## 1.3.2.1. PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS**

**S2**

**SINUCLEAR PAEDIATRIC SYRUP/STROOP**

**Pseudoephedrine hydrochloride 15 mg**

**Triprolidine hydrochloride 0,625 mg**

**Paracetamol 125 mg**

**Contains sugar: Sorbitol 1,018 g**

**Contains sweetener: Saccharin sodium 45 mg**

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

SINUCLEAR PAEDIATRIC SYRUP/STROOP is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use SINUCLEAR PAEDIATRIC SYRUP/STROOP carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SINUCLEAR PAEDIATRIC SYRUP/STROOP 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 SINUCLEAR PAEDIATRIC SYRUP/STROOP is and what it is used for
2. What you need to know before you take/give SINUCLEAR PAEDIATRIC SYRUP/STROOP
3. How to take/give SINUCLEAR PAEDIATRIC SYRUP/STROOP
4. Possible side effects

5. How to store SINUCLEAR PAEDIATRIC SYRUP/STROOP
6. Contents of the pack and other information

## 1. What SINUCLEAR PAEDIATRIC SYRUP/STROOP is and what it is used for

SINUCLEAR PAEDIATRIC SYRUP/STROOP belongs to a group of medicines called sympathomimetics. It contains both a decongestant and an antihistamine. It is used to relieve the symptoms of cold and flu including nasal congestion, sniffing and headaches.

## 2. What you need to know before you take/give SINUCLEAR PAEDIATRIC SYRUP/STROOP

**Do not take/give SINUCLEAR PAEDIATRIC SYRUP/STROOP:**

- If you are hypersensitive (allergic) to pseudoephedrine hydrochloride, triprolidine hydrochloride, paracetamol, or any of the other ingredients of SINUCLEAR PAEDIATRIC SYRUP/STROOP (listed in section 6).
- If you have liver disease.
- If you have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure.
- If you are taking nasal decongestants including sprays or medications known as beta-blockers (used for high blood pressure).
- If you have heart disease or high blood pressure.
- If you have an overactive thyroid gland.
- If you have diabetes (high sugar levels in blood).
- If you have a prostate disorder.
- If you have bladder problems.
- If you have glaucoma (raised pressure inside the eyeball).
- If you have phaeochromocytoma (tumour of the adrenal gland).
- During an asthma attack in asthmatic patients.

- If you have taken medicines for depression (monoamine oxidase inhibitors) within the last two weeks.
- If you will be having a procedure under anaesthesia.
- To newborn babies or babies born prematurely.
- If you are pregnant or breastfeeding.
- SINUCLEAR PAEDIATRIC SYRUP/STROOP should not be given to children under two years of age.
- If you are using ephedrine or medicines which can cause similar reactions.
- If you have or are at risk of developing respiratory failure.

**Warnings and precautions**

Take special care with SINUCLEAR PAEDIATRIC SYRUP/STROOP:

- If you develop a severe allergic reaction, which can include blistering of the skin, mouth, eyes, and genitals. This can be a sign of a serious side effect (see section 4). Paracetamol can cause rare but serious skin conditions. If you present with any skin rash or reaction, stop using this medicine immediately and consult your healthcare practitioner.
- Do not take more than the recommended dosage of SINUCLEAR PAEDIATRIC SYRUP/STROOP as doses higher than those recommended may cause damage to your liver.
- If you have a history of liver or kidney disease.
- Do not take any other product containing paracetamol whilst taking SINUCLEAR PAEDIATRIC SYRUP/STROOP; paracetamol can be fatal in overdose.
- Consult a healthcare professional if pain or fever persists or get worse at the recommended dosage, if new symptoms occur or if redness and swelling is present, as these could be signs of a more serious condition.
- If you have problems with your bladder.

