PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S2

SINUSTAT FLU CAPSULES

Ascorbic acid

Caffeine anhydrous

Chlorphenamine maleate

Paracetamol

Phenylephrine hydrochloride

Contains sugar: Lactose monohydrate 32, 0 mg

Please read this leaflet carefully before using SINUSTAT FLU CAPSULES

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

1. What SINUSTAT FLU CAPSULES is and what it is used for

SINUSTAT FLU CAPSULES contains 300 mg paracetamol, 75 mg ascorbic acid, 5 mg phenylephrine hydrochloride, 2 mg chlorphenamine maleate and 30 mg caffeine anhydrous.

SINUSTAT FLU CAPSULES are used for the temporary relief of blocked nasal and sinus passages, sniffing, headache or where pain and fever also exists due to colds and flu.

2. **What you need to know before you use SINUSTAT FLU CAPSULES:**

Please read this leaflet before you take **SINUSTAT FLU CAPSULES**. It gives you important information about your capsules. Please keep this leaflet safe. You may want to read it again. If you have any questions or if you are not sure about anything, ask your doctor or pharmacist.

Do not take SINUSTAT FLU CAPSULES:

- If you are allergic (hypersensitive) to paracetamol, ascorbic acid, phenylephrine hydrochloride, chlorphenamine maleate, caffeine anhydrous or to any of the ingredients in **SINUSTAT FLU CAPSULES** (see **WHAT SINUSTAT FLU CAPSULES CONTAINS**).
- Prostatic enlargement, paralytic gut, blockage of the lower stomach
- Closed angle glaucoma (increase of the pressure of the fluid in the eye) or with a narrow angle between the iris and the cornea,
- If you have any heart disorder or high blood pressure.
- If you have an overactive thyroid gland.
- If you suffer from epilepsy (fits/seizures).
- If you have diabetes.
- Phaeochromocytoma (benign tumor that forms in the middle part of the adrenal gland)
- If you have severe kidney or liver impairment.
- If you are pregnant or suspect that you are pregnant.
- If you have been using an antidepressant called a monoamine oxidase inhibitor in the last 10 days.
- Do not give SINUSTAT FLU CAPSULES to children under the age of six years.

Warning and precautions

Take special care with SINUSTAT FLU CAPSULES:

- If you have been taking these capsules for more than 10 days. Consult your doctor.
- If you use other paracetamol products concomitantly. Concomitant use with other medicines containing paracetamol may lead to an overdose.
- If you have liver or kidney disease.
- If you have a stomach ulcer (characterised by blood in your faeces).
- Using **SINUSTAT FLU CAPSULES** for a long period of time may lead to rebound congestion (swelling and enlargement of the nasal passages, which causes a blocked nose). Please see your doctor if symptoms persist.
- If you have a history of peptic ulceration (a small sore on the lining of your stomach, small

intestine or oesophagus).

- If you have problems with your thyroid gland, heart problems or had any heart operation.
- If you have bronchitis or bronchiectasis (coughing up thickened mucus and shortness of breath) and asthma (difficulty breathing, chest pain, cough and wheezing).
- If you are an elderly patient and may sometimes be confused.
- **SINUSTAT FLU CAPSULES** should not be used with other antihistamine containing products, including antihistamine containing cough and cold medicines.
- Severe cutaneous adverse reactions (SCARs) such as toxic epidermal necrolysis (TEN), Steven-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), eosinophilia and systemic (DRESS)/Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) have been reported in patients treated with paracetamol containing medicines. If a patient develops SCAR, treatment with **SINUSTAT FLU CAPSULES** must immediately be discontinued and appropriate treatment instituted.

Other medicines and SINUSTAT FLU CAPSULES

Consult your doctor, pharmacist or healthcare professional for advice if you need to take any other medicines. If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **SINUSTAT FLU CAPSULES** with these medicines may cause undesirable interactions.

Not all medicines that may interact with **SINUSTAT FLU CAPSULES** are included below. Do not take the following medicines in combination with **SINUSTAT FLU CAPSULES**:

- Medicines used to treat epilepsy (e.g. phenytoin, primidone (used for the treatment or prevention of seizures).
- Medicines used to treat nausea (metoclopramide / domperidone).
- Medicines used to reduce cholesterol levels in your blood (cholestyramine).
- Probenecid, used in treating gout.
- Aspirin or other salicylates, used to treat pain.
- Desferrioxamine (medicine used to remove excess iron from the body).
- Levodopa and bromocriptine (used to treat Parkinson's disease).
- Medicines used in the treatment of depression (monoamine oxidase inhibitors or tricyclic antidepressants).
- Medicines used to increase to sensitivity of the heart and to stabilise the rhythm of the heart i.e.

Adenosine (used to treat a rhythm disturbance of the heart).

- Thyroid hormones (used to treat thyroid gland disorders).
- Antihypertensive medicines (to lower high blood pressure) i.e. beta-blockers, (propranolol, timolol) and thiazide diuretics (used to treat high blood pressure).
- Ergot alkaloids (used to treat migraines or very severe headaches).
- Aminophylline or theophylline (used to treat asthma).
- Central nervous system depressants including alcohol, lithium, barbiturates, (used to treat anxiety and depression), hypnotics (used to treat sleeping disorders), opioid analgesics (strong pain killers).
- Adrenergic bronchodilators such as salbutamol (used to treat the symptoms of asthma, chronic bronchitis, emphysema and other lung diseases).
- Cimetidine, omeprazole (used in treating and preventing heartburn from acid indigestion or sour stomach).

