

# Non-Drowsy Sinutab<sup>®</sup>

paracetamol, pseudoephedrine

- 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.

### **X Do not use this medicine...**

- If you have ever had a **bad reaction** to any of the ingredients in this medicine (listed in section 6).
- If you have **high blood pressure** or **heart disease**.
- If you have **diabetes**.
- If you have a **phaeochromocytoma** (a 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 acute (sudden) or chronic (long-term) kidney disease or kidney failure**.
- 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 difficulty with passing water and / or an enlarged prostate (which may mean you need to pass water more 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, bretylium 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")**.
  - **Anticongulsants** (drugs used to treat **epilepsy**).

Please inform your doctor or pharmacist if you are taking **flucloxacillin** (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

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 redness of the skin (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 gastrointestinal 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.
- Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using Non-Drowsy Sinutab immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section 4 "Possible side effects" for symptoms).

### **! If you are pregnant or breast-feeding**

- If you are pregnant, or breast-feeding, think

turn over ►

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

One of the active ingredients in Non-Drowsy Sinutab, pseudoephedrine, has the potential to be abused and large doses of pseudoephedrine can be toxic. Continuous use may lead to taking more Non-Drowsy Sinutab than the recommended dose to get the desired effect, resulting in an increased risk of overdosing. The recommended maximum dose and treatment duration should not be exceeded (see section 3).

## 3 How to take this medicine

**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.

### **i Children under 12 years**

Do not give to children under 12 years old.

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

Age	Dose
Adults and children aged 16 years and over	2 tablets every 4-6 hours, up to 4 times a day
Children aged 12 years to 15 years	1 tablet 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, stop use and 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:**

- Reduced blood flow to the heart which can cause angina (discomfort or pain in the chest, neck, back, jaw, shoulders or arms), or heart attack.
- Stroke (weakness of the face, arms or legs, or speech problems).
- 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).
- Sudden onset of 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.
- 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 (seeing or hearing things that are not there, irrational thoughts or feelings).
- Inflammation of the colon due to insufficient blood supply (ischaemic colitis). Symptoms

may include sudden abdominal pain or rectal bleeding.

- Feeling unusually tired, unexpected bruising or bleeding and getting more infections (such as colds) than normal.

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

- 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**

- - Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS).
- Anxiety, restlessness, irritability, feeling jittery or feelings of extreme happiness
- Sleep disturbances
- A fast or irregular heartbeat or an increased awareness of the heartbeat (palpitations)
- Drowsiness
- High blood pressure
- Stomach pain, diarrhoea or vomiting
- Pain when passing water
- Tingling or numbness of the hands or feet (pins and needles)
- A tremor or shakiness
- Reduced blood flow to the optic nerve (Ischaemic optic neuropathy)

Very rare cases of serious skin reactions have been reported with paracetamol.

Stop using Non-Drowsy Sinutab immediately and seek urgent medical attention if you develop symptoms, that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS).

These include: • severe headache with a sudden onset • feeling sick • vomiting • confusion • seizures changes in vision

### **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, 50 - 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

**Manufacturer:** JNTL Consumer Health (France) SAS, Domaine de Maigremont, 27100 Val de Reuil, France.

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