PACKAGE LEAFLET: INFORMATION FOR THE USER

FEBRICET

200 mg suppositories

PARACETAMOL

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What FEBRICET is and what it is used for
2. Before you take FEBRICET
3. How to take use FEBRICET
4. Possible side effects
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1. WHAT FEBRICET IS AND WHAT IT IS USED FOR

FEBRICET suppositories contain Paracetamol which is analgesics and antipyretics. FEBRICET is prescribed for the treatment of mild to moderately severe pain and / or reduction of fever. It is intended for the use in conditions such as headache, toothache, muscle pain, flu-like conditions.

2. BEFORE YOU TAKE FEBRICET

Do not take FEBRICET

• if you are allergic (hypersensitive) to Paracetamol or to any of the other ingredients in this medicine(see chapter 6. Other ingredients)

• if you have or had recently have inflammation of the last part of the colon or rectum; bleeding from the colon

• if you have severe liver disease

Take special care with COBALAMIN

You should not exceed the recommended dose.
Avoid the use of other medicines against flu, colds or other medicines containing paracetamol. In the case of prolonged headaches, immediately contact your doctor.

Immediately consult a doctor in case of overdose or accidental intake of extremely high doses.
When applying suppositories there is a possibility of development of local irritation. The frequency and severity of irritation could increase depending on the duration of treatment, the interval between doses and the dose applied.

If in spite of the use of the medicinal product pain continues for more than 5 days, fever longer than 3 days or if you develop any other symptoms, you should see a doctor.

In case of severe liver or kidney disease, you should see a doctor before the application of paracetamol.

In the case of diarrhea, the use of suppositories is not recommended.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
In order to avoid possible interactions with other medicines, you should always inform doctor or pharmacist about the use of another medicine. If it is necessary to determine the child's concentration of uric acid or sugar in the blood, be sure to inform your doctor about using this medicine.
Tell your doctor if you are taking anticoagulant medications (against blood coagulation).
If necessary, your doctor will adjust the dose of oral anticoagulants, for the duration and after discontinuation of treatment with paracetamol.

Pregnancy and breastfeeding

Before you start taking any medication, consult your doctor or pharmacist.

Under normal circumstances, paracetamol can be used in pregnancy and during breastfeeding.
Before using any medicine during pregnancy and during breast-feeding you should consult with a doctor or pharmacist.

Driving and using machines

There are no data that paracetamol affects the ability to drive and use machines.

3. HOW TO TAKE FEBRICET

Always take FEBRICET exactly as you are told by your doctor. If you are unsure, check with your doctor or pharmacist.

Dose

This medicine is intended for children weighting from 12 to 16 kg (age 2-5 years).

The dose depends on the child`s weight; approximate age for a certain weight is given only as a relative direction.

The recommended daily dose of paracetamol is 60 mg / kg / day, divided into 4 single doses, or 15 mg / kg every 6 hours.

Due to the possibility of development of local toxicity, suppositories should not be used more often than 4 times a day. Duration of rectal treatment should be as short as possible.

In the case of diarrhea, the use of suppositories is not recommended.
This medicine is intended for children weighting from 12 to 16 kg (age 2-5 years): one suppository of 200 mg. If necessary, the dose can be repeated after 6 hours. The maximum daily dose is 4 suppositories per 24 hours.

If necessary, suppositories may be administered in patients who weight more, in combination with other forms of the medicine (Febricet tablets or Febricet syrup), while the recommended dose should be respected.

Proper application of the medicine helps to avoid fluctuations when it comes to the intensity of pain and body temperature.
In children, the medicine is dosed at regular intervals both during the day and during the night, preferably every 6 hours, whereby the time space between the doses should not be less than 4 hours.

In case of severe kidney disease, the interval between two uses of the medicinal product must be at least 8 hours.

Do not use longer than 3 days without consulting a doctor or pharmacist. If symptoms do not withdraw, contact a doctor.

When and how to use the suppository?
FEBRICET suppository is applied after a bowel movement. Insert FEBRICET suppositories (pointed end first) completely into rectum with gentle pressure.

How long should I use FEBRICET suppository?
The length of treatment is determined by the doctor.

If you take more FEBRICET than you should
If you think that you or your child have used a higher dose of Febricet suppositories than recommended, or if someone else took your medicine, immediately contact your doctor, pharmacist or nearest hospital!

Symptoms of paracetamol overdose in the first 24 hours are paleness, nausea, vomiting, loss of appetite and abdominal pain.

The overdose may cause hepatic necrosis (extinction of liver tissue). Get medical attention immediately in the case of overdose, even if the child looks good, because of the risk of delayed, serious liver damage.

If you forget to take FEBRICET
Do not take a double dose to make up for the missed dose!
If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, FEBRICET can cause side effects, although not everybody gets them.
In rare cases, it can cause hypersensitivity reactions such as anaphylactic shock (a severe form of allergic reaction), Quincke's edema, redness, hives and rashes on the skin.
You should immediately discontinue use of this product and consult a doctor.

Extremely rarely have been reported the reduced number of certain white blood cells or other blood cells (platelets).
The application of suppositories may lead to irritation of the last part of the colon or rectum.
If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of suspected side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE FEBRICET

Keep out of the reach and sight of children.

Do not store above 25 ºC.

Do not use FEBRICET after the expiry date which is stated on the label, 3 years from the date of manufacture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What FEBRICET contains

1 suppository contains:
200 mg paracetamol

The other ingredients are:
- Medium chain triglycerides (Miglyol 812)
- Polysorbate 80
- Silica, colloidal anhydrous
- Hard fat (Witepsol H15)

What FEBRICET looks like and contents of the pack
Suppository, form of pointed roller, white.
PVC / PE strip.
One strip contains 5 suppositories.
Cardboard box containing 1 strip packaging.

Regime of dispensing
The medicine is issued without a doctor's prescription.

Manufacturer
Hemofarm d.o.o. Banja Luka
Novakovići b.b., Banja Luka, Bosnia and Herzegovina

Manufacturer of the medicinal product
Hemofarm d.o.o. Banja Luka
Novakovići b.b., Banja Luka, Bosnia and Herzegovina