

Package leaflet: Information for the user

NON-DROWSY

SUDAPLUS®

Tablets

Paracetamol 500mg

Pseudoephedrine hydrochloride 30mg

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

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2. What you need to know before you use Non-Drowsy Sudaplus Tablets
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1 What Non-Drowsy Sudaplus Tablets is and what it is used for

Non-Drowsy Sudaplus is used for the relief of nasal congestion when combined with fever and/or pain such as sore throat, sinus pain or headache in the common cold or flu.

This medicine contains two active ingredients. Paracetamol is a painkiller and reduces your temperature when you have a fever.

Pseudoephedrine hydrochloride is a decongestant which unblocks your nose and sinuses helping you breathe more easily.

This medicine is for use in adults and children aged 12 years and over.

2 What you need to know before you use Non-Drowsy Sudaplus Tablets

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 **diabetes**.
- If you have a **pheochromocytoma** (a tumour which affects your heart rate and blood pressure).

- 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 an **overactive thyroid**.
- If you have **glaucoma** (increased pressure in the eye).
- If you have **severe acute (sudden) or chronic (long-term) 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 *beta blockers* (used to treat **high blood pressure**).
- If you are taking any **other cough and cold medicines**.
- In children under 12 years.

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

Warnings and precautions

Talk to your doctor or pharmacist...

- If you are taking any other medicines containing **paracetamol**.
- If you have difficulty in passing water or need to pass water often (for example, due to prostate problems, or infection or inflammation of the bladder or urinary tract).
- If you have **epilepsy**.
- If you have **blocked arteries** or **veins** (occlusive vascular disease).
- If you have **liver** or **kidney problems**.
- 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 50 kg**, suffer from **chronic malnutrition** or are **dehydrated**.

If you experience the following, stop taking the product immediately and contact your doctor:

- A feverish generalised erythema associated with pustules (*see section 4*).
- Sudden abdominal pain or rectal bleeding may occur with Non-Drowsy Sinutab Tablets, due to inflammation of the colon (ischemic colitis). If you develop these gastro-intestinal symptoms, stop taking Non-Drowsy Sinutab Tablets, and contact your doctor or seek medical attention immediately. (*See section 4*).
- Sudden severe headaches, nausea, vomiting, confusion, fits, visual disturbances.

- Reduction of blood flow to your optic nerve may occur with Non-Drowsy Sudaplus Tablets. If you develop sudden loss of vision, stop taking Non-Drowsy Sudaplus Tablets and contact your doctor or seek medical attention immediately. (See section 4).

During treatment with Non-Drowsy Sudaplus Tablets, tell your doctor straight away if:

- If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Other medicines and Non-Drowsy Sudaplus Tablets

- Tell your doctor or pharmacist if you are taking any **other medicines**, including:
 - *Moclobemide* (used to treat **mood disorders**).
 - *Oxytocin* (drug used to help **contractions** during childbirth).
 - *Cardiac glycosides* (drugs used to control **heart rhythms** or **contractions** e.g. digoxin).
 - *Ergot alkaloids* (used to **treat migraine** such as ergotamine and methysergide).
 - *Stimulants or appetite suppressants* and drugs used to treat **congestion** and **asthma** (*sympathomimetic drugs*).
 - *Oral contraceptives* ("the pill").
 - *Anticonvulsants* (drugs used to treat **epilepsy**).
 - *Antihypertensives* (drugs to treat **high blood pressure** such as *guanethidine, methyldopa, adrenergic neurone blockers debrisoquine, bretylium, reserpine* and *betanidine*).
 - *Anticoagulants* (to **thin the blood** such as warfarin).
 - *Metoclopramide* and *domperidone* (to treat **nausea** and **vomiting**).
 - *Cholestyramine* (to **lower blood cholesterol**).
 - *Tricyclic antidepressants* (used to treat **mood disorders**).
 - *Anticholinergic drugs* (drugs used to treat **cramps** or **spasms** such as atropine).
 - *flucloxacillin* (antibiotic) due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

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**.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

One of the active ingredients in Non-Drowsy Sudaplus Tablets, pseudoephedrine, has the potential to be abused and large doses of pseudoephedrine can be toxic. Continuous use may lead to taking more Non-Drowsy Sudaplus Tablets 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).

Take special care with Non-Drowsy Sudaplus Tablets

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 Sudaplus tablets 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).

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.

Non-Drowsy Sudaplus Tablets 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 Non-Drowsy Sudaplus Tablets

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	2 tablets every 4 to 6 hours and over 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 Non-Drowsy Sudaplus Tablets 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 Non-Drowsy Sudaplus Tablets

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 Sudaplus 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:

Stop using Non-Drowsy Sudaplus tablets 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

- 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 stomach pains, passing blood in your stools or bleeding from your back passage and diarrhoea.
- Severe headache, nausea, vomiting, confusion, fits, visual disturbances.
- 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).
- Reduced blood flow to the optic nerve (Ischaemic optic neuropathy).

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

Not known (frequency cannot be estimated from the available data)

- Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS).
- Agitation, anxiety, irritability, feeling jittery or feelings of extreme happiness
- Drowsiness
- High blood pressure
- Vomiting

- Pain when passing water
- Tremors
- 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)
- Tingling or numbness of the hands or feet (pins and needles)
- Very high fever
- Stomach pain or discomfort, or diarrhoea
- Inflammation of the colon due to insufficient blood supply (ischaemic colitis)
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)

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, Website: www.hpra.ie

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

5 How to store Non-Drowsy Sudaplus Tablets

Do not store above 25°C.

Store in original package to protect from light.

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 Non-Drowsy Sudaplus Tablets contain

The active ingredients in Non-Drowsy Sudaplus 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 and contents of the pack

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

Marketing Authorisation Holder:

JNTL Consumer Health I (Ireland) Limited. Block 5, High Street, Tallaght, Dublin 24, Ireland.

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

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