1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

STILPANE SYRUP 6,5 mg/ 5 mg/ 120 mg per 5 ml

Promethazine hydrochloride, codeine phosphate, paracetamol

Contains sugar: Sorbitol 1,01 g

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

STILPANE SYRUP is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to give or take STILPANE SYRUP carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share STILPANE SYRUP 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 (for adults) or 5 days (for children) if you are using STILPANE SYRUP for pain and after 3 days if you or your child are using STILPANE SYRUP for fever.

What is in this leaflet

1. What STILPANE SYRUP is and what it is used for
2. What you need to know before you give or take STILPANE SYRUP
3. How to give or take STILPANE SYRUP
4. Possible side effects
5. How to store STILPANE SYRUP

6. Contents of the pack and other information

1. What STILPANE SYRUP is and what it is used for

STILPANE SYRUP is used to treat the symptoms of mild to moderate pain and fever. It contains promethazine hydrochloride which helps with allergies, codeine phosphate to relieve pain and paracetamol for pain and fever.

2. What you need to know before you give or take STILPANE SYRUP

Do not give or take STILPANE SYRUP:

- If you are hypersensitive (allergic) to promethazine hydrochloride (or any other anti-histamine), paracetamol, codeine phosphate (or other opioid analgesic) or any of the other ingredients of STILPANE SYRUP (listed in section 6).
- If you have severe liver or kidney problems.
- If you have obstructive breathing problems or other severe breathing problems, especially in the presence of cyanosis (condition where your skin or lips turn blue due to an insufficient level of oxygen in the blood) and excessive mucus and fluid secretion in the airways.
- If you have just had an operation on your bile tract.
- If you suffer from acute alcoholism.
- If you suffer from convulsions (fits and seizures).
- If you have had head injuries and conditions in which the pressure inside the skull is increased.
- If your child is younger than two years of age. STILPANE SYRUP has been associated with sudden infant death syndrome (SIDS) i.e. "cot death".
- If you are pregnant of breastfeeding your baby.

- If you are taking a medicine classified as a monoamine oxidase inhibitor (a medicine used to treat depression), or within 14 days of stopping such treatment.
- If you have any of the following conditions where inhibition of contractions of the digestive tract (peristalsis) should be avoided: where there is a risk of a condition where the movement of the bowel is impaired (paralytic ileus), where bloating and swelling in the belly area (abdominal distension) develops, or in acute diarrhoeal conditions such as acute ulcerative colitis or antibiotic associated colitis (e.g. pseudomembranous colitis) or diarrhoea caused by poisoning.
- If you are a paediatric patient and you are undergoing a procedure to remove your tonsils or adenoids for obstructive sleep apnoea syndrome.
- During an asthma attack.
- If you have heart disease caused by chronic lung disease.

Promethazine hydrochloride and codeine phosphate, as contained in STILPANE SYRUP, should not be given to comatose patients.

Warnings and precautions

Take special care with STILPANE SYRUP:

Exceeding the prescribed dose, together with prolonged and continuous use of this medication, may lead to dependency and addiction.

STILPANE SYRUP 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.

- Consult your healthcare provider if:
  - No pain relief is obtained from the recommended dosage after 10 days for adults and 5 days for children.
  - There is no improvement in fever after 3 days.
  - New symptoms occur or if redness and swelling is present.
- STILPANE SYRUP can lead to drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants (such as anti-depressants, anti-anxiety medication and or medicines used to help you sleep). You are advised, particularly at the initiation of therapy, against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.
- STILPANE SYRUP should not be used with any other paracetamol containing medicine.
- If you have a compromised ability to remove chemicals from the body (glutathione depleted states), as the use of paracetamol, as contained in STILPANE SYRUP, can increase your risk of developing a condition in which too much acid accumulates in the body (metabolic acidosis).
- If you are an elderly patient as you may be more prone to experience side effects such as dizziness, sleepiness, confusion, low blood pressure, dry mouth and urinary retention.
- If you have any of the following:
  - under active thyroid gland (a condition where the thyroid gland does not produce enough hormones),
  - adrenocortical insufficiency (a condition where the adrenal glands do not produce enough steroid hormone),

