1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

STILPANE CAPSULES 150 mg/8 mg/320 mg

Meprobamate, Codeine phosphate, Paracetamol

Sugar free

Read all of this leaflet carefully before you start taking STILPANE CAPSULES

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- STILPANE CAPSULES has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

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

STILPANE CAPSULES is indicated for short term use (no longer than 10 days) in mild to moderate pain and fever, and pain associated with anxiety or tension.

2. What you need to know before you take STILPANE CAPSULES

Do not take STILPANE CAPSULES:

- If you are hypersensitive (allergic) to meprobamate, codeine phosphate, paracetamol or to any of the ingredients in STILPANE CAPSULES (see section 6).
- If you're allergic to other opioid painkillers.
- If you are pregnant or breastfeeding.
- If you have porphyria (a disorder relating to the pigment of blood).
- If you have a history of fits (epilepsy).
- If you have severe liver, kidney or lung problems.
- If you have asthma or breathing problems.
- If you have just had an operation on your bile tract.
- If you are an alcoholic.
- If you have had a recent head injury or if you have a condition in which the pressure in your skull is increased.
- During an asthma attack.
- If the patient is in a coma.
- If you have heart failure caused by chronic lung disease.
- If you are using monoamine oxidase inhibitors (usually used to treat depression) or within fourteen days of stopping such treatment.
- If you are an ultra-metaboliser of the enzyme CYP2D6.
- If you are a child younger than 12 years.
- 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 younger than 18 years and you are undergoing a procedure to remove your tonsils or adenoids due to a sleep-related breathing disorder in which breathing repeatedly stops and starts (obstructive sleep apnoea syndrome).

Warnings and precautions

STILPANE 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.
Taking more than the prescribed dose together with continuous use of STILPANE CAPSULES may lead to dependency and addiction (see section How to take STILPANE CAPSULES).

Even if taken at normal doses, STILPANE CAPSULES can cause increased morphine (active metabolite of codeine) levels which may produce clinical signs of morphine intoxication.
The lowest effective dose should be used, and the duration of treatment should be as short as possible.

Take special care with STILPANE CAPSULES:

- If you have an underactive thyroid gland (a condition where the thyroid gland does not produce enough hormones),
- If you have a condition where the adrenal glands do not produce enough steroid hormone (adrenocortical insufficiency),
- If you have problems with your liver and kidney function,
- If you have an enlarged prostate gland,
- If you have low blood pressure,

- If you suffer from shock (a condition where there is not enough blood flow through the body),
- If you have inflammatory or obstructive bowel disorders (a problem or blockage of your bowel),
- If you suffer from a disease or condition that cause weakness of muscles around the eyes, mouth and throat (myasthenia gravis),
- STILPANE CAPSULES should be avoided in elderly and debilitated (very weak or sick) patients and those with mental depression,

- If you drink alcohol or use medicines that cause you to fall asleep. When these are taken together with STILPANE CAPSULES, it may result in enhance impairment of judgement and coordination (feeling dizzy and drowsy),
- If you have a compromised ability to remove chemicals from the body (glutathione depleted states), as the use of paracetamol, as contained in STILPANE, can increase your risk of developing a condition in which too much acid accumulates in the body (metabolic acidosis),
- if you develop very serious skin reactions that are potentially life threatening (see section Possible side effects),
- if you are taking an antibiotic called flucloxacillin (see section Other medicines and STILPANE CAPSULES),
- if you experience an increased sensitivity to pain (hyperalgesia) or experience pain from a stimulus that normally would not cause pain (allodynia),
- if you had or have a problem with an addiction to painkillers, alcohol or other illegal substance.
- If you are a child and you might have compromised respiratory function, as worsened symptoms of morphine toxicity can occur.

- if you have a personal or family history of substance abuse or mental health conditions, as you may be at an increased risk of becoming addicted to STILPANE CAPSULES.

Do not use STILPANE CAPSULES for more than 10 days without consulting your doctor. This can cause dependence and give you withdrawal symptoms from the medicine when you stop taking it. Your doctor will need to reduce your dose gradually to avoid withdrawal symptoms.

Children and adolescents

STILPANE CAPSULES are not recommended for use in children under the age of 12 years (see Do not take STILPANE CAPSULES).

Other medicines and STILPANE CAPSULES

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

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

- Flucloxacillin and co-trimoxazole: used to treat bacterial infections.
- Isoniazid: used to treat tuberculosis (TB).
- Anti-depressants (e.g. fluvoxamine, monoamine oxidase inhibitors and tricyclic anti-depressants): used to treat depression.
- Anti-epileptics (e.g. phenytoin, carbamazepine, phenobarbital, primidone and lamotrigine): use to treat fits (seizures).
- Medicines that cause liver toxicity such as antibiotics and painkillers.
- Metoclopramide and domperidone: used to treat and prevent nausea and vomiting.
- Probenecid: used for the treatment of gout.
- Colestyramine: used to lower high cholesterol levels in the blood.

