PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

SINUTAB® SINUS PAIN NON-DROWSY tablets

Pseudoephedrine hydrochloride and paracetamol

Sugar free.

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

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

Nevertheless, you still need to use SINUTAB® SINUS PAIN NON-DROWSY carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SINUTAB® SINUS PAIN NON-DROWSY 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 10 days.

What is in this leaflet

1. What SINUTAB® SINUS PAIN NON-DROWSY is and what it is used for.
2. What you need to know before you take SINUTAB® SINUS PAIN NON-DROWSY.
3. How to take SINUTAB® SINUS PAIN NON-DROWSY.
4. Possible side effects.
5. How to store SINUTAB® SINUS PAIN NON-DROWSY.
6. Contents of the pack and other information.

1. What SINUTAB® SINUS PAIN NON-DROWSY is and what it is used for

This medicine is used to relieve the symptoms of colds and flu, including blocked nose and sinuses, aches and pains, headache and to reduce fever.

It contains paracetamol, which acts to relieve pain and fever.

It also contains pseudoephedrine, a decongestant, which acts to relieve a blocked nose and blocked sinuses.

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

2. What you need to know before you take SINUTAB® SINUS PAIN NON-DROWSY

Do not take SINUTAB® SINUS PAIN NON-DROWSY

- If you are hypersensitive (allergic) to paracetamol, pseudoephedrine or any of the other ingredients in SINUTAB® SINUS PAIN NON-DROWSY.
- If you suffer from high blood pressure, heart disease, diabetes, phaeochromocytoma or an over-active thyroid.
- If you suffer from prostate disease or glaucoma (pressure in the eye).
- If you suffer from liver or kidney disease.
- If you are taking medicines prescribed by your doctor, particularly antidepressants or atropine including those known as monoamine oxidase inhibitors (MAOI)s.
- If you are taking any other cough and cold medicines or medicines containing paracetamol.
- If you are taking stimulants or appetite suppressants or medicines used to treat congestion and asthma (sympathomimetic medicines).

Warnings and precautions

Take special care with SINUTAB® SINUS PAIN NON-DROWSY

- SINUTAB® SINUS PAIN NON-DROWSY contains paracetamol which can cause severe liver or kidney damage when you take the tablets more than the recommended dose.

- If you have kidney or liver problems.
- If you have diseases of the heart and blood vessels.
- If you have an over-active thyroid, diabetes, glaucoma or angina.
- If you suffer from a prostate disease.
- If you have difficulty passing water (urinary retention).
- If you suffer from an obstruction in the stomach or intestines.
- Do not use SINUTAB® SINUS PAIN NON-DROWSY continuously for more than 10 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

Do not give SINUTAB® SINUS PAIN NON-DROWSY to children under 12 years of age.

Other medicines and SINUTAB® SINUS PAIN NON-DROWSY

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

Talk to your doctor or pharmacist before taking SINUTAB® SINUS PAIN NON-DROWSY if you are taking or using:

- monoamine oxidase inhibitors, or antidepressants
- decongestants, appetite suppressants or stimulants
- medicines for high blood pressure or other cardiovascular disorders.
- medicines for diabetes mellitus
- medicines that prevent blood clots, such as warfarin.

Do not take SINUTAB® SINUS PAIN NON-DROWSY with other medicines containing paracetamol or pseudoephedrine and similar decongestants or appetite suppressants.

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

SINUTAB® SINUS PAIN NON-DROWSY with food, drink and alcohol

Do not take SINUTAB® SINUS PAIN NON-DROWSY with alcohol.

Pregnancy, breastfeeding and fertility

The safety in pregnancy and breastfeeding has not been established.

If you are pregnant, trying to become pregnant or breastfeeding your baby while taking SINUTAB® SINUS PAIN NON-DROWSY, consult your doctor, pharmacist or other health care provider for advice before.

Driving and using machines

As SINUTAB® SINUS PAIN NON-DROWSY can cause dizziness do not drive or operate machinery until you know how it affects you.

3. How to take SINUTAB® SINUS PAIN NON-DROWSY

DO NOT TAKE MORE THAN THE RECOMMENDED DOSE.

Adults and children over 12 years:

Two tablets every four to six hours. Do not take more than eight tablets in 24 hours.

Always take SINUTAB® SINUS PAIN NON-DROWSY 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 NON-DROWSY is too strong

or too weak, tell your doctor or pharmacist.

If you take more SINUTAB® SINUS PAIN NON-DROWSY than you should

If SINUTAB® SINUS PAIN NON-DROWSY is taken more than the stated dose, it may cause nausea, vomiting and anorexia. Liver damage which may be fatal, may only appear after a few days.

If you accidentally take too many, consult your doctor immediately. If you cannot do this, go to the nearest hospital accident and emergency/casualty department or poison centre. Take along any medicine that is left and the carton so that the hospital can easily identify what medicine you have taken.

If you forget to take SINUTAB® SINUS PAIN NON-DROWSY

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

SINUTAB® SINUS PAIN NON-DROWSY can have side effects.

Not all side effects reported for SINUTAB® SINUS PAIN NON-DROWSY are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking SINUTAB® SINUS PAIN NON-DROWSY, stop the medicine and consult your health care provider for advice.

If any of the following happens, stop taking SINUTAB® SINUS PAIN NON-DROWSY 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 NON-DROWSY. 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:

- Heart disorders such as an irregular heart rhythm or heart failure.
- Becoming unusually tired, unexpected bruising or bleeding and getting more infections (such as colds) than usual.
- Abnormal blood test results for liver function tests.
- Hallucinations (seeing or hearing things that are not there), or paranoid delusions.
- The inability to empty the bladder completely or partially (urinary retention) or difficulty in passing urine.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Irritability, anxiety, feeling of fear, confusion, nervousness.
- Restlessness and difficulty in falling or staying asleep.
- Involuntary shaking of one or more parts of your body (tremor).
- Dizziness.
- A general feeling of weakness.

Less frequent side effects:

- Headache.
- Hives, severe skin reaction.
- Loss of appetite, changes in your metabolism.
- Too low levels of potassium in your blood when blood tests are done.
- An increased heartbeat, an increased awareness of your heartbeat (palpitations), high blood pressure.
- Low blood pressure, fainting, flushing.
- Increased saliva or sweating.
- Nausea (feeling sick) and vomiting (being sick).
- Blood disorders or changes in your blood glucose levels.

Frequency unknown side effects:

- Mood changes.
- Diarrhoea, pain in your stomach area.

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 NON-DROWSY.

For further information, please contact the Johnson and Johnson call centre on 0860 410032

(landline).

5. How to store SINUTAB® SINUS PAIN NON-DROWSY

- 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 tablets from the outer carton until required for use.
- Do not use after the last day of the month shown on the expiry date.
- 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 NON-DROWSY contains

The active substances are 30 mg pseudoephedrine hydrochloride and 500 mg paracetamol.

The other ingredients are magnesium stearate, microcrystalline cellulose, povidone and sodium starch glycollate.

What SINUTAB® SINUS PAIN NON-DROWSY looks like and contents of the pack

SINUTAB® SINUS PAIN NON-DROWSY is a white, round, biconvex tablet with a score on one side.

It is available in white opaque or clear blisters packed into individual cartons of 10 and 20 tablets each.

Holder of certificate of registration

Johnson & Johnson (Pty) Ltd.

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7945

South Africa

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

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Access to 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 contact Johnson & Johnson (Pty) Ltd. directly at:

Consumer Contact Centre:

0860 410032 (South Africa Only)

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EXPORT REGISTRATION DETAILS

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