- a hormone-secreting tumour that can occur in the adrenal glands (phaeochromocytoma),
- asthma (see Do not take STILPANE SYRUP),
- narrowing of the tube connected to the bladder (urethral stricture),
- enlarged prostate gland,
- low blood pressure,
- a heart disease/condition,
- breathing problems such as emphysema or chronic bronchitis,
- problems with your liver or kidneys (also see Do not take STILPANE SYRUP),
- if you have a condition in which the skin, whites of the eyes and mucous membranes turn yellow (jaundice),
- a condition where your bladder doesn't completely empty (urinary retention),
- a group of rare disorders that affect the skin and nervous system (porphyria),
- if you are an alcoholic,
- shock (a condition where there is not enough blood flow through the body),
- pre-existing central nervous system depression,
- bone marrow depression,
- inflammatory or obstructive bowel disorders (a problem or blockage of your bowel) (see Do not take STILPANE SYRUP),
- diseases or conditions that cause weakness of muscles around the eyes, mouth and throat (myasthenia gravis),
- increased pressure in the eye (glaucoma),
- a disorder of the central nervous system that affects movement, often including tremors (Parkinsonism),
- a disease that affects how the body uses sugar (glucose) (diabetes mellitus),

- Reye’s syndrome (a rare but serious condition that causes swelling in the liver and brain. Reye's syndrome most often affects children and teenagers recovering from a viral infection, most commonly the flu or chickenpox),

- If you are pregnant or in labour. STILPANE SYRUP administration during labour may cause breathing problems in the new-born infant. If women take STILPANE SYRUP during pregnancy, there is a risk that their newborn infants will experience neonatal withdrawal syndrome (see Pregnancy and breastfeeding).
- Since codeine, as contained in STILPANE SYRUP, may cause a decrease in the function and activity of the brain. This effect may be increased by medicines that slow down brain activity such as alcohol, anaesthetics, calming and sleeping tablets, and phenothiazines. The prolonged use of high doses of codeine has produced addiction similar to morphine addiction. Codeine should be used with caution in patients with a history of substance abuse or mental health disorders.
- If you use medicine for the treatment of diarrhoea, as concomitant use with STILPANE SYRUP can cause constipation (difficulty in passing stools).
- If you are also taking flucloxacillin (an antibiotic) as the combination with paracetamol, as contained in STILPANE SYRUP, has been associated with a condition where acid accumulates in the body (high anion gap metabolic acidosis), especially in patients with risk factors (see Other medicines and STILPANE SYRUP).
- As STILPANE SYRUP can cause very serious skin reactions that are potentially life threatening (see Possible side effects), you should stop taking STILPANE SYRUP if you develop any skin reactions and contact your doctor.
- If you are an ultra-rapid metaboliser of CYP2D6, you should not take STILPANE SYRUP (see Do not take STILPANE SYRUP). Even small doses of codeine can lead

to increased formation of the active metabolite morphine resulting in clinical signs of morphine intoxication.

- If you are a child and you might have compromised respiratory function, as worsened symptoms of morphine toxicity can occur (see Do not take STILPANE).
- If you are a paediatric patient and you have had your tonsils and/or adenoids removed due to obstructive sleep apnoea. Rare, but life-threating adverse events such as death can occur (see Do not take STILPANE).

Your pigments should be examined periodically by your doctor for abnormal skin pigmentation (discolourisation) or eye changes.

Children

STILPANE SYRUP is not recommended for children under 2 years of age.

Other medicines and STILPANE SYRUP

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:

- Medicines used to treat depression, referred to as monoamine oxidase inhibitors (such as selegiline) (see Do not take STILPANE SYRUP),
- medications tending to cause involuntary movements that you cannot control (extrapyramidal reactions) and those with anticholinergic effects may be potentiated. These include medicine to treat depression know as tricyclic antidepressants, maprotiline or monoamine oxidase inhibitors (MOAIs),
- medication used to treat high blood pressure, alcohol and anaesthetics, as STILPANE SYRUP may enhance the effect of these medicines,

