

Package leaflet: Information for the user

Non-drowsy Sinutab® Tablets (Paracetamol 500mg Pseudoephedrine hydrochloride 30mg)

Your medicine is available using the above name but will be referred to as 'Sinutab' throughout this leaflet.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have 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 5 days

What is in this leaflet

- What Sinutab is and what it is used for
- What you need to know before you use Sinutab
- How to use Sinutab
- Possible side-effects
- How to store Sinutab
- Contents of the pack and other information

1. What Sinutab is and what it is used for

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 12 years and over.

2. What you need to know before you use Sinutab

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 **bad reaction (allergic reaction) to paracetamol or pseudoephedrine** or any of the other ingredients (*listed in section 6*).
- If you have **high blood pressure or heart disease**.
- If you have **diabetes**.

- If you have a **phaeochromocytoma** (a tumour which affects your heart rate and blood pressure).
- If you have an **overactive thyroid**.
- If you have **glaucoma** (increased pressure in the eye).
- If you have **severe kidney problems**.
- If you have **lung disease or breathing difficulties**.
- If you are taking, or have taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs) or Reversible Inhibitors of Monoamine Oxidase (RIMAs).
- If you are taking any **other cough and cold medicines**.
- If you are taking *beta blockers* (used to treat **high blood pressure**).
- In children under 12 years.

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

Warnings and Precautions

Talk to your doctor or pharmacist...

- If you are taking any other medicines containing **paracetamol**.
- If you have **prostate problems** (difficulty passing water or needing to pass water often).
- If you have **epilepsy**.
- If you have **liver or kidney problems**.
- If you have **blocked arteries or veins** (occlusive vascular disease).
- If you have the type of **anaemia** where your red blood cells get broken down (**haemolytic anaemia**) or any risk factors for this condition.
- If you are being treated for a **thyroid disorder**.
- If you have **alcohol dependence**.
- If you **weigh less than 50kg**, suffer from **chronic malnutrition** or are **dehydrated**

Other medicines and Sinutab

- Tell your doctor or pharmacist if you are taking any **other medicines**, including:
 - Antihypertensives* (drugs to treat **high blood pressure** such as *guanethidine, methyl dopa, adrenergic neurone blockers, debrisoquine, bretylium, reserpine* and *betanidine*).
 - Oxytocin* (drug used to help **contractions** during childbirth).
 - Moclobemide* (used to treat **mood disorders**).
 - Cardiac glycosides* (drugs used to control **heart rhythms or contractions** e.g. *digoxin*).
 - Ergot alkaloids* (used to treat **migraine** such as *ergotamine* and *methysergide*).
 - Tricyclic antidepressants* (used to treat **mood disorders**).
 - Cholestyramine* (to **lower blood cholesterol**).
 - Metoclopramide* and *domperidone* (to treat **nausea and vomiting**).

- Stimulants or appetite suppressants* and drugs used to treat **congestion and asthma** (*sympathomimetic drugs*).
- Anticoagulants* (to **thin the blood** such as *warfarin*).
- Oral contraceptives* ("the pill").
- Anticonvulsants* (drugs used to treat **epilepsy**).
- Anticholinergic drugs* (drugs used to treat **cramps or spasms** such as *atropine*).

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**.

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 using this medicine.

Sinutab with drink

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

Driving and Using Machines

- This medicine may cause dizziness. If affected, do not drive or operate machinery.

Anti-doping tests

- This medicine contains pseudoephedrine hydrochloride, which may produce positive results in anti-doping tests.

3. How to use Sinutab

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 in the tables.
- Take with a glass of water.

Children under 12 years

This medicine should not be given to children under 12 years old.

Adults and children aged 16 years and over

Age	Dose
Adults and children aged 16 years and over	2 tablets every 4-6 hours as needed

- Leave at least 4 hours between doses.
- Do not take more than 8 tablets (4 doses) in 24 hours.
- Do not take for more than 5 days.
- If symptoms persist or worsen talk to your doctor or pharmacist.

Children aged 12 to 15 years

Age	Dose
Children aged 12 to 15 years	1 tablet every 4 to 6 hours as needed

- Leave at least 4 hours between doses.
- Do not take more than 4 tablets (4 doses) in 24 hours.
- Do not take for more than 5 days.
- If symptoms persist or worsen talk to your doctor or pharmacist.

If you use more Sinutab than you should

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 use Sinutab

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, Sinutab can have side-effects, although not everybody gets them.

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

- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing.
- Allergic reactions including skin rashes such as hives (which may be severe and include blistering and peeling of the skin) and itching.
- Hallucinations, paranoid delusions or fits.

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

- Restlessness or sleep disturbances.
- Trouble passing water (especially men with prostate problems).
- 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).

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)

- Dry mouth or nausea
- Difficulty sleeping, nervousness or dizziness

Other effects which may occur but it is not known how often:

- Agitation, anxiety, irritability, feeling jittery or feelings of extreme happiness
- Drowsiness
- High blood pressure
- Vomiting
- Pain when passing water
- Tremors
- Very high fever
- Stomach pain or discomfort or diarrhoea.

Long-term use

- People who use medicines 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: medsaftey@hpra.ie

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

5. How to store Sinutab

- Do not store above 25°C. Store in the original packaging.
- **Keep this medicine out of the sight and reach of children.**
- Do not use this medicine after the expiry date (EXP) which is stated on the carton and blister strips. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sinutab contains

Each tablet contains 500mg paracetamol and 30mg pseudoephedrine hydrochloride as the active ingredients.

The other ingredients are: pregelatinised maize starch, crospovidone, povidone, stearic acid, microcrystalline cellulose, sodium starch glycolate (Type A) and magnesium stearate.

What the medicine looks like and contents of the pack

Sinutab Tablets are white, round, biconvex, plain on both sides.

Sinutab Tablets are available in blister packs containing 15 tablets.

Manufacturer

Manufactured by: Janssen Cilag, Domaine de Maigremont, 27100 Val de Reuil, France.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

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(Regulatory)**