Non-Drowsy Sinutab Tablets

Paracetamol 500 mg
Pseudoephedrine Hydrochloride 30 mg

Read all of this leaflet carefully because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told 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 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.

What is in this leaflet

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

1 What this medicine is and what it is used 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 What you need to know before you take 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 are allergic to **paracetamol** or **pseudoephedrine** or any of the other ingredients of this medicine *(listed in section 6)*.
- If you have **high blood pressure**.
- If you have **cardiovascular disease**.
- If you have **diabetes**.
- If you have **phaeochromocytoma** (a tumour of the adrenal gland that can affect blood pressure).
- If you have an **over active thyroid**.
- If you have **glaucoma** (increased pressure in the eye).
- If you have **severe kidney problems**.
- 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.
- If you are taking **beta blockers** (type of drugs for high blood pressure).
- In children under 12 years.
- For more than 5 days unless your doctor tells you to.

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

Warnings and precautions

Talk to your doctor or pharmacist...

- If you are taking any other medicines containing **paracetamol**.
- If you have an **enlarged prostate**.
- If you have **urinary retention** (difficulty passing water).
- If you have **liver** or **kidney problems.**
- If you have **alcoholic liver disease** as the hazards of overdose are greater.
- If you have **blocked arteries or veins** (occlusive vascular disease).

Use of the product should be stopped if any of the following occur:

- Serious skin reactions. Symptoms may include skin redness, blisters, appearance of skin rash, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing or any other sign of hypersensitivity.
- Hallucinations
- Restlessness
- Sleep disturbances

Other medicines and this medicine

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, adrenergic neurone blockers and beta blockers, debrisoquine, bretylium, reserpine and betanidine).
- *Oxytocin* (drug used during **labour**).
- *Moclobemide* (used to treat **mood disorders**).
- *Cardiac glycosides* (drug used to treat **cardiac failure**).
- *Ergot alkaloids* (used to treat **migraine headaches**).
- *Tricyclic antidepressants* (used to treat **mood disorders**).
- *Cholestyramine* (to **lower blood cholesterol**).
- *Metoclopramide* and *domperidone* (to treat **nausea** and **vomiting**).
- *Sympathomimetics* (such as 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**).
- *Sodium bicarbonate* (used to treat **metabolic acidosis**).
- *Halogenated anaesthetics agents* (such as chloroform, cyclopropane, halothane, enflurane or isoflurane).

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

Pregnancy and Breast-feeding

- If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This medicine with drink

- Avoid alcoholic drink. Alcohol can increase the liver damage of a paracetamol overdose.

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

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Driving and Using Machines

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

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 12 years

This medicine is not recommended for children under 12 years old unless advised by a doctor.

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.
- Do not exceed the maximum daily dose: 8 tablets. Do not use continuously for more than 5 days.
- 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

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

If you experience any of the following, stop using this medicine and seek immediate help:

- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- Severe skin reactions including skin rashes such as hives (which may be severe and include blistering and peeling of the skin) and itching.
- Allergic reaction - cross sensitivity may occur with other sympathomimetics.

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

- Hallucinations, restlessness or sleep disturbances.
- A few men, especially men with prostate problems, may have trouble passing water.
- There have been 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.
- A fast or irregular heartbeat or an increased awareness of your heartbeat (palpitations).
- Delusions, epileptiform convulsions.

Other effects which may occur include:

Very common (may affect more than 1 in 10 people)

- Headache

Common (may affect up to 1 in 10 people)

- Dizziness, dry mouth
- Nausea (Feeling sick)
- Inability to sleep
- Nervousness

Uncommon (may affect up to 1 in 100 people)

- Kidney disease

Other effects which may occur but it is unknown how often

- Agitation
- Feeling anxious
- Feeling of extreme happiness
- Irritability
- Difficulty sleeping
- High blood pressure
- Vomiting
- Feeling Jittery
- Pain when passing urine
- Tremors
- Very high fever
- Stomach pain or discomfort, Diarrhoea, Vomiting

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.

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 this medicine

Do not store above 25ºC. Store in the original packaging.
Keep the product out of the sight and reach 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 Contents of the pack and other information

What this medicine contains

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 look like and content of the pack

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 January 2016.
Sinutab is a registered trade mark.

McNeil Healthcare (Ireland) Ltd.

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Johnson & Johnson	
Job Bag No.	15-0038
Version	4
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Description	PIL
Country	IRE
Date	18/01/2016
Manufacturer	Val De Reuil
Software	Illustrator CS6

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