

Approved Patient Information Leaflet for Medicines for Human Use

SCHEDULING STATUS: S2

SINUCON 200 mg/6 mg/ 20 mg/2 mg tablets

Paracetamol, ephedrine hydrochloride, caffeine and chlorpheniramine maleate

Contains sugar: lactose 148,00 mg

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share SINUCON with any other person.
- Ask your health care 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 SINUCON is and what it is used for
2. What you need to know before you take SINUCON
3. How to take SINUCON
4. Possible side effects
5. How to store SINUCON
6. Contents of the pack and other information

1. What SINUCON is and what it is used for

Shanur Healthcare (Pty) Ltd, G979 (Act 101 of 1965), Sinucon Tablets, Paracetamol 200 mg, Ephedrine hydrochloride 6 mg, Caffeine 20 mg, Chlorpheniramine maleate 2 mg

SINUCON contains the active substances paracetamol (which relieves pain and reduces fever), ephedrine hydrochloride (a decongestant to relieve nasal congestion), caffeine (a stimulant to help combat the tiredness associated with a cold) and chlorpheniramine maleate (which is an antihistamine).

SINUCON is used for relief of symptoms associated with colds, influenza and hay fever such as nasal congestion, sniffing and headache.

2. What you need to know before you take SINUCON

Do not take SINUCON

- if you are hypersensitive (allergic) to paracetamol, ephedrine hydrochloride, caffeine or chlorpheniramine maleate or to any of the other ingredients of SINUCON (listed in section 6).
- if you have severe liver problems
- if you are also taking a monoamine oxidase inhibitor (treatment for depression), or if you stopped this treatment less than 14 days ago
- if you suffer from hyper-exitability
- if you have a tumour of the adrenal gland (phaeochromocytoma)
- if you are having an asthma attack.

Warnings and precautions

In the event of overdose or suspected overdose and even if you feel well and have no symptoms, contact the nearest doctor, hospital or Poison Centre immediately.

Take special care with SINUCON

- if you have kidney or liver problems, including alcoholic liver disease

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- if you suffer from alcohol dependence
- if you are taking other medicines which affect the liver such as medicines for depression (mono amine oxidase inhibitors or tricyclic antidepressants) or barbiturates (sleeping tablets)
- if you have haemolytic anaemia (abnormal breakdown of red blood cells)
- if you are suffering from dehydration or chronic malnutrition
- if you suffer from genetic conditions such as glucose-6-phosphate dehydrogenase deficiency (an enzyme deficiency) or Gilbert's syndrome
- if you have a glutathione deficiency
- if you have a problem with your blood circulation (e.g. Reynaud's Syndrome)
- if you are an asthmatic and sensitive to aspirin
- if you have a heart disease, angina, problems with your heart beat or severe hypertension
- if you have bronchitis, or any chronic lung condition
- if you have glaucoma (a disease in which the pressure inside the eyeball is too high)
- if you have hyperthyroidism (over active thyroid gland)
- if you suffer from diabetes
- if you have prostate enlargement
- if you have ever had stomach ulcers or excessive acid in your stomach
- if you have uncontrolled seizures (fits)
- serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), have been reported in patients receiving paracetamol. If you experience any signs of serious skin reactions such as swelling, itching, red severe rash, stop using SINUCON immediately and contact your doctor

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- Avoid drinking alcohol or taking any other medicines which may make you drowsy (such as medicines for pain or medicines to help you sleep) together with SINUCON, as you may feel excessively sleepy
- avoid taking other medicines which have paracetamol or antihistamines in them with SINUCON – this may lead to an overdose of paracetamol or antihistamines
- Avoid taking excessive amounts of caffeine (e.g., coffee, tea, and some canned drinks) while taking SINUCON.

Paracetamol as contained in SINUCON, may interfere with some uric and blood sugar tests. Chlorpheniramine maleate, as contained in SINUCON, may suppress positive skin test results and should be stopped several days before the test.

Children

Do not give SINUCON to children below the age of 12 years.

