Package leaflet: Information for the patient

Sominex Night 500 mg/25 mg film-coated tablets

paracetamol and diphenhydramine 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, pharmacist, or nurse 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 Night is and what it is used for
2. What you need to know before you take Sominex Night
3. How to take use Sominex Night
4. Possible side effects
5. How to store Sominex Night
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1. What Sominex Night is and what it is used for

Sominex Night is used to provide fast and effective relief of the fever, aches and pains associated with colds and flu, headaches, backache, rheumatic and muscle pains, period pains and toothache which is causing difficulty in getting to sleep.
The active ingredients are paracetamol and diphenhydramine hydrochloride.
Paracetamol is a painkiller and diphenhydramine hydrochloride is an antihistamine that causes sleepiness or drowsiness making it useful when pain is keeping you awake.

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

2. What you need to know before you take Sominex Night

Do not take Sominex Night :
- if you are allergic to paracetamol or diphenhydramine or any of the other ingredients of this medicine (listed in section 6).
- if you have porphyria (too much of the pigment called porphyrin which may discolour the urine).
- if you have glaucoma (raised pressure in the eye).
- if you have taken another medicine containing paracetamol in the last 4 hours.
- if you are elderly and suffer from confusion.

Important:
This product contains Paracetamol. Do not take with any other paracetamol-containing products. Never take more Sominex Night than recommended. Higher doses than those recommended do not increase the pain-relieving effect, but may cause very serious liver damage. The symptoms of liver damage normally do not appear until after a few days. After an overdose, it is therefore very important

to seek medical advice as soon as possible, even if you feel well. Do not take with any other flu or cold products.
Do not take with any other antihistamine-containing products.

Warnings and precautions
Talk to your doctor or pharmacist before taking Sominex Night

- if you have liver or kidney disease, including alcoholic liver disease
- if you have epilepsy, or seizure disorders
- if you have an obstruction in your stomach or gut (for example, because of an ulcer)
- if you experience difficulty passing urine
- if you are an alcoholic
- if you have an enlarged prostate
- if you have myasthenia gravis
- if you have asthma, bronchitis or Chronic Obstructive Pulmonary Disease (COPD)
- if you have been told by your doctor that you have an intolerance to some sugars.
- if you suffer from haemolytic anaemia (a reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness).
- if you suffer from reduced glutathione levels.
- if you are elderly as elderly people are more likely to experience possible side effects. Carers should be aware that this medicine should not be given to elderly patients with confusion.
- if you are malnourished, dehydrated or weigh less than 50 kg.

Taking a painkiller for headaches too often or for too long can make them worse

Tolerance may develop with continuous use.

Other medicines and Sominex Night
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
This is particularly important if you have taken monoamine oxidase inhibitors (MAOis) in the last 2 weeks or tricyclic antidepressants (prescribed for depression); atropine; metoclopramide or domperidone (for nausea or vomiting); colestyramine (to lower blood cholesterol); medicines for stomach cramps (e.g. dicycloverine) or travel sickness (e.g. hyoscine); medicines to treat anxiety or to help you sleep; medicines that make you drowsy or give you a dry mouth; or blood thinning drugs (anticoagulants e.g. warfarin).

Sominex Night with alcohol
Do not drink alcohol while using Sominex Night .

Pregnancy and 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.
Do not take Sominex Night if you are pregnant or breast feeding.

Driving and using machines
Do not drive or operate machinery after taking Sominex Night . Sominex Night is intended to produce sleepiness or drowsiness soon after the dose is taken.

Sominex Night contains brilliant blue FCF (E133)
This may cause allergic reactions

3. How to take Sominex Night

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.

For bedtime use only.
Swallow Sominex Night with water.

Adults (including the elderly) and adolescents 16 years and over:
Take 2 tablets about 20 minutes before bedtime.
Do not take more than 2 tablets per night.
When taking Sominex Night at bedtime, you may take other tablets containing paracetamol during the day but do not take more than 4,000 mg paracetamol (including this product) in any 24 hours with at least 4 hours between doses.

