamine maleate

Read all of this leaflet carefully before you start taking 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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What SNIP is and what it is used for
2. What you need to know before you take SNIP
3. How to take SNIP
4. Possible side effects
5. How to store SNIP
6. Contents of the pack and other information

1. What SNIP is and what it is used for

SNIP is a combination of paracetamol, chlorphenamine, and pseudoephedrine. Paracetamol is one of a group of medicines with analgesic (painkiller) and anti-pyretic (reduces fever) activity.

Pseudoephedrine is a decongestant which helps you to breathe more easily. Chlorphenamine is an antihistamine used to relieve respiratory allergies.

SNIP is indicated to relieve the symptoms associated with cold and flu, such as: cough, nasal congestion, rhinitis, sneeze, fever, light to severe pain of different origin.

SNIP is also indicated for alleviating symptoms of hay fever and other allergies of upper respiratory tract associated with fever.

2. What you need to know before you take SNIP

One of the active ingredients in Snip, pseudoephedrine, has the potential to be abused and large doses of pseudoephedrine can be toxic. Continuous use may lead to taking more Snip than the recommended dose to get the desired effect, resulting in an increased risk of overdosing. The recommended maximum dose and treatment duration should not be exceeded (see section 3).

Do not take SNIP:

- if you are allergic to paracetamol, chlorphenamine, pseudoephedrine or any other ingredients of this medicine (listed in section 6).
- if you take monoamine oxidase inhibitors (for treatment of depression and other psychiatric disorders). In order to start taking SNIP you should not have been taking such medicines for at least 2 weeks.
- if you have severe heart, kidney and liver diseases, diabetes, glaucoma, high blood pressure, or asthma.
- if you have very high blood pressure (severe hypertension) or hypertension not controlled by your medication.
- if you have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure.

Warnings and precautions

Talk to your doctor before taking SNIP:

- If you have other kidney, pulmonary, severe heart or liver problems (including a disease caused by drinking alcohol).
- If you are a man with prostate problems.
- If you have thyroid disease, bladder neck obstruction, stenosing peptic ulcer, asthma, emphysema or chronic bronchitis, glaucoma (increased intraocular pressure), diabetes, anaemia or hypertension (increased blood pressure).
- If you are taking other decongestants.

Sudden abdominal pain or rectal bleeding may occur with SNIP, due to inflammation of the colon (ischemic colitis). If you develop these gastro-intestinal symptoms, stop taking SNIP and contact your doctor or seek medical attention immediately. See section 4.

Reduction of blood flow to your optic nerve may occur with Snip. If you develop sudden loss of vision, stop taking Snip and contact your doctor or seek medical attention immediately. See section 4.

Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using Snip immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section 4 "Possible side effects" for symptoms).

If you develop a feverish generalised erythema associated with pustules, stop taking SNIP and contact your doctor or seek medical attention immediately. See section 4.

You should avoid drinking alcohol while you are taking SNIP, because your vigilance may be reduced.

You should avoid the concomitant use of SNIP with other paracetamol-containing products as this may result in paracetamol overdose.

If you take antihypertensive drugs (to reduce your high blood pressure) and/ or antidepressants you should consult with a specialist.

If the fever persists for more than 3 days and all other symptoms for more than 5 days, you should consult with your doctor.

Do not exceed the maximum recommended daily dose or the dose prescribed by your doctor.

Other medicines and SNIP

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those medicines you buy without a prescription. It is especially important to tell the doctor if you are taking:

- Central acting sedatives
- Cholestyramine
- Metoclopramide (used to treat migraine)
- Domperidone (used to treat nausea and vomiting)
- Antihypertensive therapy
- Antidepressant therapy
- Anticoagulant therapy - used to thin the blood (e.g. warfarin)
- Anticonvulsants (e.g. phenytoin, barbiturates, carbamazepine) - used to treat epilepsy fits or convulsions
- Drugs which make you sleepy or drowsy or relax your muscles
- Sympathomimetic agents, such as decongestants, appetite suppressants and psychostimulants
- amphetamine-like monoamine oxidase inhibitors
- Other pain killer products
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

The antihypertensive efficacy of methyldopa (used to treat high blood pressure), α and β adrenergic blockers, and guanethidine can lose their effect in concomitant administration with pseudoephedrine hydrochloride.

It is important that you tell your doctor, nurse or pharmacist about all the medicines that you are taking including those bought without a prescription.

