PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

PYNSTOP

Each tablet contains:

Codeine phosphate 10 mg

Doxylamine succinate 5 mg

Paracetamol 450 mg

Caffeine 45 mg

Sugar free

What is in this leaflet

1. What PYNSTOP is and what it is used for

PYNSTOP contains codeine phosphate, doxylamine succinate, paracetamol and caffeine which belongs to a group of medicines referred to as analgesic combinations (pain, fever and allergic medication). PYNSTOP is used for the symptomatic relief of mild to moderate pain and pain associated with tension and fever.

2. What you need to know before you take PYNSTOP

Do not take PYNSTOP:

- If you are hypersensitive (allergic) to codeine phosphate, doxylamine succinate, paracetamol and caffeine, or any of the other ingredients of PYNSTOP tablets (listed in section 6).

- If you have severe liver function impairment.
- if you have been told by your doctor that you have a metabolic disorder called acute intermittent porphyria. Signs include severe abdominal pain, constipation or diarrhoea, nausea and vomiting, and pain in your chest, legs or back.
- If you have respiratory depression.
- If you have bronchial asthma.
- If you have lung disease, that could lead to heart failure.
- If you have head injuries in which intracranial pressure is raised.
- If you have acute alcoholism.
- If you have just had a biliary tract operation.
- if you are taking a medicine of the class known as Monoamine Oxidase Inhibitors (MAOIs, e.g. selegiline, moclobemide), which are used as antidepressants, or if you had taken any medicine of this group in the past 14 days.
- if you have been told by your doctor that you are a patient who is known to break down (metabolize) medications very quickly due to a specific enzyme (CYP2D6 ultra-rapid metabolisers)
- if your liver function is severely impaired.
- If your child is under the age of 12 years old.
- If you are breastfeeding.
- If you are in third trimester of pregnancy.
- For pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome.

Warnings and Precautions

PYNSTOP contains codeine, which is an opioid medicine.

Repeated use of PYNSTOP may result in you becoming accustomed to it (needing to take higher doses). Repeated use of PYNSTOP may also lead to dependence, abuse and addiction, which may result in life-threatening overdose.

If you experience any of the following signs whilst taking PYNSTOP, talk to your doctor or pharmacist as it could be an indication that you are dependent or addicted.

- You need to take this medicine for longer than advised
- You need to take more than the recommended dose
- You are using this medicine for reasons other than medical reasons, for instance, 'to stay calm' or to 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of this medicine
- When you stop taking this medicine you feel unwell, and you feel better once taking this medicine again ('withdrawal effects')

Special care should be taken with PYNSTOP:

- As this product 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.
- Do not use for more than ten days without consulting a doctor.
- As exceeding the prescribed dose, together with prolonged and continuous use of this medication may lead to dependence and addiction.
- If you have liver and kidney disease, consult your health care practitioner.
- As dosages in excess of those recommended may cause severe liver damage.
- if you have high blood pressure or any heart problems.
- if you have trouble to pass urine.
- If you have a history of peptic (stomach) ulceration.
- If you are epileptic.
- if you suffer from myasthenia gravis, a condition which weakens the muscles.

- If you have glaucoma and prostatic hypertrophy.
- if you are elderly or you are physically weak as your dosage may need to be reduced.
- If you have low thyroid function, Addison's disease (low levels of cortisol or aldosterone hormones), liver damage, enlarged prostate or shock.
- If you have inflammatory or obstructive bowel disorders.
- if you have had a recent operation on the gastrointestinal tract.
- if you have gall stones.
- If you are an epileptic and you suffer from seizures.
- If you have a history of alcohol or drug abuse
- If you under psychiatric treatment;
- if you are taking a benzodiazepine (used for treatment of anxiety or sleep disorders), e.g. diazepam, clobazam, lorazepam, chlordiazepoxide, oxazepam, temazepam, nitrazepam, loprazolam, lormetazepam or clonazepam
- if you have low glutathione reserves
- if you have Glucose-6-phosphate-dehydrogenase deficiency
- if you have Gilbert's syndrome
- if you have chronic constipation
- if you suffer from life threatening skin reactions such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN).
- if you develop a red, scaly widespread rash with bumps under the skin and/or blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the start of treatment (acute generalized exanthematous pustulosis).
- if you develop a skin rash, swelling of lymph nodes and increase of eosinophils (a type of white blood cells). This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
- if you develop or have a history of Fixed Drug Eruptions (FDE) (may look like round or oval patches and swelling of the skin), blistering (hives), itching.
- Tolerance dependence, and addiction: Increased risk of addiction in patients with personal or family history of substance abuse or mental health disorders.

