1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

SINUGESIC 30 mg/ 500 mg tablets

Pseudoephedrine and paracetamol

Sugar free

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

SINUGESIC is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use SINUGESIC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SINUGESIC with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

1. What SINUGESIC is and what it is used for
2. What you need to know before you take SINUGESIC
3. How to take SINUGESIC
4. Possible side effects
5. How to store SINUGESIC
6. Contents of the pack and other information

1. What SINUGESIC is and what it is used for

SINUGESIC is used to relieve the symptoms of cold and flu including nasal congestion, and headaches. It contains pseudoephedrine hydrochloride that relieves nasal congestion and paracetamol for pain and fever.

2. What you need to know before you take SINUGESIC

Do not take SINUGESIC:

- if you are hypersensitive (allergic) to paracetamol or pseudoephedrine hydrochloride or any of the other ingredients of SINUGESIC (listed in section 6).
- if you are taking medication used to treat depression known as monoamine oxidase inhibitors or within 14 days of stopping the medication.
- if you suffer from a tendency to be easily and excessively excited (hyperexcitability).
- if you have been diagnosed with a tumour of the adrenal gland (phaeochromocytoma).
- if you suffer from severe liver disease.
- if you are pregnant or breastfeeding.
- if you suffer from severe kidney disease and/or failure.
- if you suffer from any heart disease including high blood pressure.
- if you suffer from diabetes.
- if you have been told that you have an overactive thyroid gland (hyperthyroidism).
- if you have been told that you have increased pressure in your eye/s or glaucoma.
- if you are already taking other medicine to decongest (open) your nose.
- if you are already taking beta-blockers due to high blood pressure or increased heart rate (see Other medicines and SINUGESIC).
- if your child is younger than 6 years of age.

Warnings and precautions

SINUGESIC contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

Special care should be taken with SINUGESIC:

- if you take doses in excess of those recommended, SINUGESIC may cause severe liver damage.
- if you develop any skin reaction, SINUGESIC should be stopped (see Possible side effects).
- if you develop hallucinations (seeing or hearing things that are not really there), restlessness or sleep disturbances, SINUGESIC should be stopped (see section Possible side effects).
- if you experience sudden stomach-ache, or rectal bleeding, you should seek medical advice (ischaemic colitis) (see section Possible side effects).
- if you experience sudden loss of vision or a decrease in your ability to distinguish shapes and details of objects at a given distance (ischaemic optic neuropathy) (see section Possible side effects).
- if you experience sudden, severe headache or thunderclap headache, feeling sick, being sick, confusion, fits or visual disturbances, SINUGESIC should be stopped, and medical attention should be sought (posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)) (see section Possible side effects).
- if you are taking/receiving flucloxacillin (to treat a bacterial infection) together with SINUGESIC (see Other medicines and SINUGESIC).

- do not use SINUGESIC for longer than 10 days as you are at risk of developing tolerance (it means the medicine does not have the same effect at the recommended dose and interval) and consequently an increased risk for overdose exists (see section How to take SINUGESIC).
- if you have been told that you have a glucose-6-phosphate dehydrogenase deficiency, you are at risk of haemolysis (a condition where the red blood cells are destroyed).
- if you do not find relief at the recommended dose, please consult your doctor.
- if you are taking medicine for high blood pressure as SINUGESIC may increase your blood pressure.
- if you suffer from prostate problems, SINUGESIC may increase problems with passing of urine.
- if you consume an excess of alcohol on a regular basis.
- if you are already taking paracetamol in other medicine.

Children

SINUGESIC should not be given to children under 6 years.

Other medicines and SINUGESIC

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Monoaminoxidase inhibitors e.g., moclobemide used to treat low mood (depression) as SINUGESIC may increase the blood pressure to dangerous levels.
- Medicine to treat high blood pressure including guanethidine and beta-blockers. SINUGESIC increases blood pressure. The effects of pseudoephedrine, as contained in SINUGESIC, are diminished by guanethidine, reserpine and methyldopa.

