

1.6.3 PATIENT INFORMATION LEAFLET (PIL)

FINACE - MR (Aceclofenac, Paracetamol and Chlorzoxazone Tablets)

Brand Names: FINACE - MR

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor 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 or pharmacist.

In this leaflet:

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

1. What FINACE - MR is and what they are used for

It is used in treatment of Osteoarthritis rheumatoid arthritis ankylosing spondylitis, Aceclofenac is an analgesic antiinflammatory drug belongs to NSAIDs nonsteroidal antiinflammatory drugs.

Aceclofenac is a phenylacetic acid derivative that inhibits synthesis of the inflammatory cytokines interleukin-1b and tumour necrosis factor, and inhibits prostaglandin E2 production. It increases glycosaminoglycans (GAG) synthesis, the principal macromolecule of the extracellular matrix, which aids in repair and regeneration of articular cartilage. Thus, aceclofenac has +ve effects on cartilage anabolism combined with modulating effect of matrix catabolism. Paracetamol has analgesic and antipyretic action with weak anti-inflammatory activity. It produces analgesia by increasing pain threshold and antipyresis by acting on the hypothalamic heat-regulating centre.

Treating discomfort caused by muscle spasms. It is used in combination with rest, physical therapy, and other measures.

Chlorzoxazone is a skeletal muscle relaxant. Exactly how it works to relieve discomfort caused by muscle spasms is not known.

It is used in treatment of Pain and inflammation.

2. Before you take FINACE MR

Module-1

Some medicines are not suitable for people with certain conditions, and sometimes a medicine may only be used if extra care is taken. For these reasons, before you start taking aceclofenac, it is important that your doctor knows:

If you have asthma or any other allergic disorder.

If you have ever had a stomach or duodenal ulcer, or if you have an inflammatory bowel disorder such as Crohn's disease or ulcerative colitis.

If you are pregnant, trying for a baby, or breast-feeding.

If you are under 18 or over 65 years of age.

If you have liver or kidney problems.

If you have a heart condition, or a problem with your blood vessels or circulation.

If you have high blood pressure.

If you have ever had blood clotting problems.

If you have a connective tissue disorder, such as *systemic lupus erythematosus* (an inflammatory condition also called lupus or SLE).

If you have a rare blood disorder known as porphyria.

If you are taking any other medicines. This includes any medicines you are taking which are available to buy without a prescription, such as herbal and complementary medicines.

If you have ever had an allergic reaction to any other NSAID (such as aspirin, naproxen, diclofenac, and indometacin) or to any other medicine.

Most people can take paracetamol without any problem, but to make sure it is the right treatment for you, speak with a doctor or pharmacist before you start taking it if:

You are pregnant or breast-feeding. This is because, while you are expecting or feeding a baby, you should only take medicines on the recommendation of a doctor.

You have a serious problem with the way your liver works, or if you regularly drink large amounts of alcohol.

You are taking medicines prescribed by a doctor.

You have ever had an allergic reaction to a medicine.

If you are pregnant, planning to become pregnant, or are breast-feeding

If you are taking any prescription or nonprescription medicine, herbal preparation, or dietary supplement

If you have allergies to medicines, foods, or other substances

If you have liver problems or a blood disease called porphyria

Some MEDICINES MAY INTERACT with chlorzoxazone. Tell your health care provider if you are taking any other medicines, especially any of the following:

Sodium oxybate (GHB) because the sedative effects of chlorzoxazone may be increased

This may not be a complete list of all interactions that may occur. Ask your health care provider if chlorzoxazone may interact with other medicines that you take. Check with your health care provider before you start, stop, or change the dose of any medicine.

How to take aceclofenac and Paracetamol

Before you start taking aceclofenac, read the manufacturer's printed information leaflet from inside the pack. The manufacturer's leaflet will give you more information about the tablets and provide a full list of side-effects which you may experience from taking them.

Take aceclofenac exactly as your doctor tells you to. The usual dose for adults is one 100 mg tablet taken twice daily, preferably morning and evening.

