1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

PYNSPAS 150 mg/500 mg tablet

Mephenesin and paracetamol

Sugar free

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share PYNSPAS 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.

What is in this leaflet

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

1. What PYNSPAS is and what it is used for

PYNSPAS is used for generalised pain associated with tension.

2. What you need to know before you take PYNSPAS

Do not take PYNSPAS:

- If you are hypersensitive (allergic) to mephenesin, paracetamol or any of the other ingredients of PYNSPAS (listed in section 6).
- If you have problems with your kidneys and/or liver.
- If you are pregnant or breastfeeding.

Warnings and precautions

Take special care with PYNSPAS:

- Serious skin reactions have been reported in association with PYNSPAS treatment. You should stop taking PYNSPAS and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction (see section 4).
- You should not exceed the recommended dose. Consult a healthcare provider if no relief is obtained from the recommended dosage and if pain associated with tension becomes persistent.
- If you suffer from non-serious arthritis and need to take painkillers every day, consult your doctor before taking PYNSPAS.
- If you are using any other medicines containing paracetamol for example other pain medication or medication to treat colds and flu.

Children and adolescents

There is no experience with PYNSPAS in children and adolescents.

Other medicines and PYNSPAS

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:

- Barbiturates, medicines used to treat epilepsy/seizures.
- Other pain killers referred to as opioids.
- Warfarin, used for thinning of your blood.
- Alcohol.
- Medicines such as colestyramine to treat high cholesterol. Colestyramine should not be taken within one hour of PYNSPAS if maximal pain relief is required.
- Metoclopramide and domperidone, medicines used as an anti-nausea medicine.
- Chloramphenicol, a medicine used to treat bacterial infections.
- Flucloxacillin, a medicine used to treat bacterial infections, especially if your kidneys are not functioning properly, if you have an infection that has spread throughout your body and blood, if you lack proper nutrition or if you are misusing alcohol regularly.

Pregnancy, breastfeeding and fertility

You should not take PYNSPAS if you are pregnant or breastfeeding your baby.

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 PYNSPAS.

Driving and using machines

PYNSPAS may influence your ability to drive as it may cause drowsiness. You should not drive, use machinery or perform any tasks that require concentration until you are certain that PYNSPAS does not adversely affect your ability to do so safely (see section 4).

It is not always possible to predict to what extent PYNSPAS 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 PYNSPAS affects you.

PYNSPAS contains sodium

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

3. How to take PYNSPAS

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

DO NOT EXCEED THE RECOMMENDED DOSE.

Always take PYNSPAS exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.

Adults (18 years and older):

Take one to two tablets every four hours. Do not take more than eight tablets per day.

Consult a healthcare provider if no relief is obtained with the recommended dosage.

Do not use continuously for more than 10 days without consulting a doctor.

Your doctor will tell you how long your treatment with PYNSPAS will last. If you have the impression that the effect of PYNSPAS is too strong or too weak, tell your doctor or pharmacist.

If you take more PYNSPAS than you should

PYNSPAS contains paracetamol which may be fatal in overdose. In the event of overdosage, immediately consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of paracetamol overdosage in the first 24 hours include pale skin colour, nausea, vomiting, lack/loss of appetite and possibly abdominal pain.

Talk to a healthcare provider 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.

If you forget to take PYNSPAS

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

4. Possible side effects

PYNSPAS can have side effects.

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

If any of the following happens, stop taking PYNSPAS 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, itching, red or skin-coloured welts on the skin's surface,

- fainting,
- wheezing or shortness of breath (bronchospasm),
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) or Acute Generalised Exanthematous Pustulosis (AGEP).

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

- Yellowing of skin or the whites of your eyes as this could be signs of problems with your liver (hepatic dysfunction),
- upper abdominal pain, abdominal pain that radiates to the back, tenderness when touching the abdomen which might be signs of inflammation of the pancreas (acute pancreatitis),
- changes in the way your heart beats, for example, if you notice it beating faster (tachycardia),
- fever, chills, swelling, sore throat, fatigue, which may be signs of an infection due to low white blood cell count (leucopenia, agranulocytosis, neutropenia),
- any unusual or unexplained bruising or bleeding due to a low blood platelet count (thrombocytopenia),
- weakness, bruising or increased likelihood of an infection due to too few blood cells of all types (pancytopenia),

- decreased number of red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side effects with an unknown frequency:

- Decreased appetite (anorexia), nausea, vomiting, abdominal pain,
- drowsiness,
- low blood pressure,
- mental weakness, lack of energy (lassitude).

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

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

5. How to store PYNSPAS

Store all medicines out of reach of children.

Store or at below 25 °C.

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 PYNSPAS contains

The active ingredients are 150 mg mephenesin and 500 mg paracetamol.

The other ingredients are calcium hydrogen phosphate anhydrous, carmellose sodium (sodium carboxymethyl cellulose), colloidal anhydrous silica (aerosil 200), maize starch B, magnesium stearate, purified talc, sodium starch glycolate.

Sugar free

Sodium 1,31 mg

What PYNSPAS looks like and contents of the pack

PYNSPAS is a round, white to off-white, flat bevelled edged, bisected uncoated tablet debossed with 'F' and '41' on either side of bisect and plain on the other side.

24 tablets (3 x 8's or 2 x 12's) are packed in a clear rigid PVC film coated with PVdC and plain aluminium foil. Blister strips are packed in an outer cardboard carton.

100 tablets are packed in a white HDPE bottle with a screw cap with induction wad.

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:

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