

PATIENT INFORMATION LEAFLET

Paracetamol Infusion (10mg/ml)- Feverach

Paracetamol BP

Read all of this leaflet carefully before you start taking using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your <doctor, health care provider or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor, health care provider or pharmacist.

In this leaflet:

- a) What Feverach is and what it is used for
- b) Before you use Feverach
- c) How to use Feverach
- d) Possible side effects
- e) How to store Feverach
- f) Further information

a) WHAT FEVERACH IS AND WHAT IT IS USED FOR

This medicine is an analgesic (it relieves pain) and an antipyretic (it lowers fever).

The 100 ml vial is restricted to adults, adolescents and children weighing more than 33 kg.

The 50 ml vial is adapted to term newborn infants, infants, toddlers and children weighing less than 33 kg.

It is indicated for the short-term treatment of moderate pain, especially following surgery, and for the short-term treatment of fever.

b) BEFORE YOU USE FEVERACH

Do not use Feverach

- If you are allergic (hypersensitive) to paracetamol or to any of the other ingredients of Feverach.
- If you are allergic (hypersensitive) to propacetamol (another analgesic for infusion and a precursor of paracetamol).
- If you suffer from a severe liver disease.

Warnings and precautions

Take special care with paracetamol 10 mg/ml, solution for infusion

- Use a suitable analgesic oral treatment as soon as this administration route is possible.
- If you suffer from a liver or kidney disease, or from alcohol abuse.
- If you are taking other medicines containing paracetamol.
- In cases of nutrition problems (malnutrition) or dehydration

Inform your doctor before treatment if any of the above mentioned conditions apply to you

Other medicines and Feverach

Do not give anything else containing paracetamol while giving this medicine. This medicine contains paracetamol and this must be taken into account if other medicines containing paracetamol or propacetamol are taken, in order not to exceed the recommended daily dose (see following section). Inform your doctor if you are taking other medicines containing paracetamol or propacetamol.

A dose reduction should be considered for concomitant treatment with Probenecid.

Please inform your doctor or pharmacist if you are taking oral anticoagulants. Closer check-ups of the effect of

the anticoagulant might be necessary.

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

Pregnancy and breast-feeding

Pregnancy

Inform your doctor if you are pregnant. **Feverach** may be used during pregnancy. However, in this case the doctor must evaluate if the treatment is advisable.

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

Breast-feeding

Feverach may be used during breast-feeding.

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

Information on sodium content

This medicinal product contains less than 1 mmol sodium (23mg) per 100 ml of Feverach, i.e. essentially

"sodium free".

c) HOW TO USE FEVERACH

You should not be given more medicine than the label says. Do not exceed the stated dose.

Intravenous use.

Feverach will be administered to you by a healthcare professional by infusion into one of your veins.

The dose will be individually adjusted by your doctor, based on your weight and general condition.

The 100 ml vial is restricted to adults, adolescents and children weighing more than 33 kg.

The 50 ml vial is adapted to term Feverach infants, infants, toddlers and children weighing less than 33 kg.

Dosage

Dosing based on patient weight (please see the dosing table here below)

Patient weight	Dose per administration	Volume per administration	Maximum volume of Feverach (10 mg/mL) per administration based on upper weight limits of group (mL)**	Maximum Daily Dose ***
≤10 kg*	7.5mg/kg	0.75 mL/kg	7.5mL	30 mg/kg
> 10 kg to 33kg	15 mg/kg	1.5mL/kg	49.5mL	60mg/kg not exceeding 2g
> 33 kg to 50kg	15 mg/kg	1.5mL/kg	75 mL	60mg/kg not exceeding 3g
>50kg with additional risk factors for hepatotoxicity	1g	100mL	100mL	3g
> 50 kg and no additional risk factors for hepatotoxicity	1g	100mL	100mL	3g

* **Pre-term new-born infants:** No safety and efficacy data are available for pre-term new-born.

****Patients weighing less will require smaller volumes.**

The minimum interval between each administration must be at least 4 hours.

The minimum interval between each administration in patients with severe renal insufficiency must be at least 6 hours.

No more than 4 doses to be given in 24 hours.

*** **Maximum daily dose:** The maximum daily dose as presented in the table above is for patients that are not receiving other paracetamol containing products and should be adjusted accordingly taking such products into account.

d) POSSIBLE SIDE EFFECTS

Like all medicines, FRVERACH 10 mg/ml, solution for infusion can cause side effects, although not everybody gets them.

- In rare cases (more than 1 out of 10,000 persons and less than 1 out of 1,000 persons), the following may occur: a malaise, a drop in blood pressure or changes in laboratory test results: abnormally high levels of hepatic enzymes found during blood checks. Should this occur, inform your doctor as regular blood checks may be required later.
- In very rare cases (less than 1 out of 10,000 persons, including isolated reports), a serious skin rash or allergic reaction may occur. Stop the treatment immediately and inform your doctor.
- In isolated cases, other changes in laboratory test results have been observed which have necessitated regular blood checks: abnormally low levels of some types of blood cells (platelets, white cells), possibly leading to bleeding from the nose or gums. Should this occur, inform your doctor.
- Cases of redness of the skin, flushing, itching and abnormally rapid beating of the heart have been reported.
- Cases of pain and burning sensation at injection site have been reported.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects directly to info@aculife.co.in.

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

e) HOW TO STORE FEVERACH

Store below 30 C, do not refrigerate or freeze.

Protect from light.

Keep out of reach of children.

f) FURTHER INFORMATION

What, Feverach contains

The active substance is Paracetamol BP. There is 10 mg of Paracetamol in each milliliter.

The other ingredients is Water for Injections BP.

What Feverach looks like and contents of the pack

Oxynir is A clear, colourless solution. The product is packed in clear, Type II glass bottle closed with bromobutyl rubber stopper and blue color flip off seal.

Holder of Certificate of Registration

Aculife Healthcare Pvt. Ltd.

Village: Sachana, Taluka:- Viramgam,

District: Ahmedabad – 382150,

Gujarat, India.

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