

Non-Drowsy Sinutab[®]

Paracetamol 500 mg Tablets
Pseudoephedrine Hydrochloride 30 mg

Read all of this leaflet carefully because it contains important information for you. This medicine is available without prescription. However you still need to take Sinutab carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- 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.

In this leaflet

1. What Sinutab is and what it is used for.
2. Before you take Sinutab
3. How to take Sinutab
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1 What the medicine is for

Non-Drowsy Sinutab relieves the symptoms of colds and flus including aches, pains, fever, nasal and sinus congestion.

The tablets contain paracetamol, an analgesic and antipyretic to relieve pain and fever, and pseudoephedrine, a decongestant to clear nasal congestion and blocked sinuses. This medicine is for use in adults and children aged 6 years and over.

2 Before taking this medicine

This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

⊗ Do not use this medicine...

- If you have ever had a **hypersensitivity reactions** (e.g. rash, swelling of the face and throat, difficulty breathing) to any of the ingredients (*See section 6*).
- If you have **severe high blood pressure**.
- If you have **coronary heart disease** (narrowing of the arteries).
- If you have **thyrotoxicosis** (an excessive secretion of thyroid hormones).
- If you have **glaucoma**.
- If you have **urinary retention** (difficulty passing water).
- If you are taking any other medicines containing **paracetamol**.
- If you are taking, or have taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs).
- If you are taking any other sympathomimetic drugs (stimulants or appetite suppressants and drugs to treat asthma and congestion).
- If you are taking the antibacterial agent furazolidine.
- In children under 6 years.

If any of these apply to you, **get advice from a doctor or pharmacist without using Non-Drowsy Sinutab.**

⚠ Take Special Care...

- If you have **liver or kidney problems**.
- If you have **high blood pressure or heart disease**.
- If you have **raised intracocular pressure** (excessive pressure in your eye).
- If you have an **overactive thyroid gland**.
- If you have an **enlarged prostate**.
- If you have alcoholic liver disease as the hazards of overdose are greater.
- Alcohol should be avoided when taking this medicine. Alcohol can increase the liver damage of a paracetamol overdose.

⚠ If you are pregnant or breast-feeding:

- Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breast-feeding.

⚠ Taking Other Medicines

Please tell your pharmacist if you are taking or have recently taken any other medicines including:

- **Antihypertensives** (drugs to treat **high blood pressure** such as guanethidine, methyldopa, alpha and beta blockers, debrisoquine, bretylium and betanidine).
- **Tricyclic antidepressants** (used to treat **mood disorders**).
- **Colestyramine** (to **lower blood cholesterol**).
- **Metoclopramide** and **domperidone** (to treat **nausea and vomiting**).
- **Sympathomimetics** (such as other decongestants, appetite suppressants and stimulant drugs sometimes used to treat attention deficit disorders or excessive sleepiness).
- **Anticoagulants** (to **thin the blood** such as warfarin).
- **Barbiturates** (used to treat **anxiety** or help you **sleep**).
- **Oral contraceptives** ("**the pill**").
- **Anticonvulsants** (drugs used to treat **epilepsy**).
- Medicines obtained without a prescription.

If you are not sure about any of the medicines you are taking, show the bottle or pack to your pharmacist.

If any of these bullet points apply to you now or in the past, **talk to a doctor or pharmacist.**

⚠ Driving and Using Machinery

Non-Drowsy Sinutab Tablets has no or negligible influence on the ability to drive and use machines.

turn over ▶



3 How to take this medicine

ⓘ Check the tables that follow to see how much medicine to take.

- For oral use only.
- Do not take more than the stated dose shown.
- Take with a glass of water.

ⓘ Children under 6 years

This medicine is not recommended for children under 6 years old unless advised by a doctor.

ⓘ Children 6 - 12 years

Age	Dose
Children 6 - 12 years	1 tablet every 4 - 6 hours, up to 4 times a day

- Leave at least 4 hours between doses.
- Do not give more than 4 doses in 24 hours.
- If symptoms persist talk to your doctor.
- Consult a doctor or pharmacist before use in children aged 6 - 12 years.
- Use only when simple measures have failed to provide adequate relief. Do not exceed the maximum daily dose: 4 tablets. Do not use continuously for more than 5 days.

ⓘ Adults and children aged 12 years and over

Age	Dose
Adults and children 12 years and over	2 tablets every 4 - 6 hours, up to 4 times a day

- Leave at least 4 hours between doses.
- Do not give more than 4 doses in 24 hours.
- If symptoms persist talk to your doctor.

⚠ If anyone has too much

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 forget to take the medicine

If you forget to take a dose, take the next dose when needed provided that the last dose was taken at least 4 hours ago. Do not take a double dose.

4 Possible side-effects

Non-Drowsy Sinutab can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

If you experience any of the following, stop using this medicine and talk to your doctor:

- A few people have had hallucinations and sleep disturbance, but this is rare.
- Occasionally people get hypersensitivity reactions - skin rash, itching, swelling of the lips, tongue, throat or face.
- A few men, especially men with prostate problems, may have trouble passing water.
- There have been rare reports of blood disorders in people taking paracetamol, the symptoms of which include unusual tiredness, unexpected bruising or bleeding and getting more infections (such as colds) than normal.

Long-term use

- People who use medicine containing paracetamol every day for a long time (several months or more) could get certain side-effects including liver and kidney damage. People taking paracetamol in the usual way for shorter periods have not had these problems.

If you experience any side-effects not included in this leaflet or are not sure about anything, **talk to your doctor or pharmacist.**

5 Storing this medicine

Do not store above 25°C. Store in the original packaging. Keep the product out of the reach and sight of children. Do not use your medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What's in this medicine?

The active ingredients in Non-Drowsy Sinutab are: 500 mg Paracetamol and 30 mg Pseudoephedrine hydrochloride per tablet.
Other ingredients are: Pregelatinised maize starch, crospovidone, povidone, stearic acid, microcrystalline cellulose, sodium starch glycolate, magnesium stearate.

What the medicine looks like

Non-Drowsy Sinutab tablets are white round tablets, available in packs of 15 tablets.

PA Holder: McNeil Healthcare (Ireland) Ltd. Airton Road, Tallaght, Dublin 24, Ireland.
Manufacturer: Janssen Cilag, Domaine de Maigremont, 27100 Val de Reuil, France.

This leaflet was revised October 2012. Sinutab is a registered trade mark.

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Healthcare (Ireland) Ltd.

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