SINUSTAT FLU CAPSULES with food or drink:

SINUSTAT FLU CAPSULES may be taken with or without food.

Pregnancy, breastfeeding and fertility:

DO NOT use **SINUSTAT FLU CAPSULES** if you are pregnant or suspect that you are pregnant. DO NOT use **SINUSTAT FLU CAPSULES** if you are breastfeeding your baby.

Driving and using machines:

SINUSTAT FLU CAPSULES may affect your ability to drive and use machinery. Do not drive, operate machinery, nor do anything else that could be dangerous until you know how **SINUSTAT FLU CAPSULES** affects you.

SINUSTAT FLU CAPSULES contains lactose monohydrate Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take **SINUSTAT FLU CAPSULES.**

3. How to take SINUSTAT FLU CAPSULES:

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

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

The usual dose is:

Adults: 2 capsules 3 times daily

Children (6-12 years): 1 capsule 3 times daily.

SINUSTAT FLU CAPSULES are contra-indicated for children under the age of 6 years.

If you have any questions about the proper dose of **SINUSTAT FLU CAPSULES**, ask your doctor.

If you take more SINUSTAT FLU CAPSULES than you should:

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

SINUSTAT FLU CAPSULES 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.

Take this leaflet and any remaining capsules with you, so that the doctor knows what you have taken.

If you forget to take your SINUSTAT FLU CAPSULES:

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at the next regular scheduled time. Do not take a double dose to make up the missed dose.

4. **Possible side effects:**

SINUSTAT FLU CAPSULES may cause side effects.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

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

Tell your doctor if you notice any of the following:

Frequent side effects

- calmness, relaxed feeling, incoordination, sleeplessness, sleepy, involuntary quivering, sudden, violent irregular movement of the body, headache, difficulty to concentrate, inability to coordinate movements, dizziness
- blurred vision
- nausea, dry mouth
- extreme tiredness

Less frequent side effects

- allergic reactions including skin rashes, swelling of deep skin tissue, mucous membranes, or other areas of the body like the lips, eyes, tongue, and genitals, Stevens Johnson syndrome, blisters and peeling of large areas of the skin and mucus membranes.
- redness and scaling of the skin, rash, itch, and sensitivity to sunlight.
- blood or liver disorders.
- bronchospasm in patients sensitive to aspirin and other nonsteroidal anti-inflammatory medicines.

Frequency unknown

- allergic reactions (i.e. rash, hives, which are itchy, raised red welts on the skin), sensitivity of your skin to sunlight, inflammation of the skin, swelling of deep skin tissue, mucous membranes, other areas of the body like the lips, eyes, tongue, and genitals
- renal colic (acute, intense pain in your back or lower stomach area, spreading to your back groin), kidney damage
- difficulty urinating and completely emptying the bladder; pain or a burning sensation when urinating
- pancreatitis (inflammation of your pancreas, characterised by stomach pain, nausea and vomiting)
- fear, anxiety, sleeplessness, confusion, nervousness, irritability, psychotic state, tremor, feeling weak, headache, increased sweating, dizziness excitability, great happiness and exhilaration, depression, nightmares
- irregular fast heartbeat, low blood pressure with dizziness, become red and hot,
- high blood pressure with headache, cerebral bleeding
- dilation of the pupil of the eye, acute angle closure most likely to occur in those with closed angle closure
- anemia, abnormalities in the composition or function of blood

- nausea, vomiting, diarrhoea, constipation, stomach pain, heart burn, pain or discomfort located in the upper abdomen, hypersalivation
- loss in appetite, anorexia
- tinnitus (ringing sound in your ears)
- chest tightness and thickening of bronchial secretions (chronic daily cough, wheezing, shortness of breath)
- inflammation in your liver, including jaundice (yellowing of the skin and eyes, dark urine and tiredness).
- muscle twitching, muscle weakness

When the recommended paracetamol-caffeine dosing regimen is combined with dietary caffeine intake, the resulting higher dose of caffeine may increase the potential for caffeine-related adverse effects such as insomnia, restlessness, anxiety, irritability, headaches, gastrointestinal disturbances and palpitations.

Post marketing experience

Fixed drug eruptions (FDE), drug-induced hypersensitivity syndrome (DIHS)

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

Reporting of side effects

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 providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety App (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. You can also report side effects to Acino Pharma via email on drugsafety_ZA@acino.swiss.

5. How to store SINUSTAT FLU CAPSULES

STORE ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

- Store at or below 25 °C. Protect from light and moisture.
- Do not remove from outer carton until required for use.
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SINUSTAT FLU CAPSULES contains

- The active substances are ascorbic acid, caffeine anhydrous, chlorphenamine maleate, paracetamol and phenylephrine hydrochloride.
- The other ingredients are: Inactive ingredients: Lactose, purified talc, colloidal silicon dioxide. The gelatin shell contains quinoline yellow, brilliant blue and titanium dioxide as colourants.

What SINUSTAT FLU CAPSULES looks like and contents of the pack

Size 0 capsule with an opaque light green cap and opaque white body.

Securitainers of 24 capsules or blister packs containing 20 capsules.

Holder of Certificate of Registration:

Acino Pharma (Pty) Ltd.

106 16th Road

Midrand

1686

This leaflet was last revised in

22 September 2023

Registration number:

27/5.8/0449

Namibia:
Reg. no.: 13/5.8/0236
Scheduling: NS1