Take your doses with a snack, or just after eating a meal. This will help protect your stomach from side-effects such as indigestion.

Swallow the tablets whole with a drink of water. Do not chew or break the tablets.

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose, in which case leave out the missed dose. Do not take two doses together to make up for a missed dose.

Before taking paracetamol, read the manufacturer's printed information leaflet from inside your pack. The manufacturer's leaflet will give you more information about paracetamol and a full list of the side-effects which you may experience from taking it.

Take paracetamol exactly as you have been told by your doctor or pharmacist, or as directed on the label of the container.

Recommended doses of paracetamol are:

For adults: 500 mg-1 g every 4-6 hours up to a maximum of 4 g daily.

For children aged 12-16 years: 480-750 mg every 4-6 hours up to a maximum of four doses daily.

For children aged 10-12 years: 480-500 mg every 4-6 hours up to a maximum of four doses daily.

For children aged 8-10 years: 360-375 mg every 4-6 hours up to a maximum of four doses daily.

For children aged 6-8 years: 240-250 mg every 4-6 hours up to a maximum of four doses daily.

For children aged 4-6 years: 240 mg every 4-6 hours up to a maximum of four doses daily.

For children aged 2-4 years: 180 mg every 4-6 hours up to a maximum of four doses daily.

For children aged 6 months-2 years: 120 mg every 4-6 hours up to a maximum of four doses daily.

For children aged 3-6 months: 60 mg every 4-6 hours up to a maximum of four doses daily.

For children aged 2-3 months following immunisation: 60 mg, repeated once after 4-6 hours if needed.

You can take a dose of paracetamol every 4-6 hours if needed, up to four times a day. Remember to leave at least four hours between doses and do not take more than four doses of paracetamol in any 24-hour period.

You can take paracetamol before or after food.

If you are giving paracetamol to your child, always check the label carefully to make sure you are giving the correct dose for the age of your child.

Never take more than the dose recommended on the label. Taking too much paracetamol can cause damage to your liver. If you suspect that you or someone else might have taken an overdose of paracetamol, go to the accident and emergency department of your local hospital at once, even if you/they feel well. Take the container with you so that the doctor knows what has been taken.

Module-1

If you forget to take a dose, do not worry. Do not take two doses together to make up for a forgotten dose.

Take chlorzoxazone by mouth with or without food. If stomach upset occurs, take with food to reduce stomach irritation.

If you miss a dose of chlorzoxazone, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once.

Getting the most from your treatment:

Your doctor will try to prescribe you the lowest dose for the shortest time to reduce the risk of side-effects. If you need to take aceclofenac for a long time, your doctor may want to prescribe another medicine along with it to protect your stomach from irritation.

Try to keep your regular appointments with your doctor. This is so your doctor can check on your progress.

If you have asthma, symptoms such as wheeze or breathlessness can be made worse by anti-inflammatories such as aceclofenac. If this happens to you, you should stop taking the tablets and see your doctor as soon as possible.

If you buy any medicines, check with a pharmacist that they are safe to take with an anti-inflammatory like aceclofenac. This is because you should not take these tablets with any other anti-inflammatory painkiller, some of which are available in cold and flu remedies which can be bought over the counter.

If you are having an operation or dental treatment, tell the person carrying out the treatment which medicines you are taking.

If your pain is not relieved by taking paracetamol, speak with your pharmacist or doctor for further advice.

It is important that you do not take more than one preparation containing paracetamol at a time. Paracetamol is an ingredient in a number of over-the-counter preparations, including many cold and flu products. Paracetamol may also be contained in painkillers which you may already have been prescribed by your doctor. Before taking any other medicines, check the label to see whether they contain paracetamol.

Can aceclofenac, Paracetamol and Chlorzoxazone cause problems?

Along with their useful effects, most medicines can cause unwanted side-effects although not everyone experiences them. The table below contains some of the most common ones associated with aceclofenac. You will find a full list in the manufacturer's information leaflet supplied with your medicine. The unwanted effects often improve as your body adjusts to the new medicine, but speak with your doctor or pharmacist if any of the following continue or become troublesome.