- hypnotics and sedatives, medicines used to make you feel sleepy,
- phenothiazines, used to treat schizophrenia as well as nausea and vomiting,
- anti-virals (e.g. interferon alfa and zidovudine), as paracetamol enhances the antiviral effect of Interferon Alfa. Severe liver toxicity has occurred after the use of paracetamol in patients taking zidovudine and co-trimoxazole,
- medicine that may cause damage to the liver or medicine that increases the metabolic activity of an enzyme (hepatotoxic or enzyme-inducing medicine), as there as is an increased risk of damage to the liver,
- prolonged concurrent use of STILPANE SYRUP with salicylates (e.g. aspirin) increases the risk of kidney side-effects,
- levodopa, a medicine used to treat Parkinson's disease,
- sodium oxybate, as concomitant administration of codeine and sodium oxybate may cause increased central nervous system depression and/or airway depression and/or lowered blood pressure (hypotension),
- medicine to prevent your blood from clotting (warfarin and other coumarins), since there is as an increased risk for bleeding in patient taking regular doses of paracetamol,
- medicines used to treat tuberculosis, including isoniazid, as severe liver damage can occur,
- anti-dysrhythmics (e.g. mexiletine, quinidine), as codeine, as contained in STILPANE SYRUP, delays the absorption of mexiletine. The pain-relieving activity of codeine, as contained in STILPANE SYRUP, is likely to be significantly impaired by quinidine which impairs the breakdown of codeine,
- domperidone and metoclopramide, as the absorption of paracetamol may be accelerated. Codeine works against the effects of metoclopramide and domperidone on gastrointestinal activity,

- cisapride, codeine works against the effects of cisapride on gastrointestinal activity,
- cholestyramine (used to lower cholesterol levels in the blood), as it reduces the absorption of paracetamol,
- probenecid (used to treat gout), as STILPANE SYRUP causes paracetamol to stay in the body for longer,
- ulcer-healing medicine (such as cimetidine), as it may cause codeine, as contained in STILPANE SYRUP, to stay in the body for longer,
- flucloxacillin, as concurrent intake with paracetamol has been associated acid accumulates in the body, especially in patients with risk factors,
- STILPANE SYRUP may affect the results of pregnancy tests (false negative or positive),
- STILPANE SYRUP may affect the results of skin tests and should be stopped several days before these tests are done,
- STILPANE SYRUP may mask the warning signs of damage caused by agents that have toxic effects on the nerve of the ear,
- The plasma-paracetamol concentrations considered an indication for antidote treatment should be halved in patients receiving enzyme inducing medicines such as rifampicin (used in the treatment of tuberculosis), carbamazepine phenobarbital, phenytoin, or primidone (used in the treatment of epilepsy or as a sedative),
- Interference with laboratory tests: Opioids may interfere with gastric emptying studies.

Codeine, as contained in STILPANE SYRUP, may delay the absorption of other medicines that you may be taking.

STILPANE SYRUP with alcohol

Do not drink alcohol when taking STILPANE SYRUP (also see Other medicines and STILPANE SYRUP).

Pregnancy, breastfeeding and fertility

You should not take STILPANE SYRUP if you are pregnant or breastfeeding your baby (see Do not take or give STILPANE SYRUP).

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 STILPANE SYRUP.

Driving and using machines

STILPANE SYRUP may cause drowsiness, dizziness and visual disturbances which may affect your ability to perform skilled tasks; if you are affected, you should not drive or operate machinery.

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

STILPANE SYRUP contains preservatives

Methyl hydroxybenzoate and propyl hydroxybenzoate which may cause allergic reactions (possibly delayed).

STILPANE SYRUP contains sorbitol

Sorbitol is a source of fructose. If your doctor told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk

to your doctor before you (or your child) take or receive STILPANE SYRUP. Sorbitol may cause gastrointestinal discomfort and mild laxative effect (see section 4. Possible side effects). STILPANE SYRUP contains 1,01 g sorbitol in each 5 ml.

STILPANE SYRUP contains propylene glycol

If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol. STILPANE SYRUP contains 83 mg propylene glycol in each 5 ml which is equivalent to 16,6 mg/ml.

3. How to give or take STILPANE SYRUP

Always take or give STILPANE SYRUP exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

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

The usual dose of STILPANE SYRUP is:

Age 2 to 5 years: One medicine measure (5 ml) three times daily.

Age 6 to 12 years: One to two medicine measures (5 ml to 10 ml) three times daily.

DO NOT EXCEED THE RECOMMENDED DOSE

A lower dosage should be used in elderly and weak patients.

If you have the impression that the effect of STILPANE SYRUP is too strong or too weak, talk to your doctor or pharmacist.

You must see a doctor if your symptoms worsen or do not improve after 10 days (for adults) or 5 days (for children) if you are taking STILPANE SYRUP for pain and after 3 days if you or your child are taking STILPANE SYRUP for fever.

If you give or take more STILPANE SYRUP than you should

STILPANE SYRUP contains paracetamol which may cause death in overdose. In the event of overdosage, or suspected overdosage and notwithstanding the fact that the person may not have symptoms, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre immediately.

