PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

STOPAYNE TABLETS

Meprobamate, Codeine phosphate, Paracetamol and Caffeine anhydrous

Contains sugar (lactose monohydrate): 1 mg

Read all of this leaflet carefully before you start taking STOPAYNE TABLETS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- STOPAYNE TABLETS 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 STOPAYNE TABLETS is and what it is used for
2. What you need to know before you take STOPAYNE TABLETS
3. How to take STOPAYNE TABLETS
4. Possible side effects
5. How to store STOPAYNE TABLETS
6. Contents of the pack and other information

1. What STOPAYNE TABLETS is and what it is used for

STOPAYNE TABLETS contain the active ingredients Paracetamol 320 mg, Codeine phosphate 8 mg, Caffeine 32 mg and Meprobamate.

STOPAYNE TABLETS is used for the short-term treatment of mild to moderate pain and fever, and pain associated with tension.

2. What you need to know before you take STOPAYNE TABLETS

Do not take STOPAYNE TABLETS

- if you have ever had an allergic reaction to paracetamol, codeine phosphate, caffeine, meprobamate or any of the other ingredients in the tablets (these are listed in section 6),
- if you have porphyria (a rare inherited blood disorder),
- if you have a history of fits (epilepsy),
- if you have any lung/airway (respiratory) 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 are experiencing an asthma attack or heart failure (secondary to a chronic lung disease),
- if you had an operation on the biliary tract (liver, gall bladder and bile ducts),
- if you suffer from acute alcoholism (alcohol poisoning due to rapid and excessive alcohol intake),
- if you suffer from a head injury or any conditions in which intracranial pressure is raised (a rise in the pressure around your brain),
- if you are taking an antidepressant in the class called monoamine oxidase inhibitors or within fourteen days of stopping such treatment.

Warnings and precautions

Take special care with STOPAYNE TABLETS and tell your doctor:

- if you are pregnant or breastfeeding as STOPAYNE TABLETS is not recommended for use during pregnancy or breastfeeding,
- if your symptoms do not improve on the recommended dosage as prescribed by your doctor,
- if you have a history of liver or kidney disease as paracetamol intake must then be carefully monitored and controlled by your doctor,
- if you are suffering from hypothyroidism (underactive thyroid gland), adrenocortical insufficiency (condition in which the adrenal glands do not produce enough steroid hormones), prostatic hypertrophy (enlarged prostate gland) or shock,
- if you suffer from or have ever suffered from inflammatory or obstructive bowel disorders, such as

ulcers (peptic ulceration), small bowel obstruction (blockage of the bowel), etc,

- if you are using anaesthetics, hypnotics, sedatives, phenothiazines and alcohol as these may, in combination with STOPAYNE TABLETS, enhance impairment of judgement and coordination (feeling dizzy or drowsy). See "**Other medicines and STOPAYNE TABLETS"**.

Do not use STOPAYNE TABLETS for more than ten (10) days at a time without consulting your doctor. If you use STOPAYNE TABLETS for too long or continuously, it may cause dependency and addiction. This can give you withdrawal symptoms from the medicine when you stop taking it. See section 3 **"If you stop taking/using STOPAYNE TABLETS"**.

STOPAYNE TABLETS contains paracetamol, which my may be fatal or cause severe liver damage in overdose. Contact the nearest doctor, hospital or poison centre immediately following overdose or suspected overdose. See section 3, "**If you take more STOPAYNE TABLETS than you should".**

The dosage of STOPAYNE TABLETS should be reduced in the elderly and in weakened (frail) patients.

Children

No data are available on the use of STOPAYNE TABLETS in children.

Other medicines and STOPAYNE TABLETS

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

STOPAYNE with food, drink and alcohol

Alcohol may increase the effects of STOPAYNE TABLETS, and your doctor may wish to monitor you carefully if you are using alcohol regularly or have a problem with alcohol abuse.

Pregnancy and breastfeeding

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 STOPAYNE TABLETS.

STOPAYNE TABLETS is, however, not recommended for use by pregnant or breastfeeding women.

Driving and using machines

It is not always possible to predict to what extent STOPAYNE TABLETS may interfere with your daily activities. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which STOPAYNE TABLETS affects them. STOPAYNE TABLETS, however, may cause drowsiness and care should be taken when driving or operating machinery.

STOPAYNE TABLETS contains lactose monohydrate

Lactose monohydrate may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take STOPAYNE TABLETS.

STOPAYNE TABLETS contains Sunset yellow FCF, E110 (colouring agent)

May cause allergic type reactions (including asthma attack) in certain individuals.

3. How to take STOPAYNE TABLETS

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

Always take STOPAYNE TABLETS exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual adult dose of STOPAYNE TABLETS is two tablets three to four times a day as required.

