SINUTAB Sinus Allergy Congestion & Pain

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

SINUTAB Sinus Allergy Congestion & Pain tablets

Pseudoephedrine hydrochloride, chlorphenamine maleate and paracetamol

Sugar free.

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

SINUTAB Sinus Allergy Congestion & Pain tablets are available without a doctor's prescription, for you to treat a mild illness (pain and fever).

Nevertheless, you still need to use SINUTAB Sinus Allergy Congestion & Pain tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SINUTAB Sinus Allergy Congestion & Pain tablets 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 SINUTAB Sinus Allergy Congestion & Pain tablets is and what it is used for.
2. What you need to know before you take SINUTAB Sinus Allergy Congestion & Pain tablets.
3. How to take SINUTAB Sinus Allergy Congestion & Pain tablets.
4. Possible side effects.
5. How to store SINUTAB Sinus Allergy Congestion & Pain tablets.
6. Contents of the pack and other information.

1. What SINUTAB Sinus Allergy Congestion & Pain tablets is and what it is used for

SINUTAB® Sinus Allergy Congestion & Pain 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.

SINUTAB® Sinus Allergy Congestion & Pain 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).

Chlorpheniramine, 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 SINUTAB Sinus Allergy Congestion & Pain tablets

Do not take SINUTAB Sinus Allergy Congestion & Pain tablets

- If you are hypersensitive (allergic) to paracetamol, pseudoephedrine, chlorpheniramine or any of other ingredients in SINUTAB® SINUS ALLERGY CONGESTION AND PAIN.
- If you have severe liver or kidney disease.
- 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 monoamine oxidase inhibitors (MAOI)s.
- If you suffer from high blood pressure, 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 SINUTAB Sinus Allergy Congestion & Pain tablets

- SINUTAB® SINUS ALLERGY CONGESTION AND PAIN contains paracetamol which can cause severe liver or kidney damage when you take the tablets in excess of the recommended dose concentration.
- SINUTAB® SINUS ALLERGY CONGESTION AND PAIN may affect your attention and make you sleepy. This effect can be aggravated when SINUTAB® SINUS ALLERGY CONGESTION AND PAIN is used with alcohol or other medicines that also cause drowsiness or affect concentration.
- If you have kidney or liver problems.
- If you have alcoholic dependence.
- If you have difficulty passing water (urinary retention).
- If you suffer from a prostrate disease.
- If you suffer from an obstruction in the stomach or intestines.
- Do not use SINUTAB® SINUS ALLERGY CONGESTION AND PAIN 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.

Children and adolescents

SINUTAB Sinus Allergy Congestion & Pain tablets should not be given to children under 12 years of age.

Other medicines and SINUTAB Sinus Allergy Congestion & Pain tablets

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 SINUTAB Sinus Allergy Congestion & Pain tablets if you are taking or 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).

Do not take SINUTAB® Sinus Allergy Congestion & Pain 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 healthcare professional for advice.

SINUTAB Sinus Allergy Congestion & Pain tablets with food, drink and alcohol

Do not take SINUTAB Sinus Allergy Congestion & Pain tablets 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 healthcare professional for advice before taking this medicine.

Driving and using machines

SINUTAB Sinus Allergy Congestion & Pain tablets 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 SINUTAB Sinus Allergy Congestion & Pain tablets

DO NOT TAKE MORE THAN THE RECOMMENDED DOSE.

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

- For oral use only.

The usual dose is:

Adults and children over 12 years of age:

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

Do not take more than 8 tablets in 24 hours.

Always take SINUTAB Sinus Allergy Congestion & Pain tablets 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 SINUTAB Sinus Allergy Congestion & Pain tablets is too strong or too weak, tell your doctor or pharmacist.

If you take more SINUTAB Sinus Allergy Congestion & Pain tablets 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 SINUTAB Sinus Allergy Congestion & Pain tablets and the leaflet so that the doctor can easily tell what medicine you have taken.

If you forget to take SINUTAB Sinus Allergy Congestion & Pain tablets

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 SINUTAB Sinus Allergy Congestion & Pain tablets at the next scheduled time.

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

4. Possible side effects

SINUTAB Sinus Allergy Congestion & Pain tablets can have side effects.

Not all side effects reported for SINUTAB Sinus Allergy Congestion & Pain tablets are included in this leaflet.

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

If any of the following happens, stop taking SINUTAB Sinus Allergy Congestion & Pain tablets 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 SINUTAB Sinus Allergy Congestion & Pain tablets. 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:

- 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.

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, difficulty in passing urine, stimulation, blurred vision, dry mouth, tight chest, and thickened mucus.

Less frequent side effects:

- An increased heartbeat, an increased awareness of the heartbeat (palpitations) and high blood pressure, have been experienced less frequently.
- 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 "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of SINUTAB Sinus Allergy Congestion & Pain tablets.

For further information, please contact the Johnson and Johnson call centre on 0860 410032 (landline).

5. How to store SINUTAB Sinus Allergy Congestion & Pain tablets

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in a cool, dry place.
- Protect from light and moisture.
- Do not remove the tablets from the outer carton until required for use.
- 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 SINUTAB Sinus Allergy Congestion & Pain tablets contains

The active substances are 30 mg pseudoephedrine hydrochloride, 2 mg chlorphenamine maleate

and 500 mg paracetamol.

The other ingredients are calcium phosphate dihydrate, colloidal silicon dioxide, crospovidone, F D & C yellow no. 6 (colourant), magnesium stearate, pregelatinised maize starch, povidone and stearic acid.

What SINUTAB Sinus Allergy Congestion & Pain tablets looks like and contents of the pack

SINUTAB Sinus Allergy Congestion & Pain tablets is a slightly mottled, peach coloured, round, biconvex tablet.

It is available in packs of 20 tablets which are packed into colourless, transparent plastic blister strips with an aluminium foil backing.

Holder of certificate of registration

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