

This amendment: Response to Clinical Recommendation

Date of original submission: 19.06.2015

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

SUDAFED® SINUS PAIN

Pseudoephedrine hydrochloride and paracetamol

Sugar free.

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share SUDAFED® SINUS PAIN 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 SUDAFED® SINUS PAIN is and what it is used for.
2. What you need to know before you take SUDAFED® SINUS PAIN.
3. How to take SUDAFED® SINUS PAIN.
4. Possible side effects.
5. How to store SUDAFED® SINUS PAIN.
6. Contents of the pack and other information.

1. What SUDAFED® SINUS PAIN is and what it is used for

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SUDAFED® SINUS PAIN contains an analgesic (paracetamol) and a decongestant (pseudoephedrine).

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

SUDAFED® SINUS PAIN is used to help relieve the symptoms of a blocked nose or sinuses and helps to relieve pain (including sinus pain) and fever, caused by colds and flu.

2. What you need to know before you take SUDAFED® SINUS PAIN

Do not take SUDAFED® SINUS PAIN

- If you are hypersensitive (allergic) to paracetamol, pseudoephedrine or any of other ingredients in SUDAFED® SINUS PAIN.
- If you are taking or have taken monoamine oxidase inhibitors (MAOI) for depression within the last 2 weeks.
- If you are taking furazolidone.
- If you have severe liver disease.

Safety in pregnancy and during breastfeeding has not been established

Warnings and precautions

Take special care with SUDAFED® SINUS PAIN

- SUDAFED® SINUS PAIN 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.

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- Do not use SUDAFED® SINUS PAIN 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 SUDAFED® SINUS PAIN to children under 12 years of age.

Other medicines and SUDAFED® SINUS PAIN

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 SUDAFED® SINUS PAIN if you are taking or using:

- Sympathomimetic medicines (stimulants or appetite suppressants and medicines used to treat congestion).
- Antihypertensives (medicines for high blood pressure including alpha and beta blockers).
- Monoamine oxidase inhibitors, moclobemide or antidepressants (to treat mood disorders), antipsychotics (medicines used to treat mood disorders) and inhalation anaesthetics (for general surgery).
- Medicines to treat or heart disorders.
- Anticoagulants (medicines that prevent blood clots, such as warfarin).
- Anticonvulsants (medicines used to treat epilepsy).

Do not take SUDAFED® SINUS PAIN with other medicines containing paracetamol or pseudoephedrine or medicines that have similar acting components.

If you are not sure about any of the medicines you are taking, show the pack to your pharmacist

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or healthcare professional for advice.

SUDAFED® SINUS PAIN with food, drink and alcohol

Do not take SUDAFED® SINUS PAIN 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

It is not known if SUDAFED® SINUS PAIN has an effect on the ability to drive or operate machinery.

3. How to take SUDAFED® SINUS PAIN

DO NOT TAKE MORE THAN THE RECOMMENDED DOSE.

Adults and children over 12 years: One tablet orally three times daily.

Children under 12 years: Not recommended.

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

If you take more SUDAFED® SINUS PAIN than you should

Overdose may lead to liver damage.

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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 SUDAFED® SINUS PAIN and the leaflet so that the doctor can easily tell what medicine you have taken.

If you forget to take SUDAFED® SINUS PAIN

If you forget to take a dose, take it as soon as you remember provided the last dose was at least 8 hours ago.

If it is almost time for your next dose, skip the missed dose and take SUDAFED® SINUS PAIN at the next scheduled time.

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

4. Possible side effects

SUDAFED® SINUS PAIN can have side effects.

Not all side effects reported for SUDAFED® SINUS PAIN are included in this leaflet.

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

If any of the following happens, stop taking SUDAFED® SINUS PAIN 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 SUDAFED® SINUS PAIN. You may need urgent medical attention or hospitalisation.

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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 have been observed less frequently.
- Hallucinations (seeing or hearing things that are not there) and paranoid delusions.

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:

- Headache.
- Restlessness and sleep disturbances.
- Irritability, anxiety, feeling of fear, confusion, excitation.
- Involuntary shaking of one or more parts of your body (tremor).
- An increased heartbeat, an increased awareness of the heartbeat (palpitations), high blood pressure.
- Low blood pressure with dizziness, fainting.
- Flushing.
- Difficulty in passing urine.
- A general feeling of weakness.
- Nausea and vomiting.
- Diarrhoea.
- Loss of appetite.
- Increased saliva or sweating.
- The inability to empty the bladder completely or partially (urinary retention).
- Rash, hives, itching, severe skin reaction.
- Mood changes.

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- Blood disorders or changes in your blood glucose levels.

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 SUDAFED® SINUS PAIN.

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

5. How to store SUDAFED® SINUS PAIN

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from light.
- Keep dry.
- 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 SUDAFED® SINUS PAIN contains

The active substances are 60 mg pseudoephedrine hydrochloride and 500 mg paracetamol.

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

What SUDAFED® SINUS PAIN looks like and contents of the pack

SUDAFED® SINUS PAIN is a white, elongated tablet with flat-bevelled edges, having a score on the one side.

SUDAFED® SINUS PAIN is available in PVC/PVDC / aluminium_blisters packs of 10 tablets.

Holder of certificate of registration

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South Africa

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