SNIP with food, drink and alcohol

NEVER drink any alcohol whilst taking SNIP. When taken with alcohol, the effect of your tablets may be dangerously increased and can lead to overdose.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or if you are planning to have a baby, ask your doctor for advice before taking this medicine.

SNIP should not be used in pregnancy.

If you are taking this medicine and you are breastfeeding a baby, you should discuss this with your doctor. You should not take SNIP if you are breastfeeding.

Driving and using machines:

SNIP may cause drowsiness. If affected, you should not drive or operate machinery.

3. How to take SNIP

Your doctor will tell you how much SNIP to take and when to take it. The number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are taking the medicine. Ask your doctor to explain more. Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults

The recommended dose is 1-2 tablets every 4-6 hours as needed up to maximum 12 tablets per day.

Adolescents (over 12 years old)

The recommended dose is 1-2 tablets every 6 hours as needed up to maximum 8 tablets per day.

Children 6-11 years

The recommended dose is 1 tablet every 4 to 6 hours, not to exceed 6 tablets per day. For children between 6 to 8 years old the maximum recommended dose is 5 tablets per day.

Children under 6 years old:

Not recommended

Elderly

A reduced the dosage is recommended

Hepatic and renal impairment

A reduced total daily dosage is required.

If you take more SNIP than you should

An overdose of this medicine is very dangerous. Immediate medical advice should be sought in the event of an overdose even if you feel well, because of the risk of delayed, serious liver damage. If you or someone else has taken an overdose go to the nearest hospital casualty department immediately.

The most common overdose symptoms are associated with nausea, vomiting, abdominal pain, dizziness, allergic skin reactions (most commonly redness and itching), hallucinations, sweating and malaise. Remember to take any remaining tablets and the tablet box with you.

If you forget to take SNIP

If you do forget to take a dose, leave out the missed dose and take the next dose on time. Do not take a double dose to make up for a forgotten dose. It is important not to stop taking this medicine, until the doctor advises otherwise your condition may get worse again.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

SNIP is usually well tolerated.

Rare: may affect up to 1 in 1,000 people

- seeing or hearing things that are not there (hallucinations)
- allergic reaction, like skin eruption (rash) and itching,
- angioedema

Very rare (may affect up to 1 in 10,000 people):

- different changes in the blood count could be observed on prolonged use of high doses.
- very rare cases of serious skin reactions have been reported.

Not known: frequency cannot be estimated from the available data

- serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)

Stop using Snip immediately and seek urgent medical attention if you develop symptoms, that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These include:

- severe headache with a sudden onset
- feeling sick
- vomiting

- confusion
- seizures changes in vision
- nervousness
- dizziness,
- insomnia,
- agitation and restlessness,
- drowsiness.
- tachycardia
- hypertension
- inflammation of the colon due to insufficient blood supply (ischemic colitis)
- dry mouth
- urine retention
- reduced blood flow to the optic nerve (Ischaemic optic neuropathy)

Sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalized Exanthematous Pustulosis - AGEP) may occur within the first 2 days of treatment with SNIP. See section 2.

Stop using SNIP if you develop these symptoms and contact your doctor or seek medical attention immediately.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

The Medicines Authority,

Post-Licensing Directorate,

203 Level 3, Rue D'Argens, GŻR-1368 Gżira

Website: www.medicinesauthority.gov.mt

e-mail: postlicensing.medicinesauthority@gov.mt.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store SNIP

Store below 25°C, in the original packaging in order to be protected from light and moisture.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister 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 you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What SNIP contains

- The active substances are paracetamol, pseudoephedrine as pseudoephedrine hydrochloride and chlorphenamine as chlorphenamine maleate.

SNIP tablets contain 325 mg paracetamol, 15 mg pseudoephedrine hydrochloride and 1 mg chlorphenamine maleate.

The other ingredients are:

- microcrystalline cellulose 101, microcrystalline cellulose 105, croscarmellose sodium, powdered cellulose, magnesium stearate.
- Pregelatinized starch, corn starch, PVP K-30, stearic acid, sodium starch glycolate.

What SNIP looks like and contents of the pack

SNIP tablet is white, round, flat, scored and embossed SNIP.

The tablets are supplied in are packed in PVC-Al blisters. Each blister contains ten tablets and one, two or three such blisters are further packed into a unit carton along with the patient information leaflet of the product.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

MEDOCHEMIE LTD, 1-10 Constantinoupoleos street, 3011 Limassol, Cyprus

This leaflet was last revised in July 2024.

“SNIP” is a trademark.