- If you are taking SINUCLEAR PAEDIATRIC SYRUP/STROOP and you experience the following, stop taking SINUCLEAR PAEDIATRIC SYRUP/STROOP:
  - Hallucinations (seeing something that is not present).
  - Restlessness.
  - Sleep disturbances.
- If you have an obstruction in your stomach or gut (for example, because of an ulcer or ischaemic colitis).
- If you have epilepsy.
- If you have a loss or decrease in vision, SINUCLEAR PAEDIATRIC SYRUP/STROOP should be stopped.
- If you are taking flucloxacillin (a medicine used to treat bacterial infections).
- If you are elderly as you are more likely to experience side effects.
- SINUCLEAR PAEDIATRIC SYRUP/STROOP may lead to drowsiness and a decrease in concentration. You should avoid alcohol and other medications that also can cause drowsiness.
- Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop taking/giving SINUCLEAR PAEDIATRIC SYRUP/STROOP immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section 4 "Possible side effects" for symptoms).

**Children**

SINUCLEAR PAEDIATRIC SYRUP/STROOP should not be given to premature infants, neonates, or children under two years of age.

**Other medicines and SINUCLEAR PAEDIATRIC SYRUP/STROOP**

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

**This medicine contains paracetamol.**

**Do not take anything else containing paracetamol while taking this medicine.**

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

- Monoamine oxidase inhibitors (MAOIs) (e.g. moclobemide, selegiline): medicines used to treat depression.
- Anaesthetics (cyclopropane, halothane): medicine used during an operation to make you sleep.
- Cardiac glycosides (digoxin): medicine for the heart.
- Quinidine: medicines used to treat irregular heartbeats.
- Anticholinergics (e.g. atropine and amitriptyline): medicines which are used as premedication before operations and to treat depression.
- Tricyclic antidepressants (e.g. amitriptyline) used to treat depression.
- Medicines to reduce your appetite.
- Medicines which stimulate the nervous system, e.g. amphetamines.
- Medicines which lower your blood pressure.
- Ergotamine and methysergide: medicines used to treat migraines.
- Alcohol and other medications that depress the central nervous system such as pain killers, tranquilisers, antipsychotics and medications to help you sleep.
- Kaolin: medicine used to treat diarrhoea.
- Doxapram: medicine used to treat breathing problems.
- Oxytocin: medicine used during labour.
- Aluminium hydroxide: medicine used as an antacid.

- Domperidone or metoclopramide for feeling sick or being sick (may increase the rate of absorption of paracetamol).
- Warfarin or other blood thinners.
- Chloramphenicol to treat infections.
- Certain antibiotics such as gentamicin or flucloxacillin.
- Cholestyramine for reducing blood fat levels (may reduce the absorption of paracetamol).
- Non-steroidal anti-inflammatory drugs (NSAIDs): medicines used to treat pain and inflammation.
- Zidovudine: medicine used for the treatment of HIV infection.
- If you are having an allergen skin test as SINUCLEAR PAEDIATRIC SYRUP/STROOP may affect the results.

**SINUCLEAR PAEDIATRIC SYRUP/STROOP with food, drink and alcohol**

SINUCLEAR PAEDIATRIC SYRUP/STROOP should not be taken together with alcohol as this may cause excessive drowsiness and impaired concentration.

**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 SINUCLEAR PAEDIATRIC SYRUP/STROOP.

You should not take SINUCLEAR PAEDIATRIC SYRUP/STROOP if you are pregnant or breastfeeding your baby (see Do not take/give SINUCLEAR PAEDIATRIC SYRUP/STROOP).

**Driving and using machines**

Since adverse reactions such drowsiness, dizziness, sedation and blurred vision have been reported in patients taking SINUCLEAR PAEDIATRIC SYRUP/STROOP, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that taking SINUCLEAR PAEDIATRIC SYRUP/STROOP does not adversely affect your ability to do so (see Possible side effects).

It is not always possible to predict to what extent SINUCLEAR PAEDIATRIC SYRUP/STROOP may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SINUCLEAR PAEDIATRIC SYRUP/STROOP affects them.

