

Aceclofenac 100 mg Film-coated Tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Aceclofenac is and what it is used for

Aceclofenac belongs to a group of medicines called non-steroidal anti-inflammatory drugs, or NSAIDs.

Aceclofenac is used to relieve pain and inflammation that occur with:

- osteoarthritis
- rheumatoid arthritis
- ankylosing spondylitis.

2. What you need to know before you take Aceclofenac

Do not take Aceclofenac:

- if you are allergic to aceclofenac or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to aspirin (acetylsalicylic acid) or any other non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, naproxen or diclofenac
- if you have taken aspirin (acetylsalicylic acid) or any other NSAIDs and experienced one of the following:
 - * asthma attack (wheezing, chest tightness, breathlessness)
 - * runny nose, itching and/or sneezing (irritation of the nose)
 - * swelling of the face, lips, tongue or throat (angioedema) leading to difficulty breathing
 - * raised red circular patchy rash on the skin which may have been itchy, stung or had a burning sensation, known as hives
- if you have a history of, suffer from, or suspect that you have a stomach or intestinal ulcer or bleeding especially if it is related to previous NSAIDs treatment. Signs of stomach bleeding include passing tarry stools, vomiting blood or particles that look like coffee granules
- if you have bleeding or bleeding disorders
- if you have established heart disease and / or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages
- if you have or have had problems with your blood circulation (peripheral arterial disease)
- if you suffer from severe liver failure or severe kidney failure
- if you are more than 6 months pregnant (in your last trimester).

Warnings and precautions

Talk to your doctor or pharmacist before taking Aceclofenac if you:

- have any of the following gastrointestinal disorders:
 - * inflammatory bowel disease (ulcerative colitis)
 - * chronic inflammatory bowel disease (Crohn's disease)Signs of these illnesses include heartburn, indigestion, feeling sick (nausea) or being sick (vomiting), bloating, diarrhoea or constipation.
- are a smoker
- have diabetes
- have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides
- suffer from asthma or any other breathing problems
- suffer from any form of liver or kidney disease, your doctor will monitor you closely and give you the lowest possible dose to treat your symptoms
- suffer from a blood clotting disorder
- suffer from a blood disorder known as porphyria or any other blood disorder
- have recently undergone major surgery
- are elderly (your doctor will prescribe you the lowest effective dose for the shortest period of time)
- have systemic lupus erythematosus (SLE) or other problems with the skin as you may be more likely to develop a form of meningitis that cannot be passed on to other people
- are currently suffering from chicken pox or shingles.

- are less than 6 months pregnant (first or second trimester), planning to become pregnant or if you have problems becoming pregnant.

During treatment

In the first month of treatment you are at a higher risk of having serious skin reactions. Stop taking aceclofenac if you get a skin rash, mouth lesions (damage to the skin or gums) or any other signs of an allergic reaction (see section 4 'Possible side effects').

If you are receiving long-term treatment with Aceclofenac, especially at high doses, your doctor may wish to monitor your progress with some blood tests. Medicines such as Aceclofenac may be associated with an increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment.

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary. Do not exceed the recommended dose or duration of treatment.

Other medicines and Aceclofenac

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, especially any of the following:

- medicines used to treat depression or manic depression (lithium, fluoxetine, citalopram)
- medicines used to treat heart failure and irregular heart beats (cardiac glycosides e.g. digoxin)
- medicines used to increase the rate of urine excretion (diuretics or 'water tablets' e.g. furosemide)
- medicines that stop blood clotting (anticoagulants e.g. warfarin, heparin)
- medicines used to lower blood sugar levels (antidiabetic drugs e.g. metformin)
- methotrexate which is used to treat cancer and autoimmune disorders
- mifepristone which is used as an emergency contraceptive or to induce abortions
- any other NSAIDs (e.g. aspirin (acetylsalicylic acid), ibuprofen, naproxen, diclofenac)
- medicines to reduce inflammation (corticosteroids e.g. prednisolone, hydrocortisone)
- medicines used to prevent organ or tissue rejection (ciclosporin or tacrolimus)
- medicines used to treat an infection (quinolone antibiotics, e.g. ciprofloxacin)
- medicines used to treat high blood pressure (antihypertensives)
- zidovudine, a medicine used to treat HIV infection.

