SINUTAB® SINUS PAIN EXTRA STRENGTH

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

SINUTAB® SINUS PAIN EXTRA STRENGTH

Pseudoephedrine hydrochloride, codeine phosphate, chlorphenamine maleate and paracetamol

Sugar free.

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

SINUTAB® SINUS PAIN EXTRA STRENGTH is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use SINUTAB® SINUS PAIN EXTRA STRENGTH carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SINUTAB® SINUS PAIN EXTRA STRENGTH with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- Do not use continuously without consulting a doctor:
  - for pain: for more than 5 days in adults and children over 12 years of age.
  - for fever: for more than 3 days

What is in this leaflet

1. What SINUTAB® SINUS PAIN EXTRA STRENGTH is and what it is used for.
2. What you need to know before you take SINUTAB® SINUS PAIN EXTRA STRENGTH.
3. How to take SINUTAB® SINUS PAIN EXTRA STRENGTH.
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1. What SINUTAB® SINUS PAIN EXTRA STRENGTH is and what it is used for

SINUTAB® SINUS PAIN EXTRA STRENGTH contains two analgesics (paracetamol and codeine), a decongestant (pseudoephedrine) and an antihistamine (chlorphenamine).
It belongs to a class of medicines which are used to relieve the symptoms of cold and flu.
SINUTAB® SINUS PAIN EXTRA STRENGTH is used to relieve nasal and sinus congestion, fever, headaches and body pains from hay fever, cold and flu.
Paracetamol is an analgesic and an antipyretic which means that it helps to relieve pain and fever (high temperature). Chlorphenamine is an antihistamine which helps to relieve coughing, sneezing, watery eyes, itchy and runny noses. Pseudoephedrine is a decongestant which helps unblock stuffy noses and blocked sinuses. Codeine is an analgesic which also helps to relieve headache, pain and body aches.

2. What you need to know before you take SINUTAB® SINUS PAIN EXTRA STRENGTH

Do not take SINUTAB® SINUS PAIN EXTRA STRENGTH

- If you are hypersensitive (allergic) to paracetamol, codeine phosphate, pseudoephedrine, chlorphenamine or any of other ingredients in SINUTAB® SINUS PAIN EXTRA STRENGTH.
- If you are taking or have taken medicines called monoamine oxidase inhibitors (MAOI)s in the last 14 days, which are used for depression.
- If you suffer from chronic respiratory problems
- If you have severe liver or kidney disease.
- If you suffer from any type of cardiovascular disease, including angina, high blood pressure, hyperthyroidism, hyperexcitability, phaeochromocytoma and closed angle glaucoma.
- If you are undergoing anaesthesia with halothane or other halogenated anaesthetic agents.

Warnings and precautions

Take special care with SINUTAB® SINUS PAIN EXTRA STRENGTH

- SINUTAB® SINUS PAIN EXTRA STRENGTH contains paracetamol which can cause severe liver or kidney damage when you take the tablets in excess of the recommended dose.
- SINUTAB® SINUS PAIN EXTRA STRENGTH may affect your attention and make you sleepy. This effect can be aggravated when SINUTAB® SINUS PAIN EXTRA STRENGTH is used with alcohol or other medicines that also cause drowsiness or affect attention.
- 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 prostate disease.
- If you suffer from an obstruction in the stomach or intestines.
- If you are receiving treatment for high blood pressure.
- If you suffer from diabetes (high blood sugar levels).
- If you have asthma or other respiratory conditions.
- If you develop a severe skin reaction while taking SINUTAB® SINUS PAIN EXTRA STRENGTH, contact your doctor immediately.
- If you are over 60 years of age or in poor health.

If pain or fever persists or gets worse, or if new symptoms occur, speak to your doctor.

Children and adolescents

Do not give SINUTAB® SINUS PAIN EXTRA STRENGTH to children under 12 years of age.

Other medicines and SINUTAB® SINUS PAIN EXTRA STRENGTH

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 PAIN EXTRA STRENGTH 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 PAIN EXTRA STRENGTH with other medicines containing paracetamol, codeine, 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 PAIN EXTRA STRENGTH with food, drink and alcohol

Do not take SINUTAB® SINUS PAIN EXTRA STRENGTH 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 SINUTAB® SINUS PAIN EXTRA STRENGTH.

Driving and using machines

SINUTAB® SINUS PAIN EXTRA STRENGTH 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 PAIN EXTRA STRENGTH

DO NOT TAKE MORE THAN THE RECOMMENDED DOSE.

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

The usual dose is:

Adults and children over 12 years:	One to two tablets every four to six hours. Do not take more than eight tablets in 24 hours.

Always take SINUTAB® SINUS PAIN EXTRA STRENGTH 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 PAIN EXTRA STRENGTH is too strong or too weak, tell your doctor or pharmacist.

If you take more SINUTAB® SINUS PAIN EXTRA STRENGTH 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 PAIN EXTRA STRENGTH and the leaflet so that the doctor can easily tell what medicine you have taken.

If you forget to take SINUTAB® SINUS PAIN EXTRA STRENGTH

If you forget to take a dose, take it as soon as you remember provided the last dose was at least four to six hours ago If it is almost time for your next dose, skip the missed dose and take SINUTAB® SINUS PAIN EXTRA STRENGTH 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 PAIN EXTRA STRENGTH can have side effects.

Not all side effects reported for SINUTAB® SINUS PAIN EXTRA STRENGTH are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking SINUTAB® SINUS PAIN EXTRA STRENGTH, please consult your health care provider for advice.

If any of the following happens, stop taking SINUTAB® SINUS PAIN EXTRA STRENGTH 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 PAIN EXTRA STRENGTH. 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, confusion.
- Headache.

- Upset stomach, constipation.
- Feeling sick (nausea), being sick (vomiting).
- Difficulty in passing urine.
- 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.
- 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 PAIN EXTRA STRENGTH.

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

5. How to store SINUTAB® SINUS PAIN EXTRA STRENGTH

- 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 PAIN EXTRA STRENGTH contains

The active substances are 2 mg chlorphenamine maleate, 10 mg codeine phosphate, 500 mg paracetamol and 30 mg pseudoephedrine hydrochloride.

The other ingredients are calcium phosphate dihydrate dibasic, colloidal silicon dioxide, crospovidone, FD & C Red no. 3 (colourant), magnesium stearate, povidone, pregelatinised maize starch, pregelatinised starch and stearic acid.

What SINUTAB® SINUS PAIN EXTRA STRENGTH looks like and contents of the pack

A slightly mottled, pink, round, biconvex tablet with a bisecting score on one side.

SINUTAB® SINUS PAIN EXTRA STRENGTH is available in PVC/aluminium blister packs containing 12 and 24 tablets.

Holder of certificate of registration

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