1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

SINUCLEAR 18 mg/325 mg capsules

Phenylpropanolamine hydrochloride, paracetamol

Sugar free

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share SINUCLEAR 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 7 days.

What is in this leaflet

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

1. What SINUCLEAR is and what it is used for

SINUCLEAR is used for the temporary relief of nasal sinus and eustachian tube congestion (middle ear) associated with pain and fever due to colds and influenza.

2. What you need to know before you take SINUCLEAR

Do not take SINUCLEAR:

- if you are hypersensitive (allergic) to phenylpropanolamine hydrochloride, paracetamol or any of the other ingredients of SINUCLEAR (listed in section 6).
- if you have experience sleeplessness, dizziness, light-headedness, weakness, involuntary muscle movements (tremulousness) or irregular heartbeat (cardiac dysrhythmia) when taking small doses of medicines that stimulate the nervous system.
- If you are receiving antidepressant treatment, (monoamine oxidase inhibitor antidepressant) or if you stopped this treatment less than 14 days ago.
- if you have a heart disease and/ or suffer from high blood pressure.
- If you have overproduction of thyroid hormones (hyperthyroidism).
- If you have spontaneous and continuous muscle overactivity (hyperexcitability).
- If you have a tumour of the adrenal glands (phaeochromocytoma).
- If you have glaucoma (increased eye pressure).
- If you are pregnant or breastfeeding.

SINUCLEAR is not suitable for children younger than 6 years old.

Warnings and precautions

Take special care with SINUCLEAR:

SINUCLEAR 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.

- Do not use SINUCLEAR continuously for more than 7 days without consulting your doctor.
- If you take more than the recommended dose you may develop severe liver damage.
- SINUCLEAR may cause severe high blood pressure leading to bleeding in the brain or stroke. Speak to your doctor if you notice severe headaches, nosebleeds, tiredness, confusion, changes in the way you see, chest pain, difficulty breathing or an abnormal heartbeat. These may be signs of high blood pressure.
- If you have a heart disease, high blood pressure or your thyroid gland produces excessive hormones (hyperthyroidism). Signs of hyperthyroidism may be nervousness, irritability, mood swings, difficulty sleeping, persistent tiredness, weakness, sensitivity to heat.

- SINUCLEAR may worsen conditions such as diabetes, glaucoma (increased pressure in the eye) or an enlarged prostate. If you have an enlarged prostate, you may experience difficulty in passing urine.
- SINUCLEAR may cause severe skin reactions, if you experience skin reddening, blisters or rash stop taking SINUCLEAR and seek immediate medical assistance.

Children and adolescents

SINUCLEAR is not recommended for use in children under the age of 6 years.

Other medicines and SINUCLEAR

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:

- Monoamine oxidase inhibitors (MAOIs) (e.g. moclobemide): medicines used to treat depression. Tell your doctor if you are currently taking MAOIs or have taken MAOIs in the past 14 days (see section Do not take SINUCLEAR).
- Bromocriptine: medicine used to treat high levels of a natural substance called prolactin in the body.
- Anaesthetics: medicines used to make you feel numb before a surgical procedure.
- Colestyramine: medicine used to treat high cholesterol levels in the blood.
- Metoclopramide and domperidone: medicines used to treat nausea or vomiting.
- Anticoagulants *(*e.g. warfarin and other coumarins): medicines used to treat blood clots.
- Chloramphenicol: an antibiotic used to treat eye infections.
- Amantadine: medicine used to treat movement disorders.
- Antiviral medicines such as zidovudine, indinavir and lamivudine used to treat HIV.
- NSAIDs (non-steroidal anti-inflammatory drugs): medicines used to treat pain and inflammation in the body (e.g. indomethacin, ibuprofen, aspirin).

- Antihypertensive medicine (e.g. guanethidine, reserpine, methyldopa): medicines used to treat high blood pressure.
- Tricyclic antidepressants (e.g. clomipramine or amitriptyline): medicines used to treat depression.

Pregnancy, breastfeeding and fertility

You should not take SINUCLEAR 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

SINUCLEAR may cause giddiness, headache, sweating, muscular weakness and tremors, which can affect your ability to drive and use machinery.

It is not always possible to predict to what extent SINUCLEAR 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 SINUCLEAR affects you (see section 4).

3. How to take SINUCLEAR

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

Always take SINUCLEAR 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 of SINUCLEAR is:

Adults: One capsule every six hours.

Do not exceed five capsules in 24 hours.

DO NOT EXCEED THE RECOMMENDED DOSE.

You should not take SINUCLEAR for longer than 7 days without consulting your doctor.

If you take more SINUCLEAR 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.

If you forget to take SINUCLEAR

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

If you have missed a dose of SINUCLEAR, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take several doses, contact your doctor without delay.

4. Possible side effects

SINUCLEAR can have side effects.

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

If any of the following happens, stop taking SINUCLEAR 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.

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

- Difficulty breathing (dyspnoea),
- neutropenia (abnormally low concentration of neutrophils in the blood), pancytopenia is a medical condition in which there is a reduction in
  the number of red and white blood cells, as well as platelets), leukopenia (a decrease in the number of white blood cells),
- thrombocytopenia, a deficiency of platelets in the blood,
- purpura, a rash of purple spots on the skin caused by internal bleeding from small blood vessels,
- there may also be an increase or decrease in heart rate in response to the body's reflex mechanism to maintain balance for preventing abnormal increases in blood pressure (tachycardia, palpitations, ventricular dysrhythmias),
- low blood pressure with dizziness, fainting and flushing may occur,
- stroke caused by the rupture of a blood vessel in or on the surface of the brain with bleeding into the surrounding tissue (intracranial haemorrhage),
- constriction of blood vessels which increases blood pressure that may cause stroke or excess fluid in the lung,
- chest pain (precordial pain),
- difficulty or inability to pass urine (urinary retention, difficulty in micturition).

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

Tell your doctor if you notice any of the following:

Side effects with an unknown frequency:

- Sweating, fever
- methaemoglobinaemia, a blood disorder in which an abnormal amount of methaemoglobin is produced. agranulocytosis, a medical condition where there are very few granulocytes (a kind of white blood cell) in the blood,
- difficulty controlling blood sugar levels (altered metabolism including disturbances of glucose metabolism), reduced appetite,
- delusions or hallucinations, (psychotic state, alteration of mental status), confusion,
- difficulty falling off to sleep (insomnia), restlessness,
- a feeling of worry, nervousness, or unease (anxiety agitation), irritability,
- headache, feeling unbalanced or lightheaded (giddiness),
- blurred vision,
- a constant nasal stuffiness (rebound congestion),
- nausea, vomiting,
- large amounts of saliva in the mouth (hypersalivation),
- muscular weakness,
- thirst, 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: https://www.sahpra.org.za/health-products-vigilance/

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 SINUCLEAR.

5. How to store SINUCLEAR

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep the blister in the carton 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 SINUCLEAR contains

The active substance is 18 mg of phenylpropanolamine hydrochloride and 325 mg of paracetamol.

The other ingredients are gelatin capsule, magnesium stearate, sodium lauryl sulphate.

Sugar free

What SINUCLEAR looks like and contents of the pack

SINUCLEAR is a standard yellow opaque and blue transparent hard gelatin capsule, imprinted in white “Sinuclear” on the cap and body. Each capsule contains a fine, white, free-flowing powder.

Packs of 12 and 16 capsules in a clear polyvinyl chloride (PVC) blister strip sealed with aluminium foil. The strip is packed in an outer cardboard carton together with a leaflet.
Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

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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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