

Febradol Tablets

Paracetamol

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. See section 4.

What is in this leaflet

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

1. What Febradol is and what it is used for

Febradol tablets are used for the relief of headache, tension headache, migraine, backache, rheumatic and muscle pain, toothache and period pain.

They also relieve sore throat and the fever, aches and pains of colds and flu and are recommended for the relief of pain due to mild arthritis.

The active ingredient is paracetamol which is a painkiller and also reduces your temperature when you have a fever.

2. What you need to know before you take Febradol

Do not take Febradol

- **If you have ever had an allergic reaction** to paracetamol or to any of the other ingredients (listed in section 6).
- **If you are taking any other prescription or non-prescription medicines containing paracetamol** to treat pain, fever, symptoms of cold and flu, or to aid sleep.

Warnings and precautions

Talk to your doctor or pharmacist before taking Febradol:

- If you suffer from **mild arthritis** and need to take painkillers every day
- If you have **liver** or **kidney** problems
- If you are **underweight** or **malnourished**
- If you regularly drink alcohol
- If you have **severe infection** as this may increase the risk of **metabolic acidosis**

Signs of metabolic acidosis include:

- Deep, rapid, difficult breathing
- Feeling sick (nausea), being sick (vomiting)
- Loss of appetite

Contact a doctor immediately if you get a combination of these symptoms. You may need to avoid using this product altogether or limit the amount of paracetamol that you take.

Other medicines and Febradol

Talk to your doctor or pharmacist before taking these tablets if you are taking any prescribed medicines, particularly:

- **Metoclopramide** or **domperidone** (for **nausea** [feeling sick] or **vomiting** [being sick])
- **Colestyramine** (to lower **blood cholesterol**)

- If you take **blood thinning drugs (anticoagulants** e.g. **warfarin**) and you need to take a pain reliever on a daily basis, **talk to your doctor** because of the risk of bleeding. But you can still take occasional doses of Febradol at the same time as anticoagulants.

Pregnancy and breast-feeding

Talk to your healthcare professional before taking Febradol if you are **pregnant**. You can take this product whilst **breast feeding**.

3. How to take Febradol

Adults and children aged 16 years and over:

Swallow 1-2 tablets every 4 to 6 hours as needed.

Do not take more than 8 tablets in 24 hours.

Children aged 10-15 years:

Give 1 tablet every 4 to 6 hours as needed. Do not give more than 4 tablets in 24 hours.

Do not give for more than 3 days at a time unless your doctor tells you to.

- **Do not take more frequently than every 4 hours.**
- **Do not take more than the recommended dose.**
- **Do not give to children under 10 years.**

If you take more Febradol than you should

Talk to your 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 your symptoms continue or your headache becomes persistent, see your doctor.

4. Possible side effects

Like all medicines, Febradol can have side effects but not everybody gets them. A small number of people have had side effects. Very rare cases of serious skin reactions have been reported.

Stop taking the medicine and tell your doctor immediately if you experience:

- Allergic reactions which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath
- Skin rash or peeling, or mouth ulcers
- Breathing problems. These are more likely if you have experienced them when taking other painkillers such as ibuprofen and aspirin
- Unexplained bruising or bleeding
- Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.

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. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Febradol

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and the outer packaging. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep away from humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Febradol contains

- Active ingredient: each tablet contains 500 mg of paracetamol.
- Other ingredients: Pregelatinized starch, Povidone, Stearic acid.

What Febradol looks like and contents of the pack

Febradol tablets are white oblong tablets.

Febradol tablets are available in packs containing 20, 24, 100 or 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Pharmaline s.a.l. – Lebanon

P.O. Box 90201 Jdeidet-El-Metn, Lebanon

Contact us: pharmaline@maliagroup.com

Website: www.pharmaline.com.lb

Reg. N°. for Febradol 500 mg 100 tablets in Lebanon: 70821/1

Reg. N°. for Febradol 500 mg 20 tablets in Lebanon: 208322/97

Reg. N°. for Febradol 500 mg 24 tablets in Lebanon: 26703/89

Reg. N°. for Febradol 500 mg 1000 tablets in Lebanon: 208321/97

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

**Council of Arab Health Ministers
Union of Arab Pharmacists**

The leaflet was last revised in January 2021.