Take the tablets with a sufficient quantity of liquid (e.g., one glass of water).

Your doctor will tell you how long your treatment with STOPAYNE TABLETS will last. However, it is not recommended to use continuously for more than ten days. If you have the impression that the effect of STOPAYNE TABLETS is too strong or too weak, tell your doctor or pharmacist.

If you take more STOPAYNE TABLETS than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage. Specialised treatment is essential as soon as possible.

Symptoms

The most common symptoms of STOPAYNE TABLETS overdosage is nausea and vomiting. Additional symptoms resulting from meprobamate may include stupor (state of speechlessness, motionlessness, and unresponsiveness to stimulation, but are otherwise completely conscious), coma, convulsions (fits), shock, problems with your blood vessels (circulatory collapse) and breathing (respiratory system/respiratory collapse).

Symptoms of paracetamol overdosage in the first 24 hours include pallor (unhealthy pale appearance), nausea, vomiting, loss of appetite and possibly abdominal pain. Mild symptoms during the first two days of acute poisoning do not reflect the potential seriousness of the overdosage. Liver damage may lead to brain damage, coma and death. Kidney failure may develop even in the absence of sever liver damage and

heart rhythm problems (arrhythmias) have also been reported.

If you forget to take / missed a dose of STOPAYNE TABLETS

If you miss a dose, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

If you stop taking/using STOPAYNE TABLETS

This medicine contains codeine and meprobamate and can cause addiction if you take it continuously for more than ten days. When you stop taking it you may get withdrawal symptoms. You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms.

4. Possible side effects

STOPAYNE TABLETS can have side effects.

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

If any of the following happens, stop using STOPAYNE TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- skin rashes, urticaria (red, itchy welts that result from a skin reaction) and purpura (blood spots, which are purple-coloured spots on the skin),
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- erythema multiforme (skin or mouth lesions that have a pink-red centre surrounded by a pale ring border and an outer pink-red ring).

These are all very serious side effects. If you have them, you may have had a serious reaction to STOPAYNE TABLETS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- Mood changes,
- Drowsiness, confusion, vertigo (feeling off balance), orthostatic hypotension (a sudden drop in blood pressure when you stand from a seated or lying down position) and raised intracranial pressure (rise in pressure around your brain),
- Caffeine may cause restlessness, excitement, muscle tremor (spasms or twitching),
- Meprobamate may cause drowsiness, paraesthesia (tingling or pricking / “pins and needles”), weakness, headache, excitement, dizziness, ataxia (slurred speech, stumbling, falling, and incoordination),
- Miosis (constriction of the pupils / small pupils) and scintillating scotoma (visual aura or blind spot that affects a part of your vision), other vision disturbances,
- Ringing or buzzing noise in one or both ears,
- Codeine may cause nausea, vomiting, constipation, and dry mouth,
- Caffeine increases gastric secretions (such as stomach acid) and may cause stomach ulcers,
- Sweating, facial flushing (blushing), urticaria (skin rash) and pruritus (unpleasant itch),
- Difficulty in urination, spasms in urinary tract causing lower abdominal pain, spasm is the bile duct causing upper abdominal pain,
- Drop in body temperature (hypothermia),
- Tachycardia (rapid heartbeat), extrasystoles (skipped heartbeats). Hypotension (low blood pressure), cardiac arrhythmias (improper heartbeat),
- Blood disorders including agranulocytosis (lowered white blood cell count), eosinophilia (high level of white blood cells), leukopenia (low level of white blood cells), thrombocytopenia (low blood plate count) and aplastic anaemia (a rare condition in which the body stops producing enough new blood cells).
- Skin and subcutaneous tissue disorders (see above hypersensitivity reactions that may occur).

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of STOPAYNE TABLETS.

5. How to store STOPAYNE TABLETS

Store all medicines out of reach of children.

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

Do not use after the expiry date stated on the box, blister or HDPE bottle.

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 STOPAYNE TABLETS contains

The active substances are meprobamate (150 mg), codeine phosphate (8 mg), paracetamol (320 mg) and caffeine anhydrous (32 mg).

The other ingredients of STOPAYNE TABLETS are:

Brilliant blue FCF (E133), gelatine, lactose monohydrate, magnesium stearate, povidone, pregelatinised starch, purified talc, quinoline yellow (E104), sodium starch glycolate, sunset yellow FCF (E110).

What STOPAYNE TABLETS looks like and contents of the pack

Light green, round biconvex tablets, scored on one side and RIO embossed on the other side.

STOPAYNE TABLETS is packaged into PVC/PVDC/Aluminium blister strips in an outer carton, or in white HDPE bottles with white HDPE screw caps.

Pack sizes: 100 or 1 000 tablets. Not all pack sizes may be marketed.

Holder of Certificate of Registration

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