PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S2**

SINUSTAT CAPSULE

Paracetamol

Penylpropanolamine hydrochloride

Sugar free

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

- **SINUSTAT** is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **SINUSTAT** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **SINUSTAT** with any other person.
- Ask your 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 **SINUSTAT** is and what it is used for
2. What you need to know before you take **SINUSTAT**
3. How to take **SINUSTAT**
4. Possible side effects
5. How to store **SINUSTAT**
6. Contents of the pack and other information

1. What SINUSTAT is and what is it used

The active substances are 18 mg phenylpropanolamine hydrochloride and 325 mg paracetamol.

Temporary relief of nasal, sinus and eustachian tube mucal congestion and associated pain and fever due to colds and influenza.

2. What you need to know before you take SINUSTAT

Do not take SINUSTAT:

- if you are hypersensitive (allergic) to phenylpropanolamine hydrochloride or paracetamol or any of the other ingredients of **SINUSTAT** (see **WHAT SINUSTAT CONTAINS**).
- if you experienced sleeplessness, dizziness, light-headedness, weakness, hyperexcitability, tremulousness or changes in heart rhythms when taking other medicines.
- if you have high blood pressure or heart disease.
- if you are taking, or have taken in the last two weeks, medicines for depression known as monoamine oxidase Inhibitors (MAOIs).
- if you have an overactive thyroid gland.
- if you have glaucoma (increased pressure in the eye).
- if the child is less than 6 years old

Warnings and precautions

Take special care with SINUSTAT:

- if you have any kidney or liver problems.
- If you suffer from mild arthritis and need to take painkillers every day
- if you have difficulty urinating;
- if you are taking medications which have the ability to cause the loss of sensation (anaesthetics);

- if you have diabetes.
- If you have difficulty urinating

Children and adolescents:

Do not give **SINUSTAT** to children under 6 years of age.

Where indicated in children do not give **SINUSTAT** for more than 5 days for pain or more than 3 days for fever, without contacting your doctor.

Other medicines with SINUSTAT

Taking other medicines with SINUSTAT:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines)

SINUSTAT might have interactions with the following medicines:

- Antihypertensives (medicines used to treat high blood pressure such as guanethidine, reserpine and methyldopa)
- Tricyclic antidepressants (used to treat mood disorders)
- Monoaminoxidase inhibitors (MAOIs) (used to treat depression).
- Chloroform, cyclopropane, halothane or other halogenated anaesthetics
- Metoclopramide or domperidone (for treating nausea and/or vomiting).
- Probenecid (to increase uric acid excretion in the urine).
- Colestyramine (to reduce blood fat levels).
- Aspirin (for treating pain, inflammation and fever).
- Warfarin and other anti-blood clotting medicine/anticoagulants (for prevention of blood clots).
- Isoniazid (an antibiotic medicine used to treat tuberculosis)

SINUSTAT with food and drink:

The rate or extent of absorption of **SINUSTAT** is not influenced by food.

Pregnancy, breastfeeding and fertility

The safe use of **SINUSTAT** in pregnant women has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Driving and using machines:

SINUSTAT must be used with caution when driving and using machinery, as giddiness, headache, sweating, muscular weakness and tremors may occur during use.

3. How to take SINUSTAT

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

DO NOT EXCEED THE RECOMMENDED DOSE.

The usual dose is:

Adults: One capsule every four hours. Do not exceed five capsules in 24 hours.

Children: 6 – 12 years: One capsule every eight hours. Do not exceed four capsules in 24 hours.

It is not recommended for use in children under six years of age or for more than ten days usage.

Seek medical advice if symptoms persist for more than 10 days.

If you have the impression that the effect of **SINUSTAT** is too strong or too weak, tell your doctor or pharmacist.

If you take more SINUSTAT than you should:

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

Prompt treatment is essential. Seek immediate medical advice in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage**.**

Symptoms of an overdose include feeling or being sick, paleness, loss of appetite, stomach pain or liver damage, rapid pulse and respiration, disorientation, elevated blood pressure, headache, nausea and vomiting.

If you forget to take SINUSTAT:

If you forget to take a dose, take the next dose when needed provided that the last dose was taken at least 4 hours ago. Do not take a double dose.

4. Possible side-effects

SINUSTAT can have side-effects.

Not all side-effects reported for **SINUSTAT** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **SINUSTAT**, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking / using **SINUSTAT** 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 **SINUSTAT** Capsules. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:

The frequency of the side-effects is unknown.

Phenylpropanolamine hydrochloride:

- Giddiness, headache, sweating, muscular weakness, tremors
- Nausea, vomiting, thirst
- Difficulty in passing urine
- Hypertension
- Changes in heartbeat, chest pain
- Anxiety, restlessness, sleeplessness

- mental confusion
- dizziness
- headache
- tremor
- difficulty sleeping (insomnia)
- drowsiness
- muscle weakness

Paracetamol:

- Pinpoint red spots on your skin.
- Fever with or without chills (not present before you started taking **SINUSTAT** or as
- a result of the condition being treated).
- Sores, ulcers, or white spots on your lips or in your mouth.
- Sore throat (not present before you started taking **SINUSTAT** or as a result of the condition being treated).
- Unusual bleeding or bruising.
- Black, tarry stools.
- Blood in your stools or urine.
- Sudden decrease in amount of urine.
- Cloudy urine.
- Unusual tiredness or weakness.
- Severe and sharp pain in lower back and/or side.
- Breathing difficulties (coughing, tightness of chest, shortness of breath, wheezing). These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin.
- Loss of liver function causing yellowed skin and eyes (jaundice) along with stomach pain and swelling.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care provders are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

Acino Pharma (Pty) Ltd: E-mail: drugsafety_za@acino.swiss Tel: 060 998 7896

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

5. How to store SINUSTAT:

Store all medicines out of the reach of children.

Store at or below 25 °C. Do not store **SINUSTAT** in areas of high humidity or temperature (e.g. bathrooms and kitchens).

Do not use after the expiry date stated on the outer carton.

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 SINUSTAT CAPSULES contains

- The active substances are 18 mg phenylpropanolamine hydrochloride and 325 mg paracetamol.
- The other ingredients are magnesium stearate, sodium lauryl sulphate, size 1 standard yellow opaque/ blue transparent hard gelatin capsule.

What SINUSTAT CAPSULES looks like and contents of the pack

Standard yellow opaque and standard blue transparent hard gelatin capsule imprinted **SINUSTAT.**

White polypropylene securitainer, with a white low density polyethylene snap-on-cap with a tear tab containing 100 capsules or aluminium/PVC/PVDC blister of 8 capsules packed in an outer carton with 24 capsules per carton.

Holder of Certificate of Registration

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