

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).

Now read the rest of the leaflet before you use this medicine. It includes other information which might be especially important for you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need any more information or advice.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

1. What the medicine is 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. Before you use this medicine



Do not use the medicine if you have

- An **allergy** to any of the ingredients listed in section 6.
- An **allergy to Phenothiazine** drugs (used to treat mental illness, severe nausea/vomiting or vertigo, e.g. chlorpromazine, pericyazine).
- **Concussion, light headedness, drowsiness, dizziness or a recent head injury.**
- Taken **MAOIs (monoamine oxidase inhibitors)** for depression within the last two weeks.
- This medicine is for short term sleeping problems. It should not be used for more than 7 days without talking to the doctor.
- **Do not drink alcohol** when taking Sominex.



Talk to your doctor or pharmacist if you have

- Asthma.
- Breathing problems or 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).
- Prostate trouble.
- Kidney or liver problems.
- Heart problems.
- A blocked intestine.



Talk to your doctor or pharmacist if you are taking

- 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. 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.



Pregnant or breastfeeding

Ask your doctor or pharmacist for advice before using this medicine if you are pregnant, might be pregnant or are breastfeeding. Sominex should not be used in pregnancy unless the doctor has told you to do so.



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

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Important information about some of the ingredients

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

3. How to use this medicine

Take this medicine by mouth



Adults, the elderly and children over 16

- Take 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.



Children under 16 years

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



If you take too many

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, feeling sleepy or drowsy, convulsions, involuntary movements, uneven heartbeat, breathing difficulties, feeling or being sick, dry mouth and tongue, flushing, fever, visual disturbances. Children may also experience excitation, moving unsteadily or stumbling.

4. Possible side effects

Like all medicines, Sominex can have side effects, although these don't affect everyone. Elderly people may be more susceptible to the side effects or confusion when taking this medicine.

Important 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 difficulty in breathing, swelling of the mouth or skin, vomiting or stomach pain.
- Jaundice (yellowing of the skin and eyes).
- Palpitations or abnormal heart rhythm.
- Low blood pressure (dizziness and lightheadedness).
- Blurred or reduced vision or pain in the eye.
- Anaemia or listlessness and lack of energy.
- 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.
- Dizziness or headaches.
- Clumsiness or disorientation.
- Shaking and trembling.
- Stomach upsets or dry mouth.
- Difficulty in passing urine.
- Restlessness or excitation.
- Sensitivity to sunlight.
- Difficulty sleeping.
- Ringing in the ears.
- Blocked/stuffy nose.



5. Storing this medicine

- There are no special conditions for storing this medicine.
- Keep it out of the reach and sight of children.
- Do not use after the expiry date shown on the carton. The expiry date refers to the last day of that month.
- Medicine should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of any unused medicine. These measures will help to protect the environment.

6. Further information

What is in this medicine

The active ingredient per tablet is:

promethazine hydrochloride 20mg.

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

What the medicine looks like

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

Actavis Group PTC ehf, Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Iceland.

Manufacturer

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This leaflet was revised in September 2011

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