Other medicines and SINUCON

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

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This is particularly important if you are taking:

- monoamine oxidase inhibitors (MAOIs) or tricyclic antidepressant medicines (medicines for depression)
- barbiturates (sleeping tablets) or other medicines which are given as sleeping or calming tablets (sedatives and tranquilisers), or medicines which are used to treat severe pain such as opioids (narcotic analgesics)
- colestyramine (to lower blood cholesterol)
- metoclopramide or domperidone (to treat nausea and vomiting)

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- warfarin or other medicines which thin the blood
- aspirin (a pain reliever)
- rifampicin and isoniazid (to treat tuberculosis (TB))
- probenecid (to treat gout).
- flucloxacillin (an antibiotic)
- medicines for epilepsy such as phenytoin, lamotrigine, and carbamazepine
- sympathomimetic medicines (stimulants or appetite suppressants and medicines used to treat congestion and asthma)
- anaesthetics (used during surgery)
- medicines to treat hypertension such as atenolol, or alpha-methyl dopa
- ergot alkaloids (medicines to treat severe headaches)
- medicines to treat irregular heartbeats such as digoxin or quinidine
- corticosteroids such as dexamethasone (medicine used for inflammation especially in asthmatic patients)
- oxytocin (medicine used during childbirth)
- urinary acidifiers or alkalinisers
- lithium (used to treat depression or bipolar disorder)

SINUCON with food, drink and alcohol

Alcohol should be avoided when taking SINUCON.

Excessive intake of caffeine containing products (e.g., coffee, tea, and some canned drinks) should be avoided while taking SINUCON.

Pregnancy, breastfeeding and fertility

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 health care provider for advice before taking SINUCON.

Driving and using machines

SINUCON may lead to drowsiness and impaired concentration. These effects may be worsened by taking alcohol or other central nervous system depressants at the same time. Do not to drive a motor vehicle, operate dangerous machinery or climb dangerous heights, as impaired decisions could lead to accidents. Do not engage in the above activities until you are aware of the measure to which SINUCON affects you.

SINUCON contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking SINUCON.

3. How to take SINUCON

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

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

The usual dose is

Adults: Two tablets every four hours.

DO NOT EXCEED THE RECOMMENDED DOSE.

Duration of administration

Do not use SINUCON continuously for longer than 10 days without medical supervision.

Talk to your doctor if no relief is obtained with the recommended dosage, the symptoms persist longer than 10 days, worsen or recur periodically.

Method of administration

Take the tablets with a sufficient quantity of liquid (e.g. one glass of water).

If you take more SINUCON than you should

Prompt treatment is essential.

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

SINUCON contains paracetamol, which can cause delayed, serious liver damage. A delay in starting treatment may mean that antidote is given too late to be effective. Seek medical help even if you do not experience any symptoms and you feel well.

Symptoms of overdose include nausea, vomiting, thirst, loss of appetite, stomach pain, drowsiness, convulsions (fits), palpitations, increased heart rate, difficulty breathing, delusions or hallucinations, coma and death.

If you forget to take SINUCON

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

4. Possible side effects

SINUCON can have side effects.

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

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

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- 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, peeling or ulceration of the skin, mouth, eyes and genitals with or without fever as these may be due to a serious reaction known as Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis, Drug Rash with Eosinophilia and Systemic Symptoms (DRESS)/Drug-induced hypersensitivity syndrome (DIHS) or Acute Generalised Exanthematous Pustulosis (AGEP).

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

- tightness or pain in the chest, neck, back or arms, as well as fatigue, light-headedness, abnormal heartbeat and anxiety (myocardial infarction / heart attack)
- numbness or weakness in part of the face or body, difficulty speaking or difficulty walking or other signs of a stroke (cerebral haemorrhage)
- coughing, wheezing, difficulty catching a breath (bronchospasm), especially in asthmatics
- changes in the way your heart beats, for example, if you notice it beating faster, palpitations, slower or faster pulse
- cough, chest pain, fatigue (pulmonary oedema)
- abnormal laboratory results for white blood cell counts (neutropenia, leucopenia, agranulocytosis and eosinophilia) which may be associated with symptoms such as, but not limited to, high temperature, chills, sore throat, mouth sores, tiredness, flu-like symptoms.

