

SOMINEX

(promethazine hydrochloride)

Important information about Sominex

- This medicine is used as a night time sleep aid for short term use.
- It can be taken by people over 16 years.

Do not take

- If you are under 16 years old.
- If you are pregnant. See section 2.
- Do not drink alcohol when taking this medicine.
- Do not use for longer than 7 days (see section 3).

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

- Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need any more information or advice.
- If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet:

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

1. What Sominex is and what it is used for

Sominex tablets contain promethazine hydrochloride, an antihistamine, which has a sedative effect. The medicine is used as a night time sleep aid, to correct temporary disturbances of sleep pattern where there is difficulty in going to sleep or staying asleep, caused for example by alteration of normal routine.

2. What you need to know before you take Sominex



Do not use Sominex if you:

- are **allergic** to promethazine or any of the other ingredients of this medicine (listed in section 6)
- have an **allergy to Phenothiazine** drugs (used to treat mental illness, severe nausea/vomiting or vertigo, e.g. chlorpromazine, pericyazine)
- have **concussion, light headedness, drowsiness, dizziness, a recent head injury** or if the person is unconscious (in a coma)
- have taken **MAOIs (monoamine oxidase inhibitors)** for depression within the last two weeks
- use this medicine for short term sleeping problems. It should not be used for more than 7 days without talking to your doctor.

Warnings and precautions



Talk to your doctor or pharmacist before taking Sominex if you have:

- asthma
- breathing problems or infection in your lung (bronchitis)
- experienced or are being treated for seizures (e.g. epilepsy). Sominex may affect the risk of seizure.
- difficulty passing urine
- glaucoma (raised pressure inside the eyeball)
- hearing problem
- prostate trouble
- kidney or liver problems
- serious heart problems
- personal or family history of heart disease
- irregular heartbeat
- a blocked intestine.

Medicines of this type may cause a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness when taken with other medicines that cause neuroleptic malignant syndrome, such as antipsychotics. If this happens, contact your doctor at once.



Other medicines and Sominex

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- other medicines which make you drowsy (e.g. sedatives or relaxants)
- MAOIs (monoamine oxidase inhibitors) for depression
- medicines which may give you a dry mouth or blurred vision (e.g. atropine or antidepressants)
- medicines used to reduce/prevent seizures (e.g. in epilepsy). Sominex may affect the risk of seizure.
- strong pain killers (e.g. codeine, morphine or buprenorphine)
- medicines treating mental illness (e.g. antipsychotics such as promazine, flupentixol or haloperidol)
- pregnancy tests based on urine samples, as they may give false positive or negative results if used when taking this medicine
- allergy skin tests, as they may give false negative results. Sominex should not be taken during the 3 days before the test



Sominex with alcohol

Do not drink alcohol when taking Sominex.



Use in children and adolescents

Do not give to children under 16 unless your doctor tells you to.



Pregnant or breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Sominex should not be taken 2 weeks before birth.

You should not take Sominex if you are breast-feeding. This is because small amounts may pass into mothers' milk. This can be harmful to your baby. If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine.



Driving and using machines

These tablets will cause drowsiness and you should not drive or operate machinery until the effects have worn off.



Turn over



Important information about some of the ingredients of Sominex

Lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to use Sominex

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take this medicine by mouth.



Adults, the elderly and children over 16

- The recommend dose is one tablet at bedtime.
- It may be taken up to one hour after going to bed when you can't go to sleep.
- Do not use this medicine for more than 7 days in a row. If natural sleep does not return within 7 days or you have repeated bouts of sleeplessness talk to your doctor.



Use in children and adolescents

Do not give to children under 16 unless your doctor tells you to.



If you take more Sominex than you should

If you accidentally take too many tablets, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately.

Take the pack with you to show which medicine you have swallowed. Signs of an overdose include: Loss of consciousness, dilated pupils, hot dry skin, feeling sleepy or drowsy, convulsions, involuntary movements, uneven heartbeat, heart failure, increased pressure in the skull causing painful eyes, changes in vision, a bad headache behind the eyes (hypertension), breathing difficulties, feeling or being sick, dry mouth and tongue, uncontrolled eye movements, flushing, fever, visual disturbances, mental disorder including illusions, hallucinations and disorientation, agitation, difficulty passing urine, blocked intestines, lung impairment. Children may also experience excitation, involuntary movement of hands, face and tongue, moving unsteadily or stumbling and hallucinations.

4. Possible side effects

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

Elderly people may be more susceptible to the side effects or confusion when taking this medicine.

Serious side effects

If you think you have any of the following side effects or symptoms, stop using this medicine immediately and see a doctor as soon as possible.

- allergic reactions which cause rash, difficulty in swallowing or breathing, swelling of the mouth or skin, vomiting or stomach pain
- jaundice (yellowing of the skin and eyes)
- muscle stiffness or shaking
- being unable to control some muscles in your head or face
- unusual movements of the tongue, facial muscle spasms, rolling eyes and trembling
- palpitations or abnormal heart rhythm
- low blood pressure (dizziness and lightheadedness)
- blurred or reduced vision or pain in the eye
- listlessness and lack of energy
- tiredness which lasts for a long time. This may be due to a blood problem called anaemia.
- reduction of white blood cells and platelets in the blood, causing ulcers in the mouth and throat, high temperature and bruising easily
- convulsions.

Other possible side effects

If you notice these or any other side effect not included below, stop use and tell your doctor or pharmacist. They will tell you what to do.

- drowsiness
- confusion, dizziness or headaches
- clumsiness or disorientation
- shaking and trembling
- stomach upsets or dry mouth
- difficulty in passing urine
- restlessness or excitation
- tiredness, having nightmares
- loss of appetite (anorexia), indigestion
- feeling or being sick
- sensitivity to sunlight
- difficulty sleeping
- ringing in the ears
- blocked/stuffy nose
- rashes.



Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Sominex

- There are no special conditions for storing this medicine.
- 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 carton. The expiry date refers to the last day of that month.
- Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sominex contains

The active substance is: promethazine hydrochloride 20mg.

The other ingredients are: lactose, maize starch, croscarmellose sodium, magnesium stearate.

What Sominex looks like and contents of the pack

Sominex tablets are white flat tablets with bevelled edges and are embossed 'S' on one side.

They are supplied in blister packs of 8 and 16 tablets.

Marketing Authorisation Holder

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Manufacturer

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