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**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS**

**S2**

**SINUMAX ALLERGY SINUS caplets**

Pseudoephedrine hydrochloride,  
chlorphenamine maleate and paracetamol

Sugar free.

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

SINUMAX Allergy Sinus is available without a doctor's prescription, for you to treat a mild illness (pain and fever).

Nevertheless, you still need to use SINUMAX Allergy Sinus carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SINUMAX Allergy Sinus with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see your doctor if your symptoms worsen or do not improve after 7 days.

**What is in this leaflet**

1. What SINUMAX Allergy Sinus is and what it is used for.
2. What you need to know before you take SINUMAX Allergy Sinus.
3. How to take SINUMAX Allergy Sinus.
4. Possible side effects.

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5. How to store SINUMAX Allergy Sinus.
  6. Contents of the pack and other information.

## 1. What SINUMAX Allergy Sinus is and what it is used for

SINUMAX® Allergy Sinus contains an analgesic (paracetamol), a decongestant (pseudoephedrine) and an antihistamine (chlorphenamine).

It belongs to a class of medicines which are used to relieve the symptoms of colds and flu.

SINUMAX Allergy Sinus is used to relieve the symptoms of sinus pain (including pain in the face area), cold and flu, rhinitis (hay fever) and non-allergic rhinitis.

Paracetamol, an analgesic and an antipyretic, helps to relieve pain and fever (high temperature).

Chlorphenamine, an antihistamine, helps to relieve coughing, sneezing and runny nose.

Pseudoephedrine, a decongestant, helps to unblock stuffy noses and clear nasal congestion.

## 2. What you need to know before you take SINUMAX Allergy Sinus

### Do not take SINUMAX Allergy Sinus:

- If you are hypersensitive (allergic) to paracetamol, pseudoephedrine, chlorphenamine or any of other ingredients in SINUMAX ALLERGY SINUS (listed in section 6).
- If you have severe liver disease.
- If you have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure.
- If you need to have inhaled anaesthetics for any medical or surgical procedure.
- If you are taking, or have taken in the last 14 days, medicines for depression, known as

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monoamine oxidase inhibitors (MAOI)s.

- If you suffer from high blood pressure (severe hypertension) or hypertension not controlled by your medication, heart disease, diabetes or an over-active thyroid gland.
- If you have a rare tumour which affects your heart rate and blood pressure (phaeochromocytoma).
- If you suffer from glaucoma (increased pressure in the eye).
- If you are pregnant, trying to become pregnant or are breastfeeding.

## Warnings and precautions

### Take special care with SINUMAX Allergy Sinus:

- SINUMAX ALLERGY SINUS contains paracetamol which can cause severe liver or kidney damage when you take the caplets in excess of the recommended dose.
- SINUMAX ALLERGY SINUS may affect your attention and make you sleepy. This effect can be aggravated when SINUMAX ALLERGY SINUS is used with alcohol or other medicines that also cause drowsiness or affect concentration.
- 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 SINUMAX Allergy Sinus 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 have kidney or liver problems.
- If you have alcoholic dependence.

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- If you have difficulty passing water (urinary retention).
  - If you suffer from a prostate disease.
  - If you suffer from an obstruction in the stomach or intestines.
  - If you are taking a medicine called flucloxacillin (see Other medicines and SINUMAX Allergy Sinus).
  - Do not use SINUMAX ALLERGY SINUS for continuously for more than 7 days without consulting a doctor. If pain or fever persists or gets worse, or if new symptoms occur, speak to your doctor.

### **Stop taking SINUMAX ALLERGY SINUS if the following happens to you**

You develop any skin adverse reaction, such as toxic epidermal necrolysis (TEN), Steven-Johnson syndrome (SJS), drug rash with eosinophilia and systemic symptoms (DRESS) or drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE), treatment with SINUMAX ALLERGY SINUS must immediately be discontinued. These reactions can be life-threatening and are characterised by redness, inflamed or swollen skin, blisters, hives, itching and sometimes peeling or pain. Should you experience any of these symptoms, contact your health care provider immediately.

