

Doliprane® 1000_{mg}

PARACETAMOL

tablet

Read this leaflet carefully before you start taking this medicine. It contains important information for your treatment.

If you have other questions, or any doubts, ask your doctor or pharmacist for more information.

- 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 do not improve after 5 days.

Composition

The active substance is:

Paracetamol.....1000.00 mg

For one tablet

The other ingredients are:

Povidone, pregelatinised starch, sodium starch glycolate (type A), talc, magnesium stearate.

Holder / Distributor:

sanofi-aventis France

1-13, boulevard Romain Rolland
75014 Paris - France

Manufacturer:

Sanofi Winthrop Industrie
ZI Nord Est - Rue Edouard Branly
14104 Lisieux Cedex - France

1. WHAT DOLIPRANE 1000 mg, tablet IS AND WHAT IT IS USED FOR?

This medicine contains paracetamol and is in tablet form (Box of 8).

It is used to treat pain and/or fever, including headache, flu-like symptoms, toothache, aches and pains, and period pain. It can also be prescribed by your doctor when you have pain from osteoarthritis.

This dosage form is only for use in adults and children weighing more than 50 kg (i.e. from 15 years of age).

Read Section 3 carefully: HOW TO TAKE DOLIPRANE 1000 mg, tablet?

Other dosage forms of paracetamol are available for children weighing less than 50 kg. Ask your doctor or pharmacist for advice.

2. BEFORE YOU TAKE DOLIPRANE 1000 mg, tablet

Do not take this medicine:

- If you are allergic to paracetamol or to one of the ingredients,
- If you have serious liver disease.

Take special care with DOLIPRANE 1000 mg, tablet:

Special precautions

- If pain persists for more than 5 days or fever for more than 3 days, or if the medicine is insufficiently effective or any other symptoms occur, do not pursue treatment without consulting your doctor.
- If you have serious liver or kidney disease, consult your doctor before taking paracetamol.

Warnings

In the event of overdose, or accidental intake of an excessive dose, consult your doctor immediately.

This medicine contains paracetamol, as do other medicines. Do not take this medicine with other paracetamol-containing products, so as not to exceed the recommended daily dose (see Section 3. HOW TO TAKE DOLIPRANE 1000 mg, tablet?).

Pregnancy and breast-feeding

Under normal conditions of use, paracetamol can be used throughout pregnancy and while breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Taking or using other medicines or other interactions

Inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Inform your doctor that you or your children are taking this medicine, if he/she prescribes tests to determine blood uric acid levels.

3. HOW TO TAKE DOLIPRANE 1000 mg, tablet?

Attention: the dosage strength in each tablet is 1000 mg of paracetamol: **do not take 2 tablets at the same time.**

Dosage

Due to the dosage strength, this medicine is only for use in adults and children weighing more than 50 kg.

The usual dosage is one 1000 mg tablet taken in one dose, repeated every 6 to 8 hours. If needed, the dose can be repeated at intervals of not less than 4 hours.

It is generally not necessary to take more than 3000 mg of paracetamol per day, i.e. 3 tablets.

However, in patients experiencing more intense pain, and on your doctor's advice, the dose can be increased to 4000 mg per day, i.e. 4 tablets.

Dosages greater than 3000 mg of paracetamol per day require medical advice.

- **Never take more than 4000 mg of paracetamol per day** (taking into consideration all medicines containing paracetamol).
- Always take doses at least 4 hours apart.

Following a regular dose schedule makes it possible to avoid fluctuations in pain or fever.

In patients with serious kidney disease (severe renal insufficiency), doses must be taken 8 hours apart. Do not take more than 3 tablets per day.

Method and route of administration

Oral use.

The tablets are to be swallowed whole with a liquid (e.g. water, milk or fruit juice).

If you take more DOLIPRANE 1000 mg, tablet than you should: Consult your doctor or pharmacist immediately.

If you forget to take DOLIPRANE 1000 mg, tablet: Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

Like all medicines, DOLIPRANE 1000 mg, tablet may cause undesirable effects:

- In certain rare cases, skin rash or redness, or an allergic reaction may occur, showing as sudden swelling of the face and neck, or sudden malaise with a fall in blood pressure. You must stop treatment immediately and inform your doctor; and never take any medicines containing paracetamol again.
- Exceptional cases of abnormal laboratory values have been observed, requiring control of blood parameters: abnormally low levels of certain white blood cells or blood cells such as platelets, possibly causing nosebleeds or bleeding gums. In such instances, seek medical advice.

If you notice any undesirable effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE DOLIPRANE 1000 mg, tablet?

Keep out of the reach and sight of children.

Do not store above 30°C.

Do not exceed the expiry date indicated on the outer packaging

This leaflet was last approved on March 2009.