

# Doliprane® 150 mg 8 à 12 kg

PARACETAMOL

## Suppositories

### IDENTIFICATION OF THE MEDICINE

#### Composition

Paracetamol .....150 mg

Excipients: hard fat for one suppository.

#### Pharmaceutical form and presentation

Suppository (box of 10).

#### Pharmaco-therapeutic class

OTHER ANALGESIC AND ANTIPYRETIC AGENTS

#### Holder

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

### WHAT Doliprane 150 mg, suppositories ARE USED FOR

This medicine contains paracetamol.

It is used to treat pain and/or fever, including headache, flu-like symptoms, toothache, aches and pains.

**This dosage form is only for use in infants weighing 8 to 12 kg (approximately from 6 to 24 months of age). Read carefully Section "Dosage".**

Other dosage forms of paracetamol are available for children weighing less than 8 kg or more than 12 kg. Ask your doctor or pharmacist for advice.

### BEFORE YOU TAKE DOLIPRANE 150 mg, suppositories

#### DO NOT TAKE Doliprane 150 mg, suppositories

(CONTRA-INDICATIONS) Do not use this medicine in the following cases :

- If you are allergic to paracetamol or to the other ingredients,
- If you have serious liver disease,
- recent anal or rectal inflammation or recent rectal bleeding.

*IF IN DOUBT, IT IS ESSENTIAL TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.*

#### TAKE SPECIAL CARE WITH DOLIPRANE 150 mg, suppositories

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 use this medicine with other paracetamol-containing products, so as not to exceed the recommended daily dose (see Section "Dosage").**

There is a risk of local toxicity with suppositories, the frequency and severity of which can be increased in the event of long-term treatment, frequent administration and high dosages.

#### PRECAUTIONS WHEN TAKING Doliprane 150 mg, suppositories

- 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 giving paracetamol to your child.

*IF YOU HAVE ANY DOUBTS, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.*

#### TAKING OTHER MEDICINES

Inform your doctor that your child is taking this medicine, if he/she prescribes tests to determine the child's blood uric acid level.

*TO AVOID ANY INTERACTION BETWEEN DIFFERENT MEDICINES, YOU MUST ALWAYS INFORM YOUR DOCTOR OR PHARMACIST OF ANY OTHER TREATMENT THE CHILD MAY BE TAKING.*

#### PREGNANCY AND BREAST-FEEDING

For information: under normal conditions of use, paracetamol can be used throughout pregnancy and while breast-feeding.

*AS A GENERAL RULE, DURING PREGNANCY OR BREAST-FEEDING, YOU SHOULD ALWAYS ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE BEFORE USING A MEDICINE.*

#### HOW TO TAKE Doliprane 150 mg, suppositories

##### HOW MUCH Doliprane 150 mg, suppositories SHOULD BE TAKEN

The dose of paracetamol to be administered depends on the child's weight; ages are provided as an indication.

**If you do not know the child's weight, you should weigh him/her in order to administer the most suitable dose.**

Paracetamol is available in several dosage strengths; this allows treatment to be adjusted to the child's weight.

The recommended daily paracetamol dose depends on the child's weight: this is approximately 60 mg/kg/day, given in 4 divided doses, i.e. approximately 15 mg/kg every 6 hours.

Due to the risk of rectal irritation, treatment with suppositories should be as short as possible, with no more than 4 doses per day, and should be replaced by oral treatment as soon as possible.

The suppository form is not appropriate in the event of diarrhoea.

This dosage form is suitable for use in infants **weighing 8 to 12 kg** (approximately from 6 to 24 months of age): the dosage is one 150 mg suppository, repeated every 6 hours if necessary, **without exceeding 4 suppositories per day**.

*IF YOU HAVE ANY DOUBTS, ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.*

#### HOW Doliprane 150 mg, suppositories ARE TAKEN

Rectal use.



Tear along the dotted line to detach a suppository first



Pull apart the 2 edges to open



How to insert the suppository (flat end to stop it slipping out)

- give your child plenty of fluids,
- do not leave your child in an excessively hot environment.

#### WHEN AND HOW OFTEN Doliprane 150 mg, suppositories SHOULD BE TAKEN

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

Children should be given doses, including during the night, at regular intervals, of at least 4 hours, and preferably 6 hours.

If the child has serious kidney disease (severe renal insufficiency), doses must be taken at least 8 hours apart.

#### IF YOU TAKE MORE Doliprane 150 mg, suppositories THAN YOU SHOULD

If overdose or accidental poisoning occurs, consult a doctor urgently.

#### UNWANTED AND UNPLEASANT EFFECTS

*THIS MEDICINE MAY HAVE EFFECTS WITH VARYING DEGREES OF DISCOMFORT IN SOME PATIENTS:*

- In certain rare cases, skin rash or redness, or an allergic reaction appearing as sudden swelling of the face and neck, or sudden malaise with a fall in blood pressure may occur. You should stop treatment immediately and inform your doctor, and never use any medicines containing paracetamol again.
- Exceptional cases of abnormal laboratory values have been observed, requiring blood count tests: abnormally low levels of certain white blood cells or blood cells such as platelets, possibly causing nosebleeds or bleeding gums. If this occurs, seek medical advice.
- With the suppository form, there is a risk of rectal or anal irritation (see Warnings).

*DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE IF YOU NOTICE ANY UNWANTED AND UNPLEASANT EFFECTS NOT MENTIONED IN THIS LEAFLET, PLEASE INFORM YOUR DOCTOR OR PHARMACIST.*

#### STORAGE

**DO NOT EXCEED THE EXPIRY DATE INDICATED ON THE OUTER PACKAGING.**

#### Special precautions for storage

Store at a temperature no higher than 30°C.

#### DATE OF LEAFLET REVISION

July 2008

The following table can help you to keep track of the doses given; note the dosing time in the sections corresponding to each dose:

Your child's name: .....	Your child's weight .....kg			
	Time of the 1st dose	Time of the 2nd dose	Time of the 3rd dose	Time of the 4th dose
1st day				
2nd day				
3rd day				

In addition, if your child has a fever over 38.5°C, you can take the following steps to improve the efficacy of the medicinal treatment:

- remove your child's excess clothing,