Adolescents 12 years to 15 years:
Take 1 tablet about 20 minutes before bedtime.
Do not take more than 1 tablet per night.
When taking Sominex Night at bedtime, you may take other tablets containing paracetamol during the day but do not take more than 3,000mg paracetamol (including this product) in any 24 hours with at least 4 to 6 hours between doses.

Do not take Sominex Night for more than 7 consecutive nights without consulting your doctor.

Do not take anything else containing paracetamol while taking this medicine.

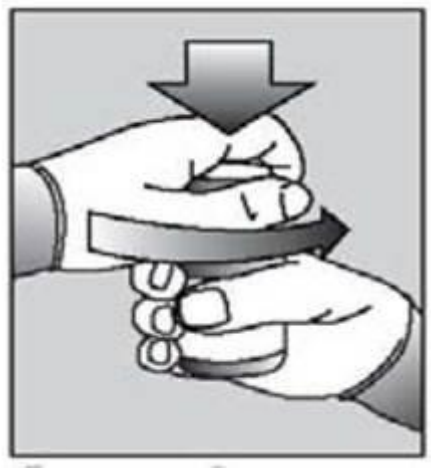
Not recommended for children under 12 years except under medical advice.

Do not exceed the stated dose.
If symptoms persist contact your doctor.
Prolonged use except under medical supervision may be harmful.

[For child resistant bottles only:]

Instructions for use of child resistant bottles:

Push down the lid and turn to open



If you take more Sominex Night than you should
Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

Do not take Sominex Night for more than one week
If your bedtime pain carries on for more than one week, or if your headache becomes persistent, see your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Older people are more prone to these side effects.
When using this product you may experience:
- Drowsiness, dizziness, tiredness, blurred vision, or difficulty concentrating
- Dry mouth.

Stop taking this medicine and tell your doctor immediately if you experience:
- Allergic reactions which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath
- Chest tightness or thickening of phlegm
- Difficulty in passing urine, headaches
- Skin rash or peeling or mouth ulcers
- Upset Stomach
- Breathing problems. These are more likely if you have experienced them before when taking other painkillers (such as ibuprofen and aspirin)
- Seizures or difficulty of muscle coordination
- Changes in heart rhythm
- Unexplained bruising or bleeding.

These reactions are rare.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail:medsafety@hpra.ie.

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

5. How to store Sominex Night

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 after EXP. The expiry date refers to the last day of that month.

Blister packs: Store below 25°C
Tablet containers: This medicine does not require any special storage conditions

Shelf life after first opening the container (plastic bottles only): 6 months

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 protect the environment.

6. Contents of the pack and other information

What Sominex Night contains

- The active substances are paracetamol and diphenhydramine. Each film-coated tablet contains 500 mg of paracetamol and 25 mg of diphenhydramine.
- The other ingredients are:
  - *Tablet core*: microcrystalline cellulose, crospovidone type A, povidone K29-32, stearic acid, silica colloidal anhydrous.
  - *Tablet coating*: polyvinyl alcohol (partially hydrolysed), titanium dioxide (E171), talc, macrogol/PEG 3350, methacrylic acid-ethyl acrylate copolymer type A, brilliant blue FCF (E133), indigo carmine (E132), sodium bicarbonate.

What Sominex Night looks like and contents of the pack

Sominex Night film-coated tablets are blue, capsule shaped, film-coated tablets, 17.6 mm x 7.5 mm, engraved with "A163" on one side.

Pack sizes:
Blister packs: 8, 12, 16 or 24 tablets.
Tablet containers: 50 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Actavis Group PTC ehf
Reykjavíkurvegi 76-78
220
Iceland

Manufacturer

Balkanpharma - Dupnitsa
AD3 Samokovsko Shosse Str.
Dupnitsa
2600
Bulgaria

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom	Paracetamol and diphenhydramine hydrochloride 500mg/25mg film-coated tablets
Bulgaria	ParacetaMax Night 500 mg/25 mg film-coated tablets
Hungary	Paracetamol/Diphenhydramine Actavis 500mg/25 mg filmtabletta
Ireland	Sominex Night 500mg/25mg Film-coated Tablet
Island	Parasetamóli/Diphenhydraminum Actavis
Poland	Omnipap Noc
Romania	Pinex Noapte

This leaflet was last revised in June 2017