1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

ACUFLU P SYRUP/STROOP 15 mg/ 0,625 mg/ 125 mg per 5 ml

Pseudoephedrine hydrochloride, triprolidine hydrochloride, paracetamol

Contains sugar: sorbitol 1,01 g

Contains sweetener: saccharin sodium 45 mg

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

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

- Keep this leaflet. You may need to read it again.
- Do not share ACUFLU P SYRUP/STROOP with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advise.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

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

1. What ACUFLU P SYRUP/STROOP is and what it is used for

ACUFLU P SYRUP/STROOP is used to relieve the symptoms of cold and flu including nasal congestion, sniffing and headaches. It contains pseudoephedrine hydrochloride that relieves nasal congestion, triprolidine hydrochloride which helps with sniffing and paracetamol for pain and fever.

2. What you need to know before you take ACUFLU P SYRUP/STROOP

Do not take ACUFLU P SYRUP/STROOP:

- If you are hypersensitive (allergic) to triprolidine hydrochloride, pseudoephedrine hydrochloride, paracetamol or to any of the other ingredients of ACUFLU P SYRUP/STROOP (see section 6).
- If you have heart disease or high blood pressure.
- If you have an overactive thyroid gland (thyrotoxicosis).
- 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 have taken nasal decongestants including sprays or medications known as beta-blockers (used for high blood pressure).
- If you are undergoing surgery.
- If you are pregnant or breastfeeding.
- ACUFLU P SYRUP/STROOP should not be given to children under two years of age.
- If you are at risk of developing respiratory failure; a condition in which your blood does not have enough oxygen or has too much carbon dioxide.

Warnings and precautions

ACUFLU SYRUP/STROOP 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.

ACUFLU P SYRUP/STROOP may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant medicines. Patients should be warned not to drive a motor vehicle, climb dangerous heights or operate dangerous machinery, as impaired mental alertness could lead to accidents.

Take special care with ACUFLU P SYRUP/STROOP:

- If you have a history of liver disease or consume excessive quantities of alcohol.
- If you have any kidney disease.
- If you have arteriosclerosis (hardening and narrowing of arteries).
- Paracetamol can cause life-threatening and serious skin conditions. If you present with any skin rash or reaction, stop using this medicine immediately and consult your healthcare provider.
- Do not take any other product containing paracetamol whilst taking ACUFLU P SYRUP/STROOP, paracetamol can be fatal in overdose.
- Consult a healthcare provider 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 are taking the antidysrhythmic medicine called digoxin.
- If you have an overactive thyroid, diabetes or an aneurysm (a weak or expanded part of a blood vessel).

- If you are taking ACUFLU P SYRUP/STROOP and you experience the following, stop using ACUFLU P SYRUP/STROOP:
  - Hallucinations (seeing something that is not present)
  - Restlessness
  - Sleep disturbances
- ACUFLU P SYRUP/STROOP may lead to drowsiness and a decrease in concentration. You should avoid alcohol and other medications that depress the central nervous system. You should not drive, use machinery or perform any tasks that require concentration, until you are certain that ACUFLU P SYRUP/STROOP does not adversely affect your ability to do so (see Driving and using machinery).
- If you have an enlarged prostate or urinary retention (inability to completely empty the bladder.
- If you have an obstruction in your stomach or gut (for example, because of an ulcer).
- If you have epilepsy.
- If you are elderly as you are more likely to experience side effects.
- If you are having an allergen skin test as ACUFLU P SYRUP/STROOP may affect the results.
- Pseudoephedrine contained in ACUFLU P SYRUP/STROOP can cause a condition called ischaemic colitis which occurs when the blood flow to part of the large intestine is reduced. You should stop taking ACUFLU P SYRUP/STROOP and seek medical attention if you develop symptoms of ischaemic colitis such as sudden stomach pains or rectal bleeding.
- If you experience sudden loss of vision or other visual disturbances as this may be a sign that the nerve in your eye is damaged due to a blockage of its blood supply.

Children

ACUFLU P SYRUP/STROOP should not be given to children under two years of age.

Other medicines and ACUFLU P SYRUP/STROOP

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:

- Tricyclic antidepressants (e.g. amitriptyline): medicines used to treat depression.
- Aminoglycosides (e.g. gentamicin): used to treat bacterial infections.
- Alcohol and other medications that depress the central nervous system such as pain killers, tranquilisers and medications to help you sleep.
- 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 used to treat heart failure and irregular heartbeats.
- Quinidine: medicine used to treat irregular heartbeats.
- Sympathomimetic medicines such as nasal decongestants, medicines to reduce your appetite and medicines which stimulate the nervous system, e.g. amphetamines.
- Antihypertensives (e.g. bretylium, bethanidine, debrisoquine, methyldopa, guanethidine, reserpine, rauwolfia alkaloids and beta-adrenergic blocking medicines): medicines which lower your blood pressure.
- Doxapram: medicine used to treat breathing problems.
- Aluminium hydroxide-containing medicines: medicines used as antacids.
- Domperidone or metoclopramide: medicines used for the treatment of nausea and vomiting.
- Colestyramine: used to lower high cholesterol levels in the blood.

