

FEVERLET FORTE
(Aceclofenac, Paracetamol and Chlorzoxazone Tablets)
Module 1

PACKAGE LEAFLET

1 Name of Product

FEVERLET FORTE (Aceclofenac, Paracetamol and Chlorzoxazone Tablets)

2 Description of Product

A yellow coloured, oval shaped, biconvex, film coated tablet having lip breakline on one side of tablet.

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

- Keep this leaflet. You may need to read it again.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor or specialist if you develop symptoms.

In this leaflet:

1. What **FEVERLET FORTE** are and what they are used for
2. Before you take **FEVERLET FORTE**
3. How to take **FEVERLET FORTE**
4. Possible side effects
5. How to store **FEVERLET FORTE**
6. Further information

1. WHAT ARE FEVERLET FORTE AND WHAT THEY ARE USED FOR

FEVERLET FORTE contains Aceclofenac BP 100 mg Paracetamol BP 325 mg, Chlorzoxazone USP 250 mg. It is used as centrally-acting muscle relaxants.

2. BEFORE YOU TAKE FEVERLET FORTE

Do not take **FEVERLET FORTE** if you:

- Have kidney problems
- Have liver problems
- Have liver disease caused by alcohol. You may be more sensitive to the toxic effects of paracetamol
- Are taking barbiturates or are malnourished. You may be more sensitive to the toxic effects of paracetamol
- Have a hereditary disease called Gilbert's syndrome
- Have a high fever, signs of a secondary infection or if symptoms persist for more than a few days, consult your doctor.

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Driving and using machines

FEVERLET FORTE medication may impair your thinking or reactions. Be careful if you drive or do anything that requires you to be alert.

3. HOW TO TAKE FEVERLET FORTE (Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

FEVERLET FORTE Adults:

1 tablet to be taken 1 - 3 times a day after meals

If you take more FEVERLET FORTE than you should

Contact your doctor. You may experience side effects. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Paracetamol: Nausea, allergic reactions, skin rashes, acute renal tubular necrosis.

Aceclofenac: Diarrhoea, headache, vertigo, dizziness, nervousness, tinnitus, depression, drowsiness, insomnia; fever, angioedema, bronchospasm, rashes; blood dyscrasias.

Potentially Fatal: Paracetamol: Very rare, blood dyscrasias (eg, thrombocytopenia, leucopenia, neutropenia, agranulocytosis); liver damage. Aceclofenac: Severe GI bleeding; nephrotoxicity.

Chlorzoxazone: Black, bloody, or tarry stools; Nausea, upper stomach pain, itching, loss of appetite, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes); coughing up blood or vomit that looks like coffee grounds; or feeling like you might pass out.

5. HOW TO STORE FEVERLET FORTE

Store below 30°C, protect from light and moisture.

6 Further information

What FEVERLET FORTE contains

- The active substance is Aceclofenac BP 100 mg Paracetamol BP 325 mg, Chlorzoxazone USP 250 mg.
- The other ingredients are: Sodium Lauryl Sulphate BP, Maize Starch BP, Fumaric Acid IHS, Purified Water BP, Hydroxypropyl Cellulose BP, Purified Talc BP, Croscarmellose Sodium BP, Colloidal Anhydrous Silica BP, Sodium Stearyl Fumarate USP NF, Sodium Metabisulphite BP, Hypromellose BP, Isopropyl Alcohol BP, Dichloromethane BP, Colour Titanium Dioxide BP, Diethyl phthalate BP, Colour Quinoline yellow IHS.

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Module 1

What FEVERLET FORTE look like

FEVERLET FORTE is a yellow coloured, oval shaped, biconvex, film coated table having lip breakline on one side of tablet.

7 Marketing Authorisation Holder and Manufacturer:

Name and Address of Manufacturer

AUROCHEM LABORATORIES (INDIA) PVT. LTD.

At 58, Palghar Taluka,

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Palghar – 401 404,

Tel No. : 0252-552332, 0252-554720

District Thane,

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Name and Address of Marketing Authorisation Holder

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8 Date of Revision of PIL
