

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

Empaped® 125 mg Suppositories

Empaped® 250 mg Suppositories

Paracetamol

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share EMPAPED® 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 symptoms worsen or do not improve after five days.

What is in this leaflet

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

1. What EMPAPED® is and what it is used for

EMPAPED® is a medicine relieving mild to moderate pain and reducing fever (analgesic and antipyretic), when oral treatment is not possible.

2. What you need to know before you use EMPAPED®

Do not use EMPAPED® suppositories:

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

Warnings and precautions

Take special care with EMPAPED®:

- if you or your child suffers from chronic alcoholism,
- if you have or your child has an impaired liver function (inflammation of the liver, Gilbert's syndrome),
- in case of pre-existing damage to the kidneys,
- with concomitant use of medicines impairing the liver function,
- in case of 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 low volume of fluids, diarrhoea or vomiting,
- in case of chronic malnutrition,
- with a body weight of less than 50 kg,
- at a higher age,

- in the presence of diseases associated with reduced glutathione levels (dose adjustment e.g. in diabetes mellitus, HIV, Down's syndrome, tumours (cancers), if applicable)

Under these circumstances, you should ask for your doctor's advice before you or your child uses EMPAPED®

You must contact a doctor if your symptoms or the symptoms of your child worsen or do not improve after 3 days or in case of high fever.

To avoid the risk of overdose, make sure that concurrently used medicines do not contain paracetamol.

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

In general, the habitual 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 renal failure (analgesic nephropathy).

Headache, tiredness, muscular pain, nervousness and vegetative symptoms may result from the abrupt removal of pain killers taken in large amounts for extended periods of time or not used properly. Such withdrawal symptoms subside after a few days.

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

EMPAPED® should not be used for long periods of time or in large doses without a medical practitioner's or a dentist's advice.

The single use of the total maximum daily dose may cause severe liver damage. In such cases, medical help should be sought immediately.

Always tell your health care provider if you or your child are taking any other medicine. (This includes all complementary or traditional medicines). The use of EMPAPED® with these medicines may cause undesirable interactions.

Please consult your doctor, pharmacist or other healthcare professional, for advice.

Medicine interactions are possible

- with medicines for the treatment of gout such as probenecid: The dose of EMPAPED® should be reduced, because its degradation can be delayed.
- with sleeping pills like phenobarbital,
medicines against epilepsy like phenytoin and carbamazepine,
medicines against tuberculosis (rifampicin),
other medicines which may have detrimental effects on the liver.

Liver damage may ensue if these medicines are used concurrently with EMPAPED®.

- with medicines used to lower elevated blood lipid levels (cholestyramine). These medicines may impair the uptake and the effect of EMPAPED®.
- with medicines against HIV infection (zidovudine). These medicines increase the patient's liability to develop neutropenia (decrease in the number of white blood cells). EMPAPED® should therefore not be used in combination with zidovudine without seeking the advice of your doctor.
- If you take warfarin (for thinning the blood), you can take occasional doses of this medicine, but talk to your doctor first before you take it on a regular basis.

- Adverse reactions on the kidneys can increase if EMPAPED[®] is used over a long period together with salicylates, such as aspirin.

Effects of EMPAPED[®] on laboratory tests:

EMPAPED[®] may affect laboratory tests such as the uric acid test and the determination of blood glucose.

Empaped[®] with food, drink and alcohol

EMPAPED[®] may not be used or given in combination with alcohol.

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 using this medicine.

Pregnancy

If necessary, EMPAPED[®] can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your fever, use it for the shortest time possible and not in combination with other medicines. Contact your doctor if the pain and/or fever are not reduced or if you need to use EMPAPED[®] more often.

Breastfeeding

Paracetamol enters human milk. Since harmful effects on the infant have not been observed, breastfeeding need not usually be stopped.

Driving and using machines

EMPAPED® has no influence on the ability to drive and use machines. Nevertheless, caution is advised after using any pain killer.

3. How to use EMPAPED®

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

Always use EMPAPED® exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. You should check with your doctor, pharmacist or nurse if you are unsure.

The dose of paracetamol 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 six hours.

The usual dose is:

Infants (6 months to 2 years):

One 125 mg suppository up to 4 times daily.

Children (2 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 foil wrapper. If it feels soft, hold the sealed wrapper in cold water until it hardens. (The suppositories may be warmed up in the hands or dipped briefly in warm water to improve their sliding properties).
- Remove the outer foil wrapper.

- Lay your child on his / her left side and raise the right knee to his / her chest.
- Insert the suppository; tip first, into the rectum for 1 – 2 cm. Hold in place for a few seconds.

Duration of treatment

EMPAPED® should not be used for more than three days without consulting a doctor.

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

Please tell your doctor or pharmacist if you feel that the effect of Empaped® is too strong or too weak.

If you use more EMPAPED® than you should

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

To avoid the risk of overdosage, make sure that no other product containing paracetamol is being used concurrently.

In children, the total daily dose must not exceed 60 mg paracetamol/kg body weight (see **Special patient groups** above).

In general, overdosage leads to nausea, vomiting, lack of appetite, paleness and abdominal pain within 24 hours.

Immediately seek medical assistance, if an amount exceeding the maximum dose of EMPAPED® has been used.

If you forget to use EMPAPED®

Give the next dosage as soon as you remember, and the following dosage more or less 6 hours thereafter. Do not give a double dose to make up for forgotten individual doses.

4. Possible side effects

EMPAPED® can have side effects.

If any of the following happens, stop using EMPAPED® 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 or shock

Side effects are reported with the following incidence rates:

Less frequent:

- mild increase in certain liver enzymes (serum transaminases)
- Changes to the blood count manifested as a decrease in the number of blood platelets (thrombocytopenia) or an intense decrease in white blood cells (agranulocytosis)
- Constriction of the airways in sensitive persons

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

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 get side effects, talk to your doctor, 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 EMPAPED®.

5. How to store EMPAPED®

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Do not use this medicine after the expiry date printed on the container.
- Keep the foil strips in the outer container.
- Do not store in a bathroom.

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 EMPAPED® contains

- The active substance is:

125 mg of paracetamol in each **EMPAPED® 125 mg** suppository

250 mg of paracetamol in each **EMPAPED® 250 mg** suppository

- The other ingredient is: hydrogenated fat

What EMPAPED® looks like and contents of the pack

White to ivory-coloured, torpedo-shaped suppositories of approximately 26 mm length.

Aluminium strips of 5 suppositories each. Available in packs of 10 suppositories.

Holder of Certificate of Registration**LITHA PHARMA (PTY) LTD**

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1686

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