

EMPAPED
Proposed Patient Information Leaflet

Read all of this leaflet carefully before you start using Empaped®

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after five days.

S2

Empaped® 125 mg Suppositories

Empaped® 250 mg Suppositories

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 ingredients are:

hard fat and soya lecithin

WHAT EMPAPED® IS USED FOR

Empaped® is a medicine relieving mild to moderate pain and reducing fever (antipyretic and analgesic)

BEFORE YOU USE EMPAPED®

Do not use Empaped® suppositories:

- If the child is hypersensitive (allergic) to paracetamol or to any of the other ingredients of the suppositories.
- If the child has serious impaired liver function (e.g. inflammation of the liver)
- If the child has Gilbert's syndrome

Take special care with Empaped®:

- If the child is recovering from any liver disease or suffering from hepatitis.
- If the child has renal disease.
- 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 **Empaped®** 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 the child does not concomitantly use any products containing paracetamol
- High fever, evidence of secondary infection and symptoms persisting for more than 3 days should receive medical attention.

Using Empaped® with other medicinal products:

If the child is taking other medicines on a regular basis, including 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.

Interactions may occur with:

- medicines for the treatment of gout like probenecid. With the concomitant use of probenecid the dosage of Empaped® should be reduced, because the degradation of Empaped® could be slowed down
- medicines to treat epilepsy (seizures), carbamazepine
- medicines to treat tuberculosis, (rifampicin)

- other potentially liver-damaging medicines

Liver damages may possibly occur if Empaped® is taken concomitantly.

- medicines for the treatment of HIV infections (zidovudine): The effect of a decrease in the number of white blood cells (neutropenia) is increased. Empaped® should only be used in combination with zidovudine on medical advice

HOW TO USE EMPAPED®

Always take **Empaped®** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The quantity of paracetamol depends on the patient's age and body weight. The single dose is usually between 10 mg and 15 mg of paracetamol per kg body weight, to a maximum up to 60 mg of paracetamol per kg body weight as a total daily dose.

The interval between doses is based upon the symptomatology and the maximum daily dose. It should be at least six hours.

The usual dose is:

Infants (3 months to 1 year):

One 125 mg suppository up to 4 times daily.

Children (1 to 5 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.
- 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

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

Special patient groups

Impaired liver function and mild impaired kidney function:

The dosage should be reduced or the interval between doses should be longer in patients with impaired liver or kidney function or with Gilbert's syndrome.

Severe kidney dysfunction:

In the presence of severe kidney dysfunction (creatinine clearance below 10 ml/min), **Empaped**[®] should be given at intervals of at least 8 hours.

If a dosage of Empaped[®] is missed:

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.

If more than the recommended dosage of Empaped[®] is administered:

In the event of over dosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

In children the total daily dose must not exceed 60 mg paracetamol/kg body weight daily.

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

POSSIBLE SIDE EFFECTS

Empaped[®] can have side effects.

These side effects are: fatigue and mild headache. Redness of the skin has been seen. Cases of allergic reactions associated with rash or of disorders of blood formation have been reported.

Further hypersensitivity (allergic) reactions such as muscular spasm in the respiratory tract leading to difficulty in breathing, swelling of the face, sweating, nausea and a fall in blood pressure (including shock) have been observed.

Treatment should be discontinued and medical advice should be sought immediately at the earliest signs of hypersensitivity reactions.

Not all side effects reported for **Empaped**[®] are included in this leaflet. Should your general health worsen while taking **Empaped**[®], please consult your doctor, pharmacist or other health care professional for advice.

STORING AND DISPOSING OF Empaped[®]

Keep all medicines out of the reach and sight of children.

Empaped[®] should be kept 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.

Return all unused medicine to your pharmacist.

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

PRESENTATION OF EMPAPED[®]

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

IDENTIFICATION OF EMPAPED[®]

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

REGISTRATION NUMBER

Empaped[®] 125 mg Suppositories: X/2.7/193

Empaped[®] 250 mg Suppositories: X/2.7/194

NAME AND ADDRESS OF REGISTRATION HOLDER

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To follow