**SINUCLEAR PAEDIATRIC SYRUP/STROOP contains**

- Sorbitol, which may have a laxative effect. If you have been told that you have an intolerance to some sugars, or a rare hereditary condition of sorbitol intolerance, you should not take SINUCLEAR PAEDIATRIC SYRUP/STROOP.
- Glycerol, which may cause headache, stomach upset and diarrhoea.
- Methyl hydroxybenzoate, propyl hydroxybenzoate and erythrosine may cause allergic reactions.

## 3. How to take/give SINUCLEAR PAEDIATRIC SYRUP/STROOP

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

Always take/give SINUCLEAR PAEDIATRIC SYRUP/STROOP exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of SINUCLEAR PAEDIATRIC SYRUP/STROOP is dependent on age.

**Children 6 to 12 years:** Take 5 ml to 10 ml (one to two medicine measures) three times daily.

**Children 2 to 6 years:** Take 5 ml (one medicine measure) three times daily.

SINUCLEAR PAEDIATRIC SYRUP/STROOP should not be given to children under 2 years of age (see Do not give/take SINUCLEAR PAEDIATRIC SYRUP/STROOP).

If you have the impression that the effect of SINUCLEAR PAEDIATRIC SYRUP/STROOP is too strong or too weak, tell your doctor or pharmacist.

**DO NOT EXCEED THE RECOMMENDED DOSE.**

If your symptoms worsen or do not improve after 10 days consult your doctor.

**If you take/give more SINUCLEAR PAEDIATRIC SYRUP/STROOP than you should**

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

**If you forget to take/give SINUCLEAR PAEDIATRIC SYRUP/STROOP**

Take your missed dose as soon as you remember, if within a few hours after missing a dose. Do not take a double dose to make up for forgotten individual doses.

## 4. Possible side effects

SINUCLEAR PAEDIATRIC SYRUP/STROOP can have side effects.

Not all side effects reported for SINUCLEAR PAEDIATRIC SYRUP/STROOP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while

taking SINUCLEAR PAEDIATRIC SYRUP/STROOP, please consult your health care provider for advice.

If any of the following happens, stop taking SINUCLEAR PAEDIATRIC SYRUP/STROOP 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 reactions known as Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Drug-induced hypersensitivity syndrome (DIHS), fixed drug eruptions (FDE), Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) or Acute Generalised Exanthematous Pustulosis (AGEP).

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

- Blood disorders such as decrease in white blood cells (leucopoenia and agranulocytosis), decrease in red blood cells (haemolytic anaemia), decrease in most blood cells (pancytopenia) and a decrease in platelets (thrombocytopenia). The first symptoms may include fever, sore throat, surface mouth ulcers, flu-like symptoms, severe tiredness, nasal and skin bleeding or unexplained bruising,
- yellowing of the skin or eyes, pale stools or upper abdominal pain (these may be signs of

liver problems),

- changes in the way your heart beats, for example, if you notice it beating faster (tachycardia) or slower (bradycardia) and palpitations,
- feeling disconnected from reality (psychotic state),
- seeing and hearing things that are not really there (hallucinations),
- excessive fluid in the lungs (pulmonary oedema) and chest pain (anginal pain) or cardiac arrest,
- bleeding inside brain tissue (cerebral haemorrhage), sudden loss of vision (ischaemic optic neuropathy),
- stomach cramps and pain due to lack of blood flowing to the large intestine (ischaemic colitis),
- pain in your upper belly that goes into your back, fever, higher heart rate, nausea, vomiting, swelling and tenderness in the belly; these may be signs that your pancreas is inflamed (pancreatitis),
- difficulty in passing urine or emptying out your bladder (urinary retention),
- feeling like you need the medicine to cope with everyday stresses (dependence),
- fits (convulsions), deep state of prolonged unconsciousness in which you cannot be awakened (coma).