- Cardiac glycosides e.g., digoxin or quinidine (to treat an irregular heartbeat). SINUGESIC increases the risk of irregular heartbeat.
- Tricyclic antidepressants e.g., amitriptyline, imipramine to improve low mood (depression). SINUGESIC increases the risk of irregular heartbeat. The effects of pseudoephedrine, as contained in SINUGESIC, may also be diminished or enhanced.
- Ergot alkaloids e.g., ergotamine found in migraine preparations, as the combination can influence your blood pressure.
- A combination with alpha-adrenoceptor blockers, such as phenoxybenzamine (used in the treatment of hypertension and sweating in phaeochromocytoma) and phentolamine (to restore sensation where an anaesthetic was used), may result in both low blood pressure and increased heart rate.
- Pseudoephedrine hydrochloride should be avoided or used with extreme caution in patients undergoing anaesthesia with cyclopropane, halothane, or other halogenated anaesthetics, as they may induce ventricular fibrillation.
- SINUGESIC may decrease the levels of potassium in the body when used at the same time as corticosteroids (anti-inflammatory medicine), potassium-depleting water tablets (to treat high blood pressure), aminophylline and theophylline (to treat inflammation in the chest).
- Medicine used to suppress appetite and amphetamine-like medicine (used for example to treat attention deficit disorder) may lead to high blood pressure.
- Using SINUGESIC with other medicine that cause decongestion may lead to high blood pressure.
- Metoclopramide (used for feeling or being sick) can increase the rate at which the paracetamol, as contained in SINUGESIC, is absorbed.
- Probenecid (used for gout) can affect the levels of paracetamol, as contained in SINUGESIC, in the blood.

- Colestyramine (used for high fats in the blood) may reduce the absorption of paracetamol, as contained in SINUGESIC, if given within one hour of each other.
- Anticonvulsants (used to treat fits) and oral contraceptives (to prevent pregnancy) may decrease the levels of paracetamol, as contained in SINUGESIC.
- Alcohol may prevent the liver to get rid of the paracetamol, as contained in SINUGESIC.
- When SINUGESIC is used long term, it can enhance the effects of anticoagulants (medicines used to prevent blood clotting) which makes bleeding more likely.
- Using SINUGESIC with non-steroidal anti-inflammatory medicine may increase the risk of unwanted effects on the kidney/s.
- Paracetamol, as contained in SINUGESIC, should be taken very carefully with flucloxacillin (to treat infections) as it can lead to a build-up of acid in the body with tiredness and confusion.

Pregnancy, breastfeeding and fertility

You should not take SINUGESIC if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machines

Since adverse reactions such as headaches, dizziness and tremors have been reported in patients taking SINUGESIC, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that SINUGESIC does not adversely affect your ability to do so.

It is not always possible to predict to what extent SINUGESIC may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which SINUGESIC affects you (see section 4).

3. How to take SINUGESIC

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

Always take SINUGESIC exactly as described in this leaflet or as your doctor or pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose of SINUGESIC for adults and children over 12 years is one to two tablets every four to six hours.

Do not exceed eight tablets in 24 hours.

The usual dose of SINUGESIC for children 6 to 12 years is half to one tablet every six hours.

Do not exceed four tablets in 24 hours.

Do not use continuously for longer than 10 days without consulting your doctor.

Not recommended for children under 6 years.

If you take more SINUGESIC than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of pseudoephedrine hydrochloride overdosage include seeing, hearing or believing things that are not real (paranoid psychosis, delusions and hallucinations).

Symptoms of paracetamol overdosage in the first 24 hours are pallor, feeling sick (nausea), being sick (vomiting), lack of appetite (anorexia), feeling tired (lethargy), sweating and stomach (abdominal) pain.