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), or severe diarrhoea. In addition to these symptoms, headache, gastrointestinal bleeding, blurred vision, ringing in the ears, confusion, dizziness, shaky eye movement, exacerbation of asthma in asthmatics may occur. At high doses, drowsiness, excitation, disorientation, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), vertigo, weakness and dizziness, blood in urine, low blood pressure, hyperkalaemia, metabolic acidosis, increased prothrombin time/INR, acute renal failure, liver damage, respiratory depression, cyanosis, cold body feeling, and breathing problems have been reported.

If you forget to give or take STILPANE SYRUP

Take or give the missed dose as soon as you remember, if within a few hours after missing a dose.

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

4. Possible side effects

STILPANE SYRUP can have side effects.

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

If any of the following happens, stop taking STILPANE SYRUP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, 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 reaction known as severe cutaneous adverse reactions (SCARs) such as Toxic Epidermal Necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS)/Drug-induced hypersensitivity syndrome (DIHS), fixed drug eruption (FDE).

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

- A significant and potentially dangerous drop in body temperature is a medical emergency (hypothermia).
- Seeing or hearing things that are not actually there (hallucinations) or a feeling of great (usually exaggerated) elation (euphoria).
- Decreased, irregular or increased heartbeat, or other changes in the way your heart beats (tachycardia, increased heart rate, bradycardia followed by tachycardia with palpitations and dysrhythmias).
- Feeling extremely tired or weak, difficulty breathing, swelling or loss of appetite, difficulty in urinating, white blood cells in the urine, spasms of the ureter or bladder muscles resulting in burning or sharp, cramping pain as these could be signs of problems with your kidneys (kidney failure/damage, nephropathy, renal colic).
- Yellowing of the whites of eyes and skin as these may be signs of liver problems (hepatic dysfunction/damage, hepatitis, jaundice).
- Convulsions and uncontrolled muscle movements (epileptiform seizures).
- Upper abdominal pain, nausea and vomiting as these may be symptoms of inflammation of the pancreas (pancreatitis).
- Headache, blurred vision, feeling less alert than usual, vomiting, changes in your behaviour, weakness or problems with moving or talking, lack of energy or sleepiness as these may be symptoms of raised intracranial pressure.
- When the clear surface of your eye becomes scarred (corneal and lens opacities) with symptoms such as, decrease or loss of vision, eye pain or light sensitivity.
- Difficulty in achieving and maintaining erection in males (erectile dysfunction).
- Extrapyramidal symptoms with muscle spasms and abnormal muscle twitches or uncontrolled muscle movements.

- Failure of the cardiovascular system to supply adequate amounts of blood to body tissues (circulatory failure), with symptoms such as pale or blue skin colour, cold fingers or toes and veins that bulge.
- Pain that occurs when a gallstone is being passed and is blocking a bile duct, typically comes and goes in a regular pattern (biliary spasm).
- Bruising, bleeding gums, and internal bleeding, pinpoint-sized reddish-purple spots on the lower legs as these may be symptoms of decreased platelets (thrombocytopenia, pancytopenia, thrombocytopenic purpura).
- Fatigue, skin pallor, shortness of breath, light-headedness, dizziness or a fast heartbeat as these may be symptoms of a condition in which the blood doesn't have enough healthy red blood cells (haemolytic anaemia, anaemia).
- Increased vulnerability to infections as this may be a sign of lowered white blood cells (neutropenia, agranulocytosis, leukopenia, pancytopenia).
- Increased number of a certain type of white blood cell (eosinophilia), that can present with symptoms such as weight loss, fevers, night sweats, cough, chest pain, rash.
- Deepening coma.
- Loss of hearing.
- Constriction of air passages which causes difficulty breathing, coughing, wheezing and chest tightness (bronchospasm, dyspnoea and large doses may produce respiratory depression).

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:

- Confusion,
- sleepiness (varying from slight drowsiness to deep sleep), lack of energy (lassitude), a strong desire to sleep (somnolence),
- paradoxical stimulation (a reaction that is opposite to what would usually be expected) of the central nervous system (made up of the brain and spinal cord),
- occasional headaches, nervousness, irritability,
- high blood pressure (hypertension), muscle weakness,
- dizziness, lack of coordination, a slight shaking movement in a person's body (tremors),
- nausea, vomiting, diarrhoea, constipation (difficulty in passing stools), lack/loss of appetite (anorexia) or increased appetite, pain in upper, middle region of stomach (epigastric pain),
- sweating.