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:*

- Drowsiness, unsteadiness, dizziness, lack of energy, slowing down of thought and movement (psychomotor impairment), headache, insomnia (inability to sleep), deep sleep, or nervousness, feeling extremely happy (euphoria), irritability, involuntary shaking movements of your body (tremors), nightmares, muscle twitching,
- blurred vision,

- thickening of airway mucous,
- dry mouth, constipation, stomach acid coming up from the stomach into the oesophagus (acid reflux),
- feeling worried and uneasy (anxiety), restlessness, fear, confusion,
- feeling weak, needing higher doses of the medicine in order for it to work effectively (tolerance).

*Less frequent side effects:*

- Decreased appetite, altered metabolism,
- nausea, vomiting, diarrhoea, stomach pain, excessive saliva flow,
- painful urination,
- sweating, very pale appearance of your skin (pallor), sores in the mucous membranes, high body temperature (fever).

*Side effects with an unknown frequency:*

- Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). Stop taking/giving SINUCLEAR PAEDIATRIC SYRUP/STROOP immediately and seek urgent medical attention if you develop symptoms, that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS).

  These include:

  - severe headache with a sudden onset
  - feeling sick
  - vomiting
  - confusion

- seizures
- changes in vision

- sleep disturbances, excitability,
- angle-closure glaucoma (raised pressure in the eyeball),
- inability to concentrate, feelings of extreme sadness and loss of interest (depression),
- tingling or prickling, “pins-and-needles” sensation (paraesthesia), muscle weakness, heaviness and weakness of the hands,
- high blood pressure, thirst,
- skin rashes, lumps and red skin patches, sensitivity to light (photosensitisation),
- ringing in the ears (tinnitus), tightness of the chest,
- decreased blood pressure (hypotension), impaired blood circulation to hands and feet,
- diarrhoea, stomach pain, colic, anorexia,
- hair loss,
- muscle aches and pain (myalgia), lack of energy (lassitude),
- feeling of being unbalanced and lightheaded (giddiness), feeling worried or upset (agitation),
- shrinking of your eye pupils (miosis), reddening of the skin (flushing),
- a sharp, stabbing or needle-like pain in the chest when breathing in (precordial pain).

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. By reporting side effects, you can help provide more information on the safety of SINUCLEAR PAEDIATRIC SYRUP/STROOP.

**Aspen Pharmacare:**

**E-mail:** Drugsafety@aspenpharma.com

**Tel:** 0800 118 088/+27 11 239-6200

## 5. How to store SINUCLEAR PAEDIATRIC SYRUP/STROOP

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

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 PAEDIATRIC SYRUP/STROOP contains**

The active substances in each 5 ml of SINUCLEAR PAEDITRIC SYRUP/STROOP are 15 mg of pseudoephedrine hydrochloride, 0,625 mg of triprolidine hydrochloride and 125 mg of paracetamol.

The other ingredients are:

Colour erythrosine (C.1. 45430), flavour raspberry special, glycerol, Kollidon 25, methyl hydroxybenzoate, propyl hydroxybenzoate, potassium acid phosphate (for pH adjustment), propylene glycol, purified water, saccharin sodium, sodium hydroxide (for pH adjustment), sorbitol.

*Preservatives:*

| | |
|---|---|
| Methyl hydroxybenzoate | 0,12 % m/v |
| Propyl hydroxybenzoate | 0,02 % m/v |

Contains sugar: Sorbitol 1,018 g

Contains sweetener: Saccharin sodium 45 mg

**What SINUCLEAR PAEDIATRIC SYRUP/STROOP looks like and contents of the pack**

SINUCLEAR PAEDIATRIC SYRUP/STROOP is a pink, viscous syrup with a raspberry odour. 100 ml is packed into a round, amber glass bottle sealed with a white polypropylene screw cap, with an expanded polyethylene liner.

**Holder of Certificate of Registration**

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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/

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