- Opioid Induced Hyperalgesia: Taking a high dose of opioid medications can paradoxically induce or sensitise patients to acute pain, this condition is called opioid-induced hyperalgesia. The type of pain experienced might be the same as or different from the original underlying pain, and in some cases, patients may experience pain from ordinarily non-painful stimuli (allodynia).
- Use in children with breathing problems: Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.
- If no relief is obtained from the recommended dosage as you should consult a doctor.
- Due to its codeine content, you should not take PYNSTOP Tablets if you have any respiratory problems.

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces pain relief. Some people have a variation of this enzyme and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief. Other people are more likely to get serious side effects because a very high amount of morphine is produced.

If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness,
small pupils, feeling or being sick, constipation, lack of appetite.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Children and adolescents

Do not give PYNSTOP to children under the age of 12 years.

Other medicines and PYNSTOP

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

Do not take this medicine and tell your doctor or pharmacist, if you are taking

- Medicines to treat depression called MAOIs (monoamine oxidase inhibitors) or have recently taken them in the last two weeks. MAOIs are medicines such as moclobemide, phenelzine,

tranylcypromine.

Tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines:

- Metoclopramide, domperidone used to treat nausea and vomiting.
- Medicines used to thin the blood such as warfarin (or other coumarins).
- Medicines which make you drowsy or sleepy (CNS depressants) (e.g. barbiturates, anaesthetics, hypnotics, other opioid analgesics, anxiolytic sedatives, antipsychotics, tricyclic antidepressants and phenothiazines) or a benzodiazepine used to treat anxiety or sleep disorders.
- Medicines for the treatment of high blood pressure (diuretics and antihypertensives).
- Medicines to treat or prevent clinical depression (antidepressants).
- Medicines used to treat mental distress or disorder (antipsychotics).
- Any of the group called antimuscarinics (e.g. atropine, hyoscine).
- Any of the group called neuromuscular blockers (e.g. tubocurarine).
- Cholestyramine used for lowering blood cholesterol levels.
- Hydroxyzine used to treat anxiety and tension.
- Mexiletine used to treat irregular heartbeat.
- Kaolin or loperamide used for the treatment of diarrhoea.
- Naloxone used to treat a narcotic overdose.
- Naltrexone used as part of a treatment program for drug or alcohol dependence.
- Cimetidine used to treat stomach ulcers.
- Cisapride used to treat gastro-oesophageal reflux disease.
- Quinidine used to treat irregular heart rate.
- Theophylline – used for wheezing or difficulty in breathing.
- Medicines for infections (antibiotics) such as enoxacin, ciprofloxacin, rifampicin and flucloxacillin.
- The oral contraceptive pill.
- Cinacalcet – to treat thyroid problems.
- Methadone – used for treating drug (opioid) dependence and severe chronic pain.

Concomitant use of opioids and benzodiazepines increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, you should only take these together if prescribed by a doctor. Please follow your doctor's dosage recommendation closely.

PYNSTOP with food and drink and alcohol

PYNSTOP should not be taken together with alcohol. The combined effect can cause major drowsiness and severely impaired breathing, concentration, vision, speech and alertness.

Avoid drinking too much coffee, or other drinks containing caffeine, while taking PYNSTOP.

Pregnancy, breastfeeding and fertility

PYNSTOP should not be used during pregnancy or when 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 this medicine.

Driving and using machines

Patients should be warned particularly at the start of therapy, against driving vehicles, using machinery or performing potentially hazardous tasks where loss of concentration may lead to accidents and injury.

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

PYNSTOP contains sodium starch glycolate

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take PYNSTOP

Always take PYNSTOP exactly as described in this leaflet, or as your doctor or pharmacist has told you.

You should check with your doctor or pharmacist if you are unsure.

Adults and children over 12 years:

Take one or two tablets every four hours (up to six times a day), only if necessary.

Do not take more than eight tablets in twenty-four hours.

DO NOT EXCEED THE RECOMMENDED DOSE.

