PATIENT INFORMATION LEAFLET FOR PYRACET 125 & 250

SCHEDULING STATUS

S2

PYRACET 125 mg and 250 mg Suppositories

Paracetamol

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share PYRACET with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your or your child's symptoms worsen or do not improve after 3 days.

What is in this leaflet

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1. What PYRACET is and what it is used for

A suppository is a small, cone-shaped medicine which is inserted into the back passage (rectum).

PYRACET contains a medicine called paracetamol. This belongs to a group of medicines called pain-killers (analgesics).

PYRACET is used for the relief of mild to moderate pain and to reduce fever.

2. What you need to know before you use PYRACET

Do not use PYRACET:

- If you are or your child is allergic (hypersensitive) to paracetamol or any of the other ingredients of the suppositories (listed in section 6).

Warnings and precautions

Take special care with PYRACET and tell your doctor or pharmacist:

- If you are or your child is recovering from any liver disease or suffering from hepatitis.
- If you have or your child has kidney disease.
- If you or your child are also using medicines impairing the liver function.
- If you or you child has hereditary deficiency of the enzyme glucose-6-phosphate dehydrogenase, which can lead to severe anaemia, also called favism.
- In case of haemolytic anaemia (anaemia due to red blood cell disintegration).
- In case of deficiency of the protein involved in liver metabolism, glutathione (for example malnutrition, alcohol abuse).
- In case of a lack of fluid in the body (dehydration) e.g. due to drinking too little fluids, diarrhoea or vomiting.
- In case of chronic malnutrition.
- If you are elderly and weigh less than 50 kg.
- If you or your child have diseases associated with reduced glutathione levels (dose adjustment e.g. in diabetes mellitus, HIV, Down’s syndrome, tumours (cancers), if applicable).
- Consult your doctor if pain or fever gets worse at the recommended dose, if new symptoms

appear or if redness and swelling is present as these could be a sign of a more serious condition.

- Do not use PYRACET continuously without consulting a medical practitioner:
  - For pain - for more than 5 days.
  - For fever - for more than 3 days.
- This product contains paracetamol which may be fatal in overdose. In the event of over dosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.
- To avoid the risk of over dosage, it must be ensured that you do not take or your child does not receive any other products containing paracetamol.
- High fever, evidence of secondary infection and symptoms persisting for more than 3 days should receive medical attention.

The prolonged improper use of large doses of pain killers may cause headache which must not be treated with increased doses of PYRACET.

In general, the usual use of painkillers, above all of those containing more than one active ingredient, may lead to permanent damage to the kidney, which might result in kidney failure (analgesic nephropathy). Headache, tiredness, muscular pain, nervousness and vegetative symptoms may result from the sudden removal of pain killers taken in large amounts for extended periods of time or not used properly. Such withdrawal symptoms decrease after a few days.

No pain killer should be taken within this period. A medical practitioner should be consulted before resuming treatment.

PYRACET should not be used for long periods of time or in large doses without medical advice.

Immediate medical advice should be sought in the event of an overdose, even if you or your child seems well, because of the risk of delayed, serious liver damage.

Other medicines and PYRACET

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

This is because PYRACET can affect the way some medicines work and some medicines can have an effect on PYRACET.

Tell your doctor or pharmacist if you or your child are taking any of the following:

- Other medicines that contain paracetamol – do not use or give your child PYRACET at the same time.
- Other potentially liver-damaging medicines - liver damages may possibly occur if PYRACET is used together.
- Barbiturates (a type of sedative).
- Carbamazepine (medicines for epilepsy or fits, also called ‘anti-convulsants’).
- Warfarin (used for treating blood clots).
- Chloramphenicol (a medicine used to treat bacterial infections).
- Probenecid (a medicine used to prevent gout and, occasionally, to increase blood levels of the antibiotic penicillin).
- Metoclopramide (used to treat and prevent nausea and vomiting).
- Cholestyramine (used to lower high levels of cholesterol in the blood).
- Rifampicin (medicines to treat tuberculosis).
- St. John’s wort (used to treat depression or attention-deficit hyperactivity disorder (ADHD)).
- Zidovudine (used to treat HIV infection). These medicines increase the patient’s chance to develop neutropenia (decrease in the number of white blood cells). PYRACET should therefore not be used in combination with zidovudine without seeking the advice of your doctor.

Effects of PYRACET on laboratory tests:

PYRACET may affect laboratory tests such as the uric acid test and the determination of blood sugar levels.

PYRACET with food, drink and alcohol

Do not take alcohol, or use any medicines containing alcohol, while using these suppositories.

Pregnancy, breastfeeding and fertility

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 using this medicine.

Driving and using machines

This medicine may cause tiredness. You should not drive a vehicle or operate machinery until you know how PYRACET affects you.

3. How to use PYRACET

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dose of PYRACET depends on the patient's age and body weight. The usual single dose is 10 to 15 mg/kg, the maximum daily dose 60 mg/kg body weight.

