

PACKAGE LEAFLET: INFORMATION FOR THE USER

FEBRICET

500 mg Tablet

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
5. How to store FEBRICET
6. Further information

1. WHAT FEBRICET IS AND WHAT IT IS USED FOR

FEBRICET contains paracetamol which is an analgesic (a pain killer that reduces aches and shivers) and antipyretic (it reduces temperature in case of fever).

FEBRICET affects the central and peripheral nervous system and prevents the transmission of feeling the pain. It also acts on the center for temperature control, causing dilation of blood vessels in the skin which leads to sweating and loss of heat which lowers fever.

FEBRICET tablets are used in the following conditions:

- headache
- musculoskeletal disorders
- menstrual pain
- toothache
- symptomatic treatment of colds and flu
- mild to moderate pain associated with osteoarthritis

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 section 6).
- If you are taking other painkillers or medicines containing paracetamol.

FEBRICET tablets must not be given to children under 6 years.

Take special care with FEBRICET

Tell your doctor if you:

- are on a diet with a low intake of potassium or have hyperkalemia (a condition with elevated levels of potassium in the blood)
- have severe liver or kidney disease, including liver disease caused by alcohol
- if headaches become persistent, contact a doctor
- In case of overdose, it is necessary to immediately consult a doctor, even if you feel good, because there is a risk of severe liver damage

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Tell your doctor before you take FEBRICET if you are taking:

- Medicines to thin the blood (anti-coagulant drugs e.g. Warfarin ,other coumarins)
- Medicines used to relieve sickness (e.g. Metoclopramide, Domperidone)
- Medicines used to treat high cholesterol (Cholestyramine)
- Other painkillers
- Medicines containing paracetamol

FEBRICET with food and drink

Chronic use of alcohol increases the risk of liver damage in patients taking paracetamol.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant see your doctor before you take FEBRICET.

Small amounts of paracetamol pass into breast milk. This medicine may be taken by mothers who are breastfeeding.

Driving and using machines

No specific precautions are required.

Important information about some of the ingredients of FEBRICET

FEBRICET tablets contain castor oil-hydrogenated, therefore, you may experience abdominal cramps and diarrhea.

3. HOW TO TAKE FEBRICET

Always take FEBRICET exactly as indicated in this package leaflet. If you are unsure, please ask your doctor or pharmacist for advice.

FEBRICET tablets are administered orally.

Adults (including the elderly) and children aged over 12 years

2 tablets 3-4 times a day if necessary, a maximum of 8 tablets in 24 hours.

Children from 6-12 years

½-1 tablet if necessary 3-4 times a day, and up to 4 tablets in 24 hours. The dose should not be repeated more frequently than every 4 hours and give a maximum of 4 doses per 24 hours.

Children under 6 years

FEBRICET tablets are not suitable for children up to 6 years.

If you take more FEBRICET than you should

Talk to a doctor 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 FEBRICET

If you forget to take a dose, take another as soon as you remember, unless it is almost time for your next dose. Remember to leave at least four hours between doses. Never double-up on a dose to make up for the one you have missed.

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

If you stop taking FEBRICET

Your doctor will advise you when to stop therapy.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking the medicine and contact your doctor or pharmacist if you have experienced any of these and / or other side effects: skin rash, allergic reactions, increased blood pressure, headache, dizziness, upset stomach (nausea or diarrhea), trouble sleeping, heart rate and blood disorders-thrombocytopenia and agranulocytosis (decrease in the number of platelets and white blood cells that occur in frequent and long-term use).

If you get any side effects, talk to your doctor or pharmacist. 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.

This medicine should no longer be used after the expiry date printed on the container and box after "EXP". The expiry date refers to last day of that month.

Expiration date:

3 (three) years

Store below 25 °C. Store in the original container to protect from moisture and light.

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

The active substances are:

1 tablet contains:
500 mg paracetamol

The other ingredients are:

- Gelatin
- Macrogol 6000
- Talc
- Croscarmellose sodium
- Castor oil- hydrogenated
- Microcrystalline cellulose
- Magnesium stearate

What FEBRICET looks like and contents of the pack

White, round tablets.

12 tablets (strip, 2 x 6 tablets).

Regime of dispensing

The medicine is issued without doctor`s prescription.

Manufacturer

Hemofarm d.o.o. Banja Luka
Novakovići bb, Banja Luka, BiH

Manufacturer of the medicinal product

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