

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

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

PYNSTOP is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use PYNSTOP carefully to get the best results from it.

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

What is in this leaflet:

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

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 medicine referred to as analgesic combinations(pain ,fever and allergic medication).

PYNSTOP is used for the symptomatic relief of mild to moderate pain associated with tension and fever.

2. What you need to know before you take PYNSTOP tablets

Do not take PYNSTOP

- If you are allergic to codeine phosphate, doxylamine succinate paracetamol and caffeine, or any of the other ingredients of PYNSTOP tablets (listed in section 6.1).
- If you have severe liver function impairment
- If you have respiratory depression
- If you have bronchial asthma
- If you have lung disease could lead to heart failure
- If you have head injuries
- If you have acute alcoholism
- If you have just had a biliary tract operation.
- If you are under the age of 12 years

Warnings and precautions

Special care should be taken with PYNSTOP:

- 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 doctor, hospital or Poison Centre must be contacted immediately.
- Exceeding the prescribed dose, together with prolonged and continuous use of this medication may lead to dependence and addiction.
- If you are taking monoamine oxidase inhibitors or within 14 days of stopping such treatment.
- If you have a history of peptic ulceration.
- If you are epileptic.
- If you have glaucoma and prostatic hypertrophy
- Do not use for more than ten days without consulting a doctor.
- If no relief is obtained from the recommended dosage consult a doctor.
- Dosages in excess of those recommended may cause severe liver damage
- If you have liver and kidney disease, consult your health care practitioner.

Children and adolescents

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

Other Medicines and PYNSTOP

Always tell your healthcare professional if you are taking any other medicine, including complementary or traditional medicines.

This medicine may lead to drowsiness and impaired concentration that may be aggravated by simultaneous intake of alcohol or other central nervous system depressants.

Doxylamine succinate may enhance the sedative effect of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers.

The depressant effects of codeine are enhanced by depressants of the central nervous system such as alcohol, anaesthetics, hypnotics and sedatives.

PYNSTOP with food and drinks

No known interactions with food and drink.

Pregnancy, breastfeeding and fertility

Safety in fertility, pregnancy and lactation has not been established.

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 professional for advice before taking this medicine.

Driving and using machines

Patients should be warned against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration may lead to accidents.

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 do not engage in the above activities until they are aware of the measure to which PYNSTOP affects them.

3. How to take PYNSTOP

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

Always take PYNSTOP exactly 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:

The recommended initial dose is one or two tablets every four hours if necessary.

Tablets to be taken with food or after meals with enough water.

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

If you take more PYNSTOP than you should

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

The most likely symptoms of overdosage are stomach pain and nausea and vomiting.

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 advise.

Tell your doctor immediately if you notice any of the following:

Frequent:

- insomnia, deep sleep, drowsiness
- confusion, inability to concentrate
- incoordination, dizziness, light headedness

- headache,
- dry mouth,
- nervousness,
- tremors, convulsions
- facial flushing

Frequency not known:

- Skin rashes
- muscular weakness and twitching
- pain in lower back area, puss in the urine, difficulty passing urine
- slow pulse or palpitations (irregular heart beat)
- drop in blood pressure upon standing causing light-headedness, facial flushing and vertigo (dizzy spells)
- constipation, nausea, vomiting, diarrhoea or dry mouth.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. 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 PYNSTOP.

May also report to Adcock Ingram Limited using the following email:

Adcock.AEReports@adcock.com

5. HOW TO STORE

Store at or below 25 °C.

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 it contains:

PYNSTOP contains the active ingredient Codeine phosphate 10 mg, Doxylamine succinate 5 mg, paracetamol 450 mg, caffeine 45 mg.

The other ingredients are: Colour Lake blend PB-21082 green, Gelatine, Maize starch, Magnesium stearate, Purified talc, Sodium starch glycolate.

What PYNSTOP looks like and contents of the pack

Green, circular, flat tablet with score line on one side and a diameter of 12,7 mm.

18, 20 and 40 in PVC/Aluminium foil blister packs. White polypropylene securitainers with white LDPE (low density polyethylene) closures containing 50 and 100 tablets. All pack sizes may not be marketed simultaneously.

Holder of Certificate of Registration

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N/A new leaflet (Approved on 01 October 2021).

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Access to the corresponding professional information

It is contained in the packaging of the medicine.

Namibia: NS1 90/2.8/00166

Botswana: B9309275 S3