### **Children and adolescents**

SINUMAX Allergy Sinus should not be given to children under 12 years of age.

### **Other medicines and SINUMAX Allergy Sinus**

Always tell your health care provider if you are taking any other medicines. (This includes complementary or traditional medicines.)

Talk to your doctor or pharmacist before taking SINUMAX Allergy Sinus if you are taking or

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using:

- Antimuscarinic medicines, such as tricyclic antidepressants (medicines to treat mood disorders), atropine (used to treat some eye conditions and occasionally bowel conditions).
- Central nervous system (CNS) depressants, such as hypnotics (sleeping tablets including barbiturates), monoamine oxidase inhibitors, moclobemide or antidepressants (to treat mood disorders), tranquillisers (medicines used to relax muscles or decrease anxiety), antipsychotics (medicines used to treat mood disorders) and inhalation anaesthetics (for general surgery).
- Antihypertensives (medicines for high blood pressure including alpha and beta blockers).
- Sympathomimetic medicines (stimulants or appetite suppressants and medicines used to treat congestion).
- Cardiac glycosides (medicines used to control heart rhythms or contractions) e.g. digoxin.
- Ergot alkaloids (medicines used to treat migraine such as ergotamine and methysergide).
- Oxytocin (medicines used to help contractions during childbirth).
- Oral contraceptives.
- Metoclopramide or domperidone (used to treat nausea and vomiting).
- Cholestyramine (used to treat high cholesterol).
- Anticoagulants (medicines that prevent blood clots, such as warfarin).
- Anticonvulsants (medicines used to treat epilepsy).
- Doxapram (medicines used to treat breathing problems).
- Flucloxacillin (used to treat bacterial infections).

Ask your health care provider before use if you are taking the antibiotic flucloxacillin.

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Do not take SINUMAX Allergy Sinus with other medicines containing paracetamol, chlorphenamine or pseudoephedrine or medicines that have similar acting components.

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

### **SINUMAX Allergy Sinus with food, drink and alcohol**

Do not take SINUMAX Allergy Sinus with alcohol.

### **Pregnancy, breastfeeding and fertility**

Safety in pregnancy and during breastfeeding has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

### **Driving and using machines**

SINUMAX Allergy Sinus can make some people feel drowsy, dizzy or have blurred vision.

Make sure that you are not affected when you need to be alert.

Do not drive a motor car or operate machinery or climb dangerous heights if you are affected as impaired decision-making could lead to accidents.

## **3. How to take SINUMAX Allergy Sinus**

### **DO NOT TAKE MORE THAN THE RECOMMENDED DOSE.**

Do not share medicines prescribed for you with any other person.

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- For oral use only.

The usual dose is:

*Adults and children over 12 years of age:*

Take two caplets every six to eight hours, as required.

Do not take more than 8 caplets in 24 hours.

Always take SINUMAX Allergy Sinus exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

If you have the impression that the effect of SINUMAX Allergy Sinus is too strong or too weak, tell your doctor or pharmacist.

### **If you take more SINUMAX Allergy Sinus than you should**

Overdose may lead to liver damage. Signs may include lack of appetite, nausea, vomiting, excessive sweating, abnormal paleness of the skin and general feeling of being unwell.

In the event of overdosage, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre. Take along the rest of the remaining SINUMAX Allergy Sinus and the leaflet so that the doctor can easily tell what medicine you have taken.

### **If you forget to take SINUMAX Allergy Sinus**

If you forget to take a dose, take it as soon as you remember provided the last dose was at least 6 hours ago. If it is almost time for your next dose, skip the missed dose and take SINUMAX Allergy Sinus at the next scheduled time.

Do not take a double dose to make up for the forgotten individual doses.

#### 4. Possible side effects

SINUMAX Allergy Sinus can have side effects.