Less frequent side-effects:

- Great happiness (elation) or persistent feeling of sadness and loss of interest (depression), changes of mood, restlessness,
- decrease in the size of the pupil of the eye (miosis),
- ringing in the ears (tinnitus),
- low blood pressure and low blood pressure when standing up (orthostatic hypotension),
- intestinal cramps (colic), abdominal pain, dryness of the mouth,
- increased sensitivity of skin to sun (photosensitivity),

- a condition in which you have high levels of white blood cells or pus in your urine (sterile pyuria),
- difficulty or pain when passing urine (difficulty in micturition, dysuria),
- weakness of the hands, muscle rigidity, facial flushing.

Side effects with an unknown frequency:

- Too much sugar in the blood (hyperglycaemia),
- a chronic inflammatory disease of connective tissue, affecting the skin and various internal organs (lupus erythematous-like syndrome), temporary increase in the body's temperature (fever),
- inability to sleep (insomnia), abuse, mental depression, nightmares, feeling uneasy (dysphoria), agitation, anxiety,
- headache, nausea, vomiting, confusion, dizziness, feeling week or tired, loss of appetite and increased heartbeat due to high acidity in the body (pyroglutamic aciduria (5-oxoprolinuria) and high-anion gap metabolic acidosis),
- light-headedness and loss of balance (vertigo),
- deposition of pigment in the eyes, blurred or double vision or other changes in vision,
- thickened secretions in the organs that are involved in breathing (respiratory tract), dryness of the nose,
- increased stomach acid or bile irritates the food pipe lining (gastric reflux), stomach cramps,
- a decrease in the amount of urine produced (antidiuretic effect),
- inhibition of the parasympathetic nervous system (antimuscarinic effects) (these effects can cause flushing, constipation, dry skin, dilatation of the pupils),

- a rise in body temperature cause by a certain medicine (medicine fever),
- weakness of hands, muscle stiffness (rigidity),
- passing abnormally large amounts of urine (polyuria), ureteric spasm, difficulty urinating and completely emptying the bladder (urinary retention),
- lowering of blood temperature (occasionally pyrexia), a general feeling of discomfort (malaise), physical and mental symptoms that occur after stopping or reducing a medicine (drug withdrawal syndrome),
- persistent, recurrent difficulty with sexual response, desire, orgasm or pain (sexual dysfunction, decreased libido/potency),
- increase in a certain enzyme as seen on blood tests (increased transaminases),
- tiredness,
- a nearly irresistible urge to move the legs, typically in the evenings (restless legs syndrome).

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:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27 (0)11 239-6200

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

5. How to store STILPANE SYRUP

Store all medicines out of reach of children.

Store at or below 25 °C, in a well closed container.

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 STILPANE SYRUP contains

The active substances are 6,5 mg promethazine hydrochloride, 5 mg codeine phosphate and 120 mg paracetamol per 5 ml.

The other ingredients are acesulfame potassium, colour blackcurrant (C.I. 1458), dye Lennon blackcurrant (C.I. 42090 & 14720), flavour blackcurrant, glycerol, hydroxyethylcellulose, methyl hydroxybenzoate, polyvinylpyrrolidone (Povidone), propylene glycol, propyl hydroxybenzoate, purified water, sorbitol (70 %) solution, sodium cyclamate and sodium saccharin.

Preservatives:

Methyl hydroxybenzoate 0,09 % *m/v*

Propyl hydroxybenzoate 0,01 % *m/v*

Contains sugar: Sorbitol 1,01 g

Contains sweeteners: Sodium cyclamate 50,46 mg, sodium saccharin 5,22 mg, acesulfame potassium 2,32 mg.

What STILPANE SYRUP looks like and contents of the pack

STILPANE SYRUP is a clear, dark reddish-purple syrupy liquid with a blackcurrant odour.

100 ml is packed into a natural high density polyethylene container and sealed with a round, flat topped white, high density polyethylene screw on child-lock cap with an expanded polyethylene liner and a translucent polyethylene tamper evident band. The bottle is placed in an outer cardboard carton.

100 ml is packed into a brown high density polyethylene bottle sealed with a round, flat topped white, high density polyethylene screw on child-lock cap with an expanded polyethylene liner and a translucent polyethylene tamper evident band. The bottle is placed in an outer cardboard carton.

500 ml is packed into a natural rectangular high density polyethylene bottle and sealed with a white low density polyethylene snap cap.

2,5 L is packed into a green, high density polyethylene, tamper evident container and sealed with a high density polyethylene rachet cap.

Not all packs or pack sizes may be marketed.

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/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Namibia: NS2 15/2.8/123
Botswana: B9322900 S3