If you take more PYNSTOP than you should

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

Signs of overdose may include unusually pale skin, nausea, vomiting, loss of appetite, abdominal pain, pupils that may be pin-point in size, a difficulty in breathing, an increased or irregular heart rate, and loin (kidney) pain.

• Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

• Remember to take any remaining tablets and the pack with you. This is so the doctor knows what you have taken.

If you forget to take PYNSTOP

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

4. Possible side effects

PYNSTOP can have side effects.

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

If any of the following happens, stop taking/giving PYNSTOP 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.

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

- low number of white blood cells. Signs include: fever, chills, sore throat;
- low number of cells involved with blood clotting. Signs include: more or worse bruises than normal, small purple or red dots under your skin, nosebleeds or bleeding gums, black or bloody-looking bowel movements, red or pink urine;
- an excessive breakdown of red blood cells causing a type of anaemia. Signs include: tiredness, headaches, shortness of breath, dizziness, looking pale and yellowing of the skin and the whites of the eyes;
- low number of red blood cells, white blood cells and cells involved with blood clotting. Signs include: weakness, tiredness, skin problems such as rashes or bruising, rapid heart rate, shortness of breath;
- changes in mood, anxiety, feeling depressed, confusion;
- perceptions of having seen, heard, touched, tasted or smelled something that wasn't actually there;
- seizures;
- slowing down of the central nervous system. Signs include: slower heart rate and breathing, extreme confusion and memory loss and poor judgement;
- increased pressure in the head. Signs include headache, blurred vision, feeling less alert than usual and vomiting;
- blurred vision, constriction of the pupil of the eye;
- ringing in the ears;
- changes in the way your heart beats, drop in blood pressure when standing up making

(causing light-headedness or fainting);

- yellowing of the skin, whites of the eyes and mucous membranes (jaundice);
- difficulty in urinating, inability to empty all the urine from your bladder;
- sudden drop in body temperature;
- skin rash or itching, which may include redness, hives (red itchy bumps), blisters, pustules or peeling of the skin (Toxic Epidermal Necrolysis) and bleeding in the lips, eyes, mouth, nose and genitals (Toxic Epidermal Necrolysis or Stevens-Johnson Syndrome);
- a red, scaly, widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (Acute Generalised Exanthematous Pustulosis);
- a severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells);
- Fixed Drug Eruptions (FDE) (may look like round or oval patches of redness and swelling of the skin), blistering (hives), itching.
- PYNSTOP, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

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:

- Insomnia, deep sleep, drowsiness, sedation, lassitude (physical or mental weariness),
- Incoordination,
- Dry mouth,
- Nervousness,
- Tremors, convulsions,

- Facial flushing.

Less frequent side effects:

- Abdominal pain including risk of inflammation of pancreas, which causes severe pain in the abdomen and back.

Frequency not known:

- Restlessness,
- sores in the mouth,
- Decreased libido,
- Lack of energy,
- Sensitivity to light,
- Tingling or prickling, “pins-and-needles” sensation in the arms, hands, legs or feet,
- Involuntary shaking of the hands, legs, face, head or vocal cords,
- Thick phlegm,
- Heartburn, diarrhoea, stomach pain, painful muscles,
- Fever,
- Hair loss,
- Reddening of the face,
- Allergy/anaphylaxis,
- Sweating,
- Gastrointestinal disturbances, increases in gastric secretions and gastric ulceration,
- Pain in lower back area,
- Pus in the urine,
- Constipation.

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 PYNSTOP.

You may also report to Adcock Ingram Limited using the following email:

Adcock.AEReports@adcock.com

5. How to store PYNSTOP

Store at or below 25 ºC.

Protect from light and moisture.

Do not remove the blister pack from the outer carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What PYNSTOP contains

PYNSTOP contains the active ingredient codeine phosphate 10 mg, doxylamine succinate 5 mg, paracetamol 450 mg and caffeine 45 mg.

The other ingredients are: colour lake blend PB-21082 green, gelatin, maize starch, magnesium stearate, purified talc, sodium starch glycolate.

What PYNSTOP looks like and contents of the pack

Green, circular, flat-faced and bevel edged tablet with score line on one side.

18, 20 and 40 tablets in PVC/Aluminium foil blister packs.

All pack sizes may not be marketed simultaneously.

Holder of Certificate of Registration

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This leaflet was last revised in

04/03/2026

Registration number (s)

C/2.8/233

Namibia: NS1 90/2.8/00166

Botswana: B9309275 S3