

- This medicine is used to relieve the symptoms of colds, flu and allergies including aches, pains, fever, nasal and sinus congestion.
- This medicine is for use by adults and children aged 12 years and over.

**Do not take this medicine:**

- There are some people who should not take this medicine. *To find out if you are one of them see section 2* ▶
- If you have ever had a **bad reaction** to any of the ingredients. *For the list of ingredients see section 6* ▶

**Speak to your doctor:**

- If you suffer from any of the conditions mentioned in section 2. *See section 2* ▶
- If you are taking any **other medicines**. *See section 2* ▶

**Follow the dosage instructions carefully.** *See section 3* ▶

**Now read this whole leaflet carefully before you use this medicine.** Keep the leaflet: you might need it again.

## 1 What the medicine is for

Non-Drowsy Sinutab relieves the symptoms of colds, flu and allergies 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 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 **bad reaction** to any of the ingredients of this medicine (listed in section 6).

- If you have **high blood pressure** or **heart disease**.
- If you have **diabetes**
- If you have a **phaeochromocytoma** (rare tumour that affects your heart rate and blood pressure)
- If you have an **overactive thyroid gland**
- If you have **glaucoma** (increased pressure in the eye)
- If you have **severe kidney problems**
- If you are taking any other **cough and cold medicines** or medicines containing **paracetamol**.
- If you are taking **beta blockers** (used to treat **high blood pressure**)
- 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 **stimulants** or **appetite suppressants** or drugs used to treat **congestion** and **asthma** (*sympathomimetic drugs*)
- For children under 12 years old.

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

**Talk to your doctor or pharmacist...**

- If you have **kidney** or **severe liver problems**.
- If you have **alcohol dependence**.
- If you have **blocked arteries** or **veins** (occlusive vascular disease)
- If you are being treated for a **thyroid disorder**
- If you have **prostate problems** (difficulty with passing water or needing to pass water often).
- If you are taking any **other medicines**, including:
  - **Anticholinergic drugs** (drugs used to treat **cramps** and **spasms** such as *atropine*)
  - **Antihypertensives** (drugs to treat **high blood pressure** such as *guanethidine*, *methyl dopa*, *adrenergic neurone blockers*, *debrisoquine*, *bretylum* and *betanidine*).
  - **Tricyclic antidepressants** (used to treat **mood disorders**).
  - **Moclobemide** (used to treat **mood disorders**)
  - **Cardiac glycosides** (drugs used to **control heart rhythms** or **contractions** such as *digoxin*)

- **Ergot alkaloids** (drugs used to **treat migraine** such as *ergotamine* and *methysergide*)
- **Oxytocin** (drug used to help **contractions** during **childbirth**)
- **Cholestyramine** (used to **lower blood cholesterol**).
- **Metoclopramide** and **domperidone** (used to treat **nausea** and **vomiting**).
- **Anticoagulants** (drugs used to **thin the blood** such as *warfarin*).
- **Oral contraceptives** ("**the pill**").
- **Anticonvulsants** (drugs used to treat **epilepsy**).

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.**

**If you experience the following, stop taking this medicine immediately and contact your doctor:**

- A feverish generalised erythema associated with pustules (see section 4)
- Sudden severe headaches, nausea, vomiting, confusion, fits, visual disturbances.
- Sudden abdominal pain or rectal bleeding may occur with this medicine, due to inflammation of the colon (ischaemic colitis). If you develop these gastro-intestinal symptoms, stop taking this medicine and contact your doctor or seek medical attention immediately. See section 4.
- Reduction of blood flow to your optic nerve may occur with this medicine. If you develop sudden loss of vision, stop taking this medicine and contact your doctor or seek medical attention immediately. See section 4.

**If you are pregnant or 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.

## 3 How to take this medicine

turn over ▶

**Check the table that follows to see how much medicine to take.**

- For oral use only.
- Do not take more medicine than the label tells you to.
- Take with a glass of water.

**Children under 12 years**

Do not give to children under 12 years old.

**Adults and children aged 12 years and over**

Age	Dose
<b>Adults and children aged 16 years and over</b>	<b>2 tablets</b> every 4-6 hours, up to 4 times a day
<b>Children aged 12 years to 15 years</b>	<b>1 tablet</b> every 4-6 hours, up to 4 times a day

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

**If anyone has too much**

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.

**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 not everybody gets them.

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

- Sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalized Exanthematous Pustulosis - AGEP) may occur within the first 2 days of treatment with this medicine (See section 2).

- Severe headache, nausea, vomiting, confusion, fits, visual disturbances.
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- Feeling unusually tired, unexpected bruising or bleeding and getting more infections (such as colds) than normal.
- Allergic reactions including skin rashes such as hives (which may be severe and include blistering and peeling of the skin) and itching
- Hallucinations or paranoid delusions
- Inflammation of the colon due to insufficient blood supply (ischaemic colitis). Symptoms may include sudden abdominal pain or rectal bleeding.

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

- Restlessness or sleep disturbances
- A fast or irregular heartbeat or an increased awareness of the heartbeat (palpitations)
- Trouble passing water (especially in men with prostate problems)

**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)**
- Difficulty sleeping, nervousness or dizziness
  - Dry mouth or nausea
- Other effects which may occur but it is unknown how often**
- Anxiety, irritability, feeling jittery or feelings of extreme happiness
  - Drowsiness
  - Heart attack/reduced blood flow to the heart which can cause discomfort or pain in the chest, neck, back, jaw, shoulders or arms (known as angina)
  - Stroke
  - High blood pressure
  - Stomach pain, diarrhoea or vomiting
  - Pain when passing water
  - Reduced blood flow to the optic nerve (Ischaemic optic neuropathy)

**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 at [www.mhra.gov.uk/yellowcard](http://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 Storing this medicine

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 which is stated on the carton after 'Expiry'. 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 K30, 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.

**Marketing Authorisation holder:**

McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

**Manufacturer:** Janssen-Cilag, Domaine de Maigremont, 27100 Val de Reuil, France.

**This leaflet was revised May 2020.**

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