Not all side effects reported for SINUMAX Allergy Sinus are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking SINUMAX Allergy Sinus, please consult your health care provider for advice.

If any of the following happens, stop taking SINUMAX Allergy Sinus and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Skin rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SINUMAX Allergy Sinus. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

*Less frequent side effects:*

- Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)
- Stop using SINUMAX Allergy Sinus immediately and seek urgent medical attention if you

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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
- Becoming unusually tired, unexpected bruising or bleeding and getting more infections (such as colds) than usual.
  - Abnormal blood test results for liver function tests have been observed less frequently.
  - Hallucinations (seeing or hearing things that are not there) and paranoid delusions.
  - Fits (seizures) have been experienced less frequently.
  - An increased heartbeat, an increased awareness of the heartbeat (palpitations).
  - Severe skin reactions, such as toxic epidermal necrolysis (TEN), Steven-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), drug rash with eosinophilia and systemic symptoms (DRESS), or drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) (symptoms include red, inflamed, scaly or swollen skin, blisters, itching and sometimes peeling or painful skin rashes).
  - The inability to empty the bladder completely or partially (urinary retention), painful urination or difficulty in passing urine.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

*Frequent side effects:*

- Dizziness, drowsiness to deep sleep, including some difficulty performing tasks that

require attention and concentration, headache, upset stomach, stimulation, blurred vision, dry mouth, tight chest, and thickened mucus.

*Less frequent side effects:*

- High blood pressure.
- Restlessness and sleep disturbances.
- Irritability, anxiety, excitability, nausea and vomiting.
- Low blood pressure, tremor, shakiness, slurred speech, ringing in the ears, confusion, depression, lack of sleep, rash, mood changes, vomiting, diarrhoea and blood disorders.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the MED Safety APP (Medsafety X SAHPRA) and reporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SINUMAX Allergy Sinus.

For further information, please contact the Johnson and Johnson via [www.kenvuecontact.com](http://www.kenvuecontact.com) or call centre on 0860 410032 (landline).

**5. How to store SINUMAX Allergy Sinus**

- Store all medicines out of reach of children.
- Store at or below 25 °C.

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- Store in a cool, dry place.
  - Protect from light and moisture.
  - Do not remove the caplets from the outer carton until required for use.
  - Keep bottles well closed.
  - Do not use your medicine after the expiry date stated on the label.
  - Return all unused medicine to your pharmacist.
  - Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **6. Contents of the pack and other information**

### **What SINUMAX Allergy Sinus contains**

The active substances are 30 mg pseudoephedrine hydrochloride, 2 mg chlorphenamine maleate and 500 mg paracetamol.

The other ingredients are Carnauba wax, Hydroxypropyl methylcellulose, Magnesium stearate, Microcrystalline cellulose, Pregelatinised starch, Sodium starch glycollate and Starch 1500.

### **What SINUMAX Allergy Sinus looks like and contents of the pack**

SINUMAX Allergy Sinus is a capsule-shaped, hard, white film-coated caplet, engraved “SAS” on one side.

It is available in packs containing one or more blister packs of 10 caplets each which are packed into colourless, transparent plastic blister strips with an aluminium foil backing or in HDPE bottles containing 10, 20, 24 or 40 caplets.

### **Holder of certificate of registration**

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For further information, please contact the Johnson and Johnson contact centre at

[www.kenvuecontact.com](http://www.kenvuecontact.com)

**This leaflet was last revised in**

Date of registration: 09 September 1997

Date of text revision: 23 April 2025

**Registration number**

31/5.8/0555

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| Nam.Reg.No.: NS1 04/5.8/0275 |
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**Access to the corresponding Professional Information**

The latest electronic Professional Information may be found at the SAHPRA website:

<https://www.sahpra.org.za/pi-pil-repository/>.

Alternatively, you may directly contact Johnson & Johnson (Pty)

Ltd.:

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Consumer Contact Centre:

[www.kenvuecontact.com](http://www.kenvuecontact.com)

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