- Anti-coagulants and coumarin anti-coagulants (e.g. aspirin, warfarin): used to prevent blood clots.
- Anti-virals (e.g. interferon alfa and zidovudine): used for the treatment of viral infections such as HIV.
- Antipsychotics (e.g. phenothiazines such as chlorpromazine): used to treat schizophrenia and other psychotic disorders.
- Anti-histamines (e.g. hydroxyzine): used to relieve the symptoms of allergies.
- Anaesthetics: used to prevent feeling any pain or sensation before or during surgery.
- Anti-dysrhythmics (e.g. mexiletine and quinidine): used to treat irregular heartbeat.
- Cisapride: used to treat heartburn.
- Anxiolytics (e.g alprazolam): used to prevent or treat anxiety symptoms or disorders.
- Hypnotics and sedatives (e.g. benzodiazepines): used to induce sleep.
- Sodium oxybate: used to treat a sleeping disorder called narcolepsy that makes people very sleepy during the day.
- Ulcer-healing medicines (e.g. cimetidine): used to treat ulcers in the stomach.

Interference with laboratory tests: Opioids, such as codeine, as in STILPANE CAPSULES may interfere with gastric emptying studies.

STILPANE CAPSULES with food, drink and alcohol

You should not drink alcohol whilst you are taking STILPANE CAPSULES. Drinking alcohol together with STILPANE CAPSULES can enhances the blood pressure lowering, sedative, respiratory and central nervous system depressant effects. Drinking alcohol with

STILPANE CAPSULES may also lead to reduced judgment and coordination (see section Do not take STILPANE CAPSULES).

Pregnancy and breastfeeding

You should not take STILPANE CAPSULES if you are pregnant or breastfeeding your baby. STILPANE CAPSULES administration during labour may cause respiratory depression in the newborn infant.

If you are pregnant or breastfeeding your baby, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking STILPANE CAPSULES.

Driving and using machines

Do not drive or operate machinery, because the use of STILPANE CAPSULES may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or anti-depressants.

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

3. How to take STILPANE CAPSULES

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

Always take STILPANE CAPSULES exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose of STILPANE CAPSULES for adults and children over 12 years is:

Two capsules orally three or four times a day as required.

DO NOT EXCEED THE RECOMMENDED DOSE.

STILPANE CAPSULES should not be used in children under 12 years of age.

Your doctor will tell you how long your treatment with STILPANE CAPSULES will last.

However, it is not recommended to use continuously for more than 10 days. If you have the impression that the effect of STILPANE CAPSULES is too strong or too weak, talk to your doctor or pharmacist.

If you take more STILPANE 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 control centre. Prompt treatment is essential. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed. Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and possibly abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormal heartbeat has been reported.

Overdosage with STILPANE CAPSULES can cause severe and fatal low blood pressure, respiratory depression, shock, heart failure and death. Extremely high doses and increased sensitivity to STILPANE CAPSULES may lead to agitation, increased urine, repeated vomiting with extreme thirst, disorientation (confusion), hallucinations, very high body temperature (41 °C or above), abnormal heartbeat including increased heart rate, electrolyte disturbances, convulsions and death.

If you forget to take STILPANE CAPSULES

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

If you stop taking STILPANE CAPSULES

STILPANE CAPSULES should not be used for longer than 10 days. If you are taking more STILPANE CAPSULES for longer periods of time, you could develop tolerance, addiction or an increased sensitivity to pain (hyperalgesia). In this case, the dose should be reduced gradually to prevent the occurrence of withdrawal symptoms. Withdrawal syndrome is characterised by some or all of the following: restlessness, watery eyes, runny nose, yawning, sweating, chills, muscle pain, pupils (of the eye) that are larger than usual and pounding or fluttering heartbeat.

Other symptoms may also develop including irritability, agitation, anxiety, excessive movement of a part of the body, tremor, weakness, sleeplessness, loss of appetite, stomach cramps, nausea, vomiting, diarrhoea, increased blood pressure, increased breathing rate or heart rate.

If you notice any of these symptoms when you stop taking STILPANE CAPSULES, please contact your doctor.

4. Possible side effects

STILPANE CAPSULES can have side effects.

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

If any of the following happens, stop taking STILPANE 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,
- 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 (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 CAPSULES. 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:

- Hearing, seeing or smelling things that are not there (hallucinations),
- shaking movement of the body that cannot be controlled (convulsions),
- reduced body temperature (hypothermia),
- yellowing of the skin and eyeballs, pain in your upper right abdomen, swollen belly, nausea and vomiting, extreme tiredness, loss of appetite, dark urine; these are signs that your liver may not be working properly (hepatic dysfunction) or it may be inflamed (hepatitis),
- stomach pains, fever, fast heart rate, nausea and vomiting; these may be signs of inflammation of the pancreas (pancreatitis),
- raised skull pressure,
- kidney failure; low urine output (anuria),
- decreased white and red blood cells and platelets (pancytopenia),
- fever and chills, faster heart rate and breathing, muscle weakness and extreme tiredness, sore throat, swollen and bleeding gums; these are signs that your white blood cell levels are lower than normal (agranulocytosis, neutropenia, leucopenia),
- decreased blood platelets which results in easy bruising, including abnormal bleeding from nose and/or gums, the presence of blood in the urine or stool and cuts that continue bleeding (thrombocytopenia),
- reduced oxygen in the blood with symptoms such as tiredness, weakness, shortness of breath, irregular heartbeat, dizziness or light headedness, chest pain and cold hands and feet (anaemia/aplastic anaemia),
- high levels of white blood cells in the blood (eosinophilia). Symptoms may include weight loss, fever, night sweats, cough, chest pain, swelling, tiredness, stomach ache, rash and weakness,
- decreased heartbeat (bradycardia),