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- tiredness, weakness, shortness of breath, irregular heartbeat, dizziness or light-headedness, chest pain and cold hands and feet could be a sign that your body is not producing enough new blood cells (aplastic anaemia).
- easy bruising, including abnormal bleeding from nose and/or gums, the presence of blood in the urine or stool and cuts that continue bleeding could be due to a low platelet count (thrombocytopenia, pancytopenia)
- convulsions (fits)
- upper abdominal pain, nausea and vomiting, fat in stool, fast heart rate and sweating could be signs that there is inflammation in the pancreas (pancreatitis)
- your skin and/or eyes become yellow, with possible nausea, abdominal pain, fatigue and fever as these could be signs that your liver is inflamed (hepatitis) or that your liver is not working (liver failure).
- your urine output is possibly decreased or increased, and you retain fluid that causes swelling in your legs, ankles or feet could be a problem with your kidneys (renal failure or nephropathy).
- sharp intense pain around the abdominal area (renal colic)
- confusion, seeing or hearing things that are not really there (hallucinations), difficulty telling reality from fantasy (psychotic states)
- bleeding in the gut (haemorrhage)
- if you feel that you have to take more to achieve the effect you get with this medicine and/ or you are taking this medicine without a medical reason (tolerance with dependence).

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:

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- feeling extremely sleepy, falling off to sleep, disturbance in concentrating, un-coordinated movements, feeling dizzy, physical or mental weakness (lassitude), extreme tiredness (fatigue)
- headache
- blurred vision
- nausea (feeling sick), dry mouth
- feeling anxious, restless
- insomnia (inability to sleep).

Less frequent side effects:

- low blood sugar levels: you may feel dizzy, confused or have heart palpitations
- feeling depressed (low mood) or confused, uneasiness or discomfort (malaise), fear
- muscle cramps, tremors (shaking or trembling movements)
- abnormal vision
- abnormal swelling of the body due to fluid retention (oedema)
- diarrhoea, vomiting, pain in the stomach
- rash with redness or raised, itchy skin, hives, sweating, swelling of the skin
- increase in body temperature (fever)
- low or high blood pressure (may feel dizzy or faint)
- purple or brownish-red spots on the skin or mucous membranes (purpura)
- redness of the face (flushing)
- decrease of appetite
- large amount of white blood cells in urine (seen on a urine test)

Side effects with frequency unknown:

- loss of appetite or increased appetite
- ringing in the ears (tinnitus)

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- indigestion, increased gastric reflux (heartburn), increased stomach secretions which may cause ulcers, hypersalivation, thirst
- miosis (constriction of the pupil of the eye)
- skin is very sensitive to light (photosensitivity)
- pain or difficulty urinating,
- tingling or pricking of the skin ('pins and needles') (paraesthesia)
- chest tightness
- feeling excited
- feeling nervous, restless, or tense (anxiety), feeling frustrated or angry over small matters (irritability), having nightmares
- muscle twitching and weakness
- shortness of breath (dyspnoea), tight chest and thick mucus (phlegm) from lungs
- a spot or flickering near the centre of your vision that prevents you from seeing (scintillating scotoma)
- swelling of the larynx
- fixed drug eruption (a rash which occurs in the same place each time the medicine is taken).

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 or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of SINUCON.

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Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za

5. How to store SINUCON

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light/moisture.

Do not store in a bathroom.

Do not use after the expiry date stated on the label/carton/bottle.

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 SINUCON contains

- The active substances are paracetamol 200 mg, ephedrine hydrochloride 6 mg, caffeine 20 mg and chlorpheniramine maleate 2 mg.
- The other ingredients are maize starch, lactose, gelatin, Carmoisine Red (CI 14720), Green S (CI 44090), magnesium stearate, talc, sodium starch glycollate.

What SINUCON looks like and contents of the pack

SINUCON 200 mg/6 mg/ 20 mg/2 mg tablets

Round, biconvex, red and blue mottled tablets, plain on both sides, 11,10 mm in diameter.

SINUCON is supplied in containers of 20 tablets.

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Holder of Certificate of Registration

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Access to the corresponding Professional Information

Professional Information and Afrikaans Patient Information Leaflet for this medicine is available on the following URL:

<https://shanur.co.za/product-info/>

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