FINACE - MR
(Aceclofenac, Paracetamol and Chlorzoxazone Tablets)
Module-1



Paracetamol rarely causes side-effects when it is taken as recommended, but if you experience any symptoms which you think may be due to it, discuss them with your pharmacist or doctor.

3. How to take FINACE MR?

The dosage of Aceclofenac–Paracetamol- Chlorzoxazone prescribed to each patient will vary. Always follow your physician’s instructions and/or the directions on the prescription drug label.
Pain and inflammation

For adults: Aceclofenac 100 mg mixed paracetamol 500 mg and Chlorzoxazone USP 375 mg: Twice a day. Maximum: 2 tablets /day.

What if you miss a dose of Aceclofenac–Paracetamol-Chlorzoxazone?

If your physician has instructed or directed you to take Aceclofenac–Paracetamol medication in a regular schedule and you have missed a dose of this medicine, take it as soon as you remember. However, if it is almost time for your next dose, then skip the missed dose and go back to your regular dosing schedule. Do not double the doses unless otherwise directed.

What if you overdose on Aceclofenac–Paracetamol-Chlorzoxazone?

Any medication taken in excess can have serious consequences. If you suspect an overdose of Aceclofenac–Paracetamol-Chlorzoxazone, seek medical attention immediately.

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. Dizziness; drowsiness; general body discomfort; light-headedness; nausea; nervousness; over-stimulation.

Seek medical attention right away if any of these SEVERE side effects occur:

Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue; unusual hoarseness); black, tarry stools; bloody or coffee ground-like vomit; fever; symptoms of liver problems (eg, loss of appetite; unusual nausea, vomiting, or tiredness; stomach pain; dark urine; pale stools; yellowing of the skin or eyes); weight loss.

This is not a complete list of all side effects that may occur. If you have questions about side effects, contact your health care provider. Call your doctor for medical advice about side effects.

5. How to store FINACE – MR?

- Keep out of the reach and sight of children.
- Store below 30°C.
- Do not use the medicine after the expiry date, which is stated on the carton after (EXP). The expiry date refers to the last day of that month.

Module-1

□ Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What FINACE - MR (Aceclofenac, Paracetamol and Chlorzoxazone Tablets Tablets) contain
Each tablet contains active ingredients are Aceclofenac BP 100mg, Paracetamol BP 500mg and Chlorzoxazone USP 375 mg. The excipients in the tablets are Maize Starch BP, Purified Water BP, Methyl Hydroxybenzoate BP, Propyl Hydroxybenzoate BP, Sodium lauryl sulphate BP, Povidone.K-30 BP, Maize Starch BP, Purified Talc BP, Croscarmellose sodium BP, Colloidal Anhydrous Silica BP, Magnesium Stearate BP, Hypromellose BP, Purified Talc BP, Titanium Dioxide BP, Isopropyl Alcohol BP, Dichloromethane BP, Diethyl phthalate BP: Colour Quinoline Yellow Lake IHS.

What FINACE - MR (Aceclofenac, Paracetamol and Chlorzoxazone Tablets Tablets) Tablets look like and contents of the pack

FINACE - MR (Aceclofenac, Paracetamol and Chlorzoxazone Tablets Tablets) are a A Yellow coloured, caplet shaped, biconvex, film coated tablet having plain on both sides.

10 Tablet in Blister & 2 such Blisters in a carton = 2 x 10 = 20 Tablet.

8. Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Ochoa Laboratories

430, Mzz. F, Gundecha Indl. Complex

Akurli Road, kandivali (E).

Mumbai – 400101. India.

E-mail: support@eurochemgroup.com

Manufacturer

Aurochem Pharmaceuticals (I) pvt. Ltd.

58, Palghar Taluka, Industrial Co.-op. Estate Ltd.

Palghar – 401 404,

District Thane,

INDIA.

8 Date of Revision of PIL