- Anticoagulants (e.g. warfarin or other blood thinners): used to prevent blood clotting.
- Flucloxacillin: medicine used to treat bacterial infections.
- Non-steroidal anti-inflammatory drugs (NSAIDs): medicines used to treat pain and inflammation.
- Zidovudine: medicine used for the treatment of HIV infection.

ACUFLU P SYRUP/STROOP may suppress the positive results of allergen skin tests and therefore should be stopped several days before skin testing.

ACUFLU P SYRUP/STROOP with food, drink and alcohol

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

Pregnancy, breastfeeding and fertility

You should not take ACUFLU P SYRUP/STROOP 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 ACUFLU P SYRUP/STROOP.

Driving and using machines

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

ACUFLU P SYRUP/STROOP contains sorbitol

ACUFLU P SYRUP/STROOP contains sorbitol and may have a laxative effect. If you have a rare hereditary condition of sorbitol intolerance you, should not take ACUFLU P SYRUP/STROOP.

3. How to take ACUFLU P SYRUP/STROOP

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

Always take ACUFLU P SYRUP/STROOP exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose of ACUFLU P SYRUP/STROOP is:

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.

DO NOT EXCEED THE RECOMMENDED DOSE

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

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

If you take more TAKE ACUFLU P SYRUP/STROOP than you should

ACUFLU P SYRUP/STROOP contains paracetamol which may be fatal in overdose. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Immediate medical attention is critical. Even if you do not show symptoms of an overdose, go immediately to your nearest hospital or poison centre.

Take this leaflet and any remaining ACUFLU P SYRUP/STROOP with you, so that the doctor knows what you have taken.

Some symptoms of overdose may include nausea, vomiting, abdominal pain, drowsiness, excitement, hallucinations, incoordination, convulsions, urinary retention, high blood pressure, difficulty breathing, abnormal heartbeat, thirst and tremors.

If you forget to take / missed a dose of ACUFLU P 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

ACUFLU P SYRUP/STROOP can have side effects.

Not all side effects reported for ACUFLU P SYRUP/STROOP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ACUFLU P SYRUP/STROOP, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking ACUFLU P 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 which may cause difficulty in breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS), toxic epidermal

necrolysis (TEN), 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 allergic reaction to ACUFLU P 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, neutropenia and agranulocytosis), decrease in red blood cells (anaemia and 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,
- seeing and hearing things that are not really there (hallucinations),
- changes in the way your heart beats, for example, if you notice it beating faster (tachycardia) or slower (bradycardia) and palpitations,
- feeling extremely tired, muscle cramps and abnormal heart rhythm as this may be a sign of low potassium levels (hypokalaemia),
- feeling disconnected from reality (psychotic state),
- excessive fluid in the lungs (pulmonary oedema), chest pain (anginal pain) and heart failure,
- 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 colon or 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, slowing down of thought and movement (psychomotor impairment), headache, inability to sleep (insomnia), 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 (gastric 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, 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:

- inability to concentrate, feelings of extreme sadness and loss of interest (depression), sleep disturbances,
- 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,
- decrease 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),
- fainting, 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 " 6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

Aspen Pharmacare:

Email: Drugsafety@aspenpharma.com

Tel: 0800 118 088

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

5. How to store ACUFLU P 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 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 ACUFLU P SYRUP/STROOP contains

The active substances are pseudoephedrine hydrochloride, triprolidine hydrochloride and paracetamol.

The other ingredients are colour erythrosine (C.I. 45430), flavour raspberry special essence, glycerol, methyl hydroxybenzoate, potassium acid phosphate (for pH adjustment), povidone,

propyl hydroxybenzoate, 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 1,01 g

Contains sweetener: Saccharin sodium 45 mg

What ACUFLU P SYRUP/STROOP looks like and contents of the pack

ACUFLU P SYRUP/STROOP is a pink, viscous syrup with a raspberry odour.

100 ml is packed into a round, amber glass bottle and sealed with a white, polypropylene screw cap with expanded polyethylene liner. The bottle is placed in an outer cardboard carton.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

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X/5.8/9

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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