PACKAGE LEAFLET: INFORMATION FOR THE USER

FEBRICET

500 mg Effervescent 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

FEBRICET contains Paracetamol, which is a mild pain killer and reduces the body temperature in fever. The tablets are recommended for use in treatment of mild to moderate pain and/or fever.

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).

Take special care with FEBRICET

Tell your doctor if you:

• Are suffering from liver problems including liver problems due to excessive alcohol consumption
• Have Gilbert's syndrome (mild jaundice)
• Are suffering from kidney problems
• Are suffering from dehydration and chronic malnutrition

- Suffer from asthma and are sensitive to aspirin
- Are taking any other paracetamol containing medicines
- Have a fever that does not improve after taking this medicine
- Have glucose-6-phosphatedehydrogenase deficiency (enzyme deficiency)
- Have hemolytic anemia (abnormal breakdown of red blood cells)

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)
- Probenecid (Medicine used to treat high levels of uric acid in the blood stream (gout))
- Medicine to treat fever or mild pain (Aspirin, Salicylamide)
- Barbiturates and tricyclic antidepressants (to treat depression)
- Medicines used to treat epilepsy (Lamotrigine)
- Medicines to treat tuberculosis (Isoniazid)

Effects of paracetamol on laboratory tests
Uric acid and blood sugar tests may be affected.

FEBRICET with food and drink
This medicine may be taken with or without food.

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, as instructed (see section 3), by mothers who are breastfeeding.

Driving and using machines
No specific precautions are required.

Important information about some of the ingredients of FEBRICET
FEBRICET contains sodium. This should be taken into account in patients on a controlled sodium diet.

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.

This presentation is reserved for use in adults and in adolescents aged 12 years and above.

Pediatric patients:
- **Children below 12 years of age:** Do not give to children younger than 12 years.
- **Adolescents of 12 to 15 years and weighing 41 to 50 kg**, the posology is one tablet per dose, repeated every 4-6 hours if necessary, without exceeding 4 tablets daily.
- **Adolescents of 16 to 18 years and weighing more than 50 kg:** as adults.

Adults:

- The usual adult dose is one to two tablets of 500 mg, repeated every 4-6 hours, up to a maximum of 8 tablets (4000 mg) in 24 hours.

Maximum daily dose:

The maximum daily dose of Paracetamol must not exceed 4 g.
Maximum single dose is 1 g (2 effervescent tablets)

If the pain persists for more than 5 days or the fever lasts for more than 3 days, or gets worse or other symptoms appear, you should stop the treatment and consult a doctor.

FEBRICET is intended for oral administration. You should put the tablet in a glass full of water, wait until it is completely dissolved and drink the solution.

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.

4. POSSIBLE SIDE EFFECTS

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

You should stop taking Paracetamol Effervescent Tablets and see your doctor immediately if you experience symptoms like:

- accumulation of fluid in the larynx including an itchy rash, throat swelling (severe allergic reaction),
- swelling on the face, mouth, hands (angioedema)
- Life-threatening skin disease causing rash, skin peeling and sores (toxic epidermal necrolysis)
- severe blistering and peeling of the skin (Stevens–Johnson syndrome)

The frequency using the following convention:

Rare (may affect up to 1 in 1,000 people):
Edema (abnormal accumulation of fluid under the skin), abnormal vision, simple skin rash or urticaria (dark red rash on the skin), hemorrhage (bleeding), abdominal pain, diarrhea, nausea, vomiting, dizziness, fever, reduction of irritability or agitation (sedation), platelet disorders (clotting disorders), stem cell disorders (disorders of the blood forming cell in the bone marrow), abnormal liver function, liver failure, hepatic necrosis (death of liver cells), jaundice, overdose and poisoning, tremor, headache, depression, confusion, hallucinations, sweating, pruritus (itching), feeling lousy (malaise).
Very rare (may affect up to 1 in 10,000 people):
hepatotoxicity (damage caused to the liver), thrombocytopenia (reduction in blood platelets, which increases the risk of bleeding or bruising), leucopenia (frequent infections due to poorly functioning white blood cells or decrease in white blood cells), neutropenia (reduced neutrophil count in blood), agranulocytosis (severe decrease in white blood cells which may lead to severe infections), hemolytic anemia (abnormal breakdown of red blood cells, which may cause weakness or pale skin), hypoglycemia (low levels of glucose in the blood), cloudy urine and kidney disorders.

Other adverse reactions of paracetamol whose frequency cannot be estimated from available data are: erythema multiforme (allergic reaction or infection of skin), anemia (decrease in red blood cells), problems with the way your kidneys work (kidney alteration), problems with the way your liver works (liver alteration), hematuria (blood in urine), anuresis (inability to urinate), gastrointestinal effects, vertigo. There have been cases of difficulty breathing, wheezing, coughing, and shortness of breath with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs such as ibuprofen.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. The side effects of medicines can be reported to the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FEBRICET

Keep out of the reach and sight of children.

Store this medicine out of the reach 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.

Store below 30 °C. Store in the original container to protect from moisture and light.

Do not use this medicine if you notice visible signs of deterioration, like brown or black spots on the tablets, bulging of tablets or discoloration of the tablets.

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 substance is Paracetamol. Each effervescent tablet contains 500 mg of Paracetamol.

The other ingredients are:
Citric acid, anhydrous; sodium hydrogen carbonate; sodium sulfate, anhydrous; lactose monohydrate; macrogol 6000; povidone K-25; lemon flavor; saccharin sodium, dihydrate; simethicone emulsion.

What FEBRICET looks like and contents of the pack

Polypropylene tube with 10 effervescent tablets and low density polyethylene cap.

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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