- feeling like you cannot function normally without using STILPANE CAPSULES (drug dependence),
- sudden, red patches and blisters usually on the palms of hands, soles of feet and face that are painful and itchy (erythema multiforme).

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:

- Constipation,
- drowsiness,
- unsteady, shaky movements (ataxia).

Less frequent side effects:

- Dry mouth, nausea, vomiting, diarrhoea,
- confusion, mood changes, restlessness,
- disturbance of vision,
- sleepiness, dizziness, faintness, excitement, weakness,
- headache,
- light headedness when standing up due to low blood pressure (orthostatic hypotension),
- a sensation that your heart is racing, pounding, or skipping a beat (palpitations),
- facial flushing,
- sensitivity reaction: red skin rash, itchy rash, sweating,
- muscle rigidity,
- difficulty in urination,
- drug withdrawal syndrome characterized by the following symptoms: sweating, muscle cramps and pains, hot and cold flushes, nausea, vomiting, diarrhoea, shaking

uncontrollably, increased heart rate and blood pressure and inability to sleep,

- slow, abnormal or irregular heartbeat (tachycardia, cardiac dysrhythmias),
- tightening of lung muscles which results in wheezing, coughing and difficulty in breathing (bronchospasm).

Side effects with an unknown frequency:

- Presence of white blood cells in urine without an infection (sterile pyuria),
- waves of sharp, intense pain caused by kidney dysfunction (renal colic),
- uncontrolled muscle movements,
- increased body temperature (fever), enlarged spleen (splenomegaly), swollen lymph nodes (lymphadenopathy),
- high blood sugar levels (hyperglycaemia),
- eating disorder resulting in severe weight loss (anorexia),
- feeling of great happiness and excitement (euphoria), feeling very unhappy, uneasy or dissatisfied (dysphoria), depressed mood (mental depression), bad dreams (nightmares),
- feeling like you or your surroundings are spinning or moving (vertigo),
- pupil (eye) contraction (miosis), blurred or double vision or other changes in vision
- shortness of breath (dyspnoea), slow and ineffective breathing (respiratory depression),
- stomach cramps, sharp, intense pain in your upper stomach near your rib cage (biliary spasm),
- itchy, swollen rash (contact dermatitis), itching of the nose, abnormal physical reaction to medicines (idiosyncrasy),
- inability to empty all the urine from your bladder (urinary retention), sudden contraction of your ureter resulting in a burning or cramping pain in your groin (ureteric spasm), painful or burning sensation when you urinate (dysuria),
- trouble having or enjoying sex (sexual dysfunction), persistent inability to achieve or

maintain an erection (erectile dysfunction), decreased potency, decreased sexual desire (decreased libido),

- general sense of being unwell (malaise), tiredness,
- pins and needles sensation (paraesthesia),
- low blood pressure (hypotension),
- purple-coloured spots and patches on the skin, and in mucous membranes including the lining of the mouth (purpura),
- headache, nausea, vomiting, confusion, dizziness, feeling weak or tired, loss of appetite and increased heartbeat due to high acid levels in the body (metabolic acidosis or pyroglutamic aciduria).

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.

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 CAPSULES.

5. How to store STILPANE CAPSULES

Store all medicines out of reach of children.

Store at or below 25 °C, protected from light and moisture.

Do not use the medicine after the expiry date printed on the carton/containers.

Keep in original packaging until required for use.

Do not store in a bathroom.

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 CAPSULES contains

The active substances are 150 mg meprobamate, 8 mg codeine phosphate, 320 mg paracetamol.

The other ingredients are colloidal silicone dioxide and magnesium stearate.

The capsule shell contains brilliant blue (CI no. 42090), quinolone yellow (CI no. 47005) and titanium dioxide (CI no. 77891).

Sugar free

What STILPANE CAPSULES looks like and contents of the pack

STILPANE CAPSULES is a white powder encapsulated with a no. 0 elongated capsule, with an opaque green cap and body printed with a Lennon logo and “Lennon” and “Stilpane”.

100 capsules are packed into a white polypropylene securitainer sealed with a white low density polyethylene cap.

500 capsules are packed into a 1 000 ml Amber-Pigmented PVC container together with a silica gel sachet and sealed with a white pilfer proof HDPE screw cap.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 (South Africa)

Tel: +27 11 239 6200 (Other)

This leaflet was last revised in

31 March 2025

Registration number

B0624 (Act 101/1965)

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

Botswana: B9322895 S1C

Namibia: NS3 15/2.8/0124

ZA_STILCAP_2503_00