The dosage interval depends on the symptoms and the maximum daily dose. It should be at least 6 hours.

The usual dose is:

Infants (6 months to 2 years):

One 125 mg suppository up to 4 times daily.

Children (2 years to 8 years):

One 250 mg suppository up to 4 times daily.

How to insert a suppository:

- Ensure that the suppository feels hard in its wrapper. If it feels soft, hold the sealed wrapper in cold water until it hardens.
- Remove the outer wrapper.
- Lay your child on their left side and raise the right knee to their chest.
- Insert the suppository; tip first, into the rectum for 1–2 cm. Hold in place for a few seconds.

Duration of treatment:

If symptoms persist for more than 3 days you should seek medical attention.

Special patient groups

Disorders of liver function and slightly impaired kidney function:

In patients with disorders of liver or kidney function or Gilbert's syndrome, the dose of PYRACET should be reduced and the dosage interval should be increased. A total daily dose of 2 g must not be exceeded without medical advice.

Severe kidney failure:

In the presence of severe kidney failure (GFR < 30 mL/min), the dosage interval should be at least eight hours.

Elderly patients:

Experience has shown that no special dose adjustment is required.

However, in weakened, immobilised elderly patients with impaired hepatic or renal function, a dose reduction or prolongation of the dosing interval may be required.

Without medical advice, the maximum daily dose of 60 mg/kg body weight (up to a maximum of 2 g/day)

should not be exceeded with:

- Body weight less than 50 kg
- Chronic alcoholism
- Dehydration
- Chronic malnutrition

Children and adolescents with low body weight:

The use of PYRACET 125 suppositories in children below the age of six months or weighing less than 7 kg, or PYRACET 250 in children under two years or weighing less than 13 kg, is not recommended.

If you have the impression that the effect of PYRACET is too strong or too weak, tell your doctor or pharmacist.

If you give more PYRACET to your child or use more than you should

Do not give your child or use more suppositories than you should. Immediate medical advice should be sought in the event of an overdose, even if you or your child seems well, because of the risk of delayed, serious liver damage. You or your child may need to have a blood test to check how well the liver is working.

Nausea, vomiting, lack of appetite, pale skin and abdominal pain may occur within 24 hours after overdosing.

If you forget to give PYRACET to your child or use PYRACET

If you forget to use or give your child a dose of PYRACET, do so as soon as you remember.
However, if it is almost time for the next dose, skip the missed dose. Do not use or give your child a double dose (two doses at the same time) to make up for a forgotten dose.

4. Possible side effects

PYRACET can have side effects.

Not all side effects reported for PYRACET are included in this leaflet. Should your or your child's general health worsen or if any untoward effects are experienced while using PYRACET, please consult your health care provider for advice.

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you or your child has them, there may have been a serious reaction to PYRACET. You or your child 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:

- Severe and dangerously low white blood cell count when blood is tested.
- Slow and ineffective breathing.
- Difficulty breathing and wheezing due to constriction of the airways.
- Yellowing of the skin and eyes, dark coloured urine, feeling tired or weak, nausea (feeling sick) which may be symptoms of liver inflammation, liver damage or death of liver cells (blood tests might be necessary to check how well the liver is working).
- Serious skin reactions, sometimes with fever and mouth sores.
- Sharp, intense pain caused by kidney dysfunction, kidney failure, frequent urges to urinate, a burning sensation when urinating, blood in urine.
- Inflammation of the pancreas often with severe abdominal pain which may be symptoms of pancreatitis.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Tiredness, mild headache.
- Redness or soreness in or around the back passage (rectum).

Less frequent side effects:

- Discoloration of the skin resulting from bleeding underneath, typically caused by bruising, low platelet count (thrombocytopenia), low white blood cell count, low counts for red blood cells, white blood cells, platelets and neutrophils, deficiency in red blood cells (anaemia).
- Sleep disturbances, a feeling or state of intense excitement and happiness, medicine dependence after a long duration of treatment.
- Eczema (itchy inflammation of the skin), rash, urticaria (hives), swelling under the skin.
- Changes in liver enzyme levels when tests are done.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you or your child gets side effects, talk to your doctor or pharmacist.

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 PYRACET.

5. How to store PYRACET

Store all medicines out of reach of children.

Store at or below 25 ºC.

Store in the original package.

Do not use after the expiry date stated on the package.

Return all unused medicine to your pharmacist.

Do not dispose of unused suppositories in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PYRACET contains:

PYRACET 125: The active substance is 125 mg paracetamol.

PYRACET 250: The active substance is 250 mg paracetamol.

The other ingredient is hard fat.

What PYRACET looks like and contents of the pack

PYRACET 125: White or almost white suppository, homogeneous appearance, odourless or low odour characteristic of the mass.

PYRACET 250: White or almost white suppository, homogeneous appearance, odourless or low odour characteristic of the mass.

Suppositories are packed in PVC/PE strips, each one containing 6 suppositories.

Pack sizes: 12 Suppositories.

Holder of certificate of registration

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