If you forget to take SINUGESIC

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

4. Possible side effects

SINUGESIC can have side effects.

Not all side effects reported for SINUGESIC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SINUGESIC, please consult your healthcare provider for advice.

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), fixed drug eruptions (FDE) and Drug-induced hypersensitivity syndrome (DIHS) or toxic epidermal necrolysis (TEN).

These are all very serious side effects. If you have them, you may have had a serious reaction to SINUGESIC. 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:

- If you experience fever, chills, weakness, sore throat, sores in the mouth or throat, bleeding gums, bone pain, low blood pressure, fast heartbeat, and trouble breathing, you may have too little of a certain blood component that fights infection (agranulocytosis, neutropenia, leucopoenia, pancytopenia). This would be evident on laboratory results,
- if you bruise easily, experience bleeding from the nose, gums, this could be due to a lack of platelets in your blood which are needed for blood clotting (thrombocytopenia),
- if you feel abnormal, out of it (psychotic states), or you see or hear things that are not there (hallucination),
- if you experience recurrent sudden onset and severe (thunderclap) headaches over 1 to 3 weeks with possibly being or feeling sick, sensitivity to light, confusion and blurred vision, you may be experiencing reversible cerebral vasoconstriction (RCVS),
- if you experience headaches, fits, altered consciousness and visual disturbances, it could be due to posterior reversible encephalopathy syndrome (PRES),
- if you notice you heart is beating irregularly (cardiac dysrhythmias),
- if you get chest pain (anginal pain) that feels like pressure, tightness, pain or squeezing or aching or pain that spreads to your shoulder, arm, back, neck, jaw could be signs of a heart attack (cardiac arrest),
- severe stomach pain that spreads to your back or chest, feeling sore, swollen or tender in the upper part of your abdomen, may be signs of inflammation of the pancreas (pancreatitis),
- injury of the large intestine due to a lack of blood flow leading to abdominal pain and bloody stools (ischaemic colitis),

- breathing problems, or extreme shortness of breath, irregular heartbeat could be signs of fluid build-up in the lungs (pulmonary oedema),
- breathing problems (dyspnoea),
- sudden or severe headache, weakness, tingling or numbness in the arms or legs (often on one side), nausea or vomiting, dizziness, confusion, difficulty speaking or understanding speech and/or loss of movement on the side of the body opposite of the head injury could be signs of a brain bleed (cerebral haemorrhage),
- difficulty in passing urine (urinary retention),
- sudden, rapid loss of vision that is painless could be due to a loss of blood supply to the eye (ischemic optic neuropathy).

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:

- Headache.

Less frequent side effects:

- Increase in blood sugar (hyperglycaemia),
- dizziness,
- dry mouth,
- coldness of hands and feet.

Side effects with an unknown frequency:

- Changes in your metabolism including changes in blood sugar levels,
- feeling restless, fearful or anxious,
- sleeping problems including sleeplessness,

- feeling very excited (excitability), or irritated (irritability),
- shaking (tremor),
- feeling confused,
- your heart beats faster (palpitations, tachycardia) or slower (bradycardia),
- high blood pressure (hypertension),
- low blood pressure (hypotension) with dizziness, fainting and flushing,
- increase in the amount of saliva in your mouth (hypersalivation), reduced appetite or lack thereof (anorexia), feeling sick (nausea) and vomiting,
- sweating,
- weakness.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of SINUGESIC.

5. How to store SINUGESIC

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep well closed and protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use 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 SINUGESIC contains

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

The other ingredients are colloidal anhydrous silica, crospovidone, magnesium stearate, povidone K30, purified talc, quinolene yellow (C.I. 47005).

Sugar free

What SINUGESIC looks like and contents of the pack

SINUGESIC is a round, yellow, convex tablet with a break line on one side.

20 or 100 tablets are packed in a white low density polyethylene container with a white low density polyethylene cap, together with a leaflet.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

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Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

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

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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