

Package leaflet: Information for the patient

SOMINEX

(promethazine hydrochloride)

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 more information or advice.
- 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.
- 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 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 take Sominex:

- If you are allergic (hypersensitive) to promethazine hydrochloride or any of the other ingredients of this medicine (listed in section 6). The signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- If the person is unconscious (in a coma) or suffers from severe dizziness, drowsiness or headache.
- If you are taking a medicine for depression called a monoamine oxidase inhibitor (MAOI). Also do not take Sominex if you have stopped taking one of these MAOI medicines within the last 14 days. If you are not sure ask your doctor or pharmacist (see 'Other medicines and Sominex').

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Sominex.

⚠ Warnings and precautions

Talk to your doctor or pharmacist before taking Sominex:

- If you have difficulty breathing, wheezing, tightness in the chest (asthma) or an infection in your lungs (bronchitis).
- If you have seizure disorders such as epilepsy.
- If you experience an allergic reaction (see section 4), seek medical help right away.
- If you have any serious heart problems.
- If you have any personal or family history of heart disease.
- If you have an irregular heartbeat.
- If you develop a fever or an infection. Talk to your doctor immediately as laboratory tests to check your blood count may be required.
- If you have liver or kidney problems.
- If you have a stomach blockage or difficulty passing water.
- If you have hearing problems.
- If you have increased pressure in the eye (narrow angle glaucoma).
- If you have had something called Reye's Syndrome or possible Reye's Syndrome signs include being sick and confused following a viral illness.

Exposure to sunlight

Sominex can make your skin more sensitive to sunlight. Keep out of direct sunlight while taking this medicine.

Tests

Taking Sominex may affect the results of certain tests. These include some pregnancy tests and skin tests. Sominex should not be taken at least 3 days before the start of a skin test.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Sominex.

✗ Children and adolescents

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

⚠ Other medicines and Sominex

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you can buy without prescription, including herbal medicines.

This is because Sominex can affect the way some medicines work. Also some medicines can affect the way Sominex works.

In particular, do not take this medicine, and tell your doctor, if you are taking or have taken the following in the last 2 weeks:

- Some medicines for depression called monoamine oxidase inhibitors (MAOIs). If you are not sure ask your doctor or pharmacist.

Also tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following:

- Anticholinergic medicines – includes some medicines used for irritable bowel syndrome, asthma or weak bladder. These can increase the risk of dizziness, dry mouth and blurred eyesight.
- Medicines for mental health problems (antipsychotics such as haloperidol and quetiapine) or depression (antidepressants such as amitriptyline and citalopram).
- Medicines to help you to sleep or feel more relaxed (such as diazepam or zolpidem).
- Medicines such as aspirin (for arthritis and pain in your joints). Sominex may hide the side effects of these medicines.
- Medicines for the treatment of irregular heartbeats (antiarrhythmics such as quinidine and amiodarone).
- Medicines that can affect your heart rhythm.
- Medicines for the treatment of epilepsy or seizures.
- Antimicrobials (such as erythromycin and levofloxacin) for the treatment of infections.

✗ Sominex with alcohol

Do not drink alcohol while you are taking Sominex. This is because it can affect the way the medicine works.

⚠ Pregnancy and breast-feeding

Use of Sominex is not recommended during pregnancy. 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.

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

You may feel drowsy, dizzy or sleepy or have blurred vision after taking this medicine or the morning after taking this medicine. If this happens,

Turn over ➡



do not drive or use any tools or machines. You should not drive a vehicle or operate machinery until you know how Sominex affect you.

Sominex contains 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.

Sominex contains 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.

Taking this medicine

- Take this medicine by mouth.
- **Do not take for longer than 7 days.** If natural sleep does not return within 7 days or you have repeated bouts of sleeplessness talk to your doctor.
- Use this medicine only as recommended. Do not exceed the recommended dose.

How much to take

The recommend dose is:

For adults, the elderly and children over 16:

- One tablet at bedtime.
- It may be taken up to one hour after going to bed when you can't go to sleep.

✗ For 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 take more Sominex than you should, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Take the medicine pack with you. This is so the doctor knows what you or your child has taken.

The following symptoms of an overdose may occur: fits (seizures), impaired consciousness, coma, uneven heart beat and depressed breathing. Children may experience excitation, unsteady or uncontrollable movements especially of the hands or feet, hallucinations, limited ability to learn and impairments in thinking, learning or memory.

If you forget to take Sominex

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask



your doctor or pharmacist.

4. Possible side effects

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

Stop taking Sominex and see a doctor or go to a hospital straight away if you notice any of the following side effects:

- Allergic reactions (that can occur either immediately or within several days of drug administration) that may be life-threatening. Symptoms may include rash, itching, difficulty breathing, shortness of breath, swelling of the face, lips, throat, or tongue, cold, clammy skin, palpitations, dizziness, weakness or fainting.
- Liver problems that may cause the eyes or skin to go yellow (jaundice) and darkening of urine.
- Muscle stiffness or shaking.
- Unusual movements of the tongue, facial muscle spasms or being unable to control some muscles in your face, rolling eyes and trembling.
- Very fast, irregular, uneven or forceful heartbeat (palpitations).
- General weakness, more frequent infections (particularly throat infection) and fever due to changes in the blood (agranulocytosis).
- Eosinophilia which is an increase in the number of eosinophils (a type of white blood cell). Eosinophilia will be detected by a blood test.
- Tiredness which lasts for a long time. This may be due to a blood problem called anaemia.
- A feeling of aggression, hallucinations and hyperactivity in children.

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days.

- Dry mouth, blurred vision or you cannot pass water (urine).
- Feeling drowsy or sleepy, tiredness, disorientation, having nightmares, headaches, feeling restless.
- Loss of appetite (anorexia), indigestion or irritated stomach.
- Feeling dizzy, lightheaded, faint (hypotension).
- Feeling confused, especially in elderly people.
- Being more sensitive to the sun than usual. If this happens keep out of direct sunlight and do not use sun lamps.
- Unpleasant sensation or an overwhelming urge to move the legs (also called Restless Legs Syndrome).

Additional side effects

Not known: frequency cannot be estimated from the available data

- Abnormal electrical activity of the heart that affects its rhythm, including life-threatening rhythm disturbance
- A serious reaction with fever, rigid muscles, changing blood pressure and coma (neuroleptic malignant syndrome)
- Low levels of blood platelets (which can lead to bleeding and bruising)
- Restlessness
- Hallucinations
- Aggression

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

- Keep this medicine out of the sight and reach of children.
- Do not take this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- 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

- Each tablet contains promethazine hydrochloride 20mg, as the active ingredient.
- The other ingredients are: lactose, maize starch, croscarmellose sodium, magnesium stearate.

What Sominex looks like and contents of the pack

A white, flat bevelled-edge tablet with 'S' engraved on one side and a score line on the other.

It is packed in cartons containing 8 or 16 tablets in foil blister strips.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Dexcel®-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire NN11 8PB, United Kingdom

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