These drugs may increase your risk of experiencing side effects.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Do not take Aceclofenac if you are pregnant or think you are pregnant. The safety of this medicine for use during pregnancy has not been established. It is not recommended for use in pregnancy unless considered essential by your doctor. Aceclofenac must not be used during the last three months of pregnancy.

Breast-feeding

Aceclofenac should not be used if you are breast-feeding. It is not known if this medicine passes into breast milk. It is not recommended for use during breast-feeding unless considered essential by your doctor.

Fertility

NSAIDs may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

Do not drive or operate dangerous machinery if you suffer from dizziness, drowsiness, a spinning sensation (vertigo), tiredness or any visual disturbances while you are being treated with non-steroidal anti-inflammatory drugs.

3. How to take Aceclofenac

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The tablets should be swallowed whole with a glass of water. Aceclofenac can be taken with or after food. Do not crush or chew the tablets.

Use in adults

The maximum recommended dose is 200 mg daily, one tablet in the morning and one tablet in the evening.

Use in elderly

If you are elderly, you are more likely to experience serious side effects (listed in section 4 'Possible side effects'). If your doctor prescribes Aceclofenac for you, you will be given the lowest effective dose for the shortest period of time.

Patients with liver problems

Your doctor may want you to take only one tablet a day to begin with.

Use in children and adolescents

Aceclofenac is not recommended for use in children and adolescents.

If you take more Aceclofenac than you should

Contact your doctor or nearest hospital emergency department **immediately**. Take the container and any remaining tablets with you. You may have a headache, feel sick (nausea), be sick (vomit), have stomach pain, bleeding or other problems with your gut, diarrhoea, reduced consciousness, feel disorientated, excited, drowsy, dizzy, ringing in the ears (tinnitus), low blood pressure, slower breathing, fainting, occasional fits, severe kidney failure or liver damage.

If you forget to take Aceclofenac

Do not take a double dose to make up for a forgotten dose. Take your dose as soon as you remember. If it is nearly time for your next dose, do not take the missed dose and carry on as normal.

If you stop taking Aceclofenac

You should not stop your treatment before speaking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

STOP taking your medicine and contact a doctor or visit your nearest hospital emergency department immediately if you experience any of the following side effects:

Rare (may affect up to 1 in 1,000 people):

- Heart failure or heart problems which can cause shortness of breath or ankle swelling.
- Severe allergic reaction (anaphylactic shock). Symptoms may include difficulty breathing, wheezing, abnormal pain and vomiting.
- Stomach ulcer, stomach bleeding or perforation of the stomach, large intestine or bowel wall. Symptoms could include severe abdominal pain, vomiting blood (or liquid with what looks like coffee grounds), blood in the faeces (stools/motions) or passing black tarry stools.
- Itchy swollen skin, skin rash, fever, tightness of the chest and difficulty with breathing (angioedema).

Very rare (may affect up to 1 in 10,000 people):

- Itchy skin, yellowing of the skin or whites of the eyes caused by liver problems (hepatitis).
- Inflammation of the pancreas which causes severe pain in abdomen and back.
- Kidney problems such as producing little or no urine, urinating more often or less often, lower back pain or have blood in your urine.
- Serious skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens Johnson syndrome).
- Severe blistering and peeling of the top layer of the skin.
- Reduced white or red blood cell count which can lead to fever, sore throat or swelling of the glands (bone marrow depression).
- Abnormal breakdown of red blood cells causing tiredness, shortness of breath or loss of appetite with a yellowing of the skin or whites of the eyes.

Not known (cannot be estimated from the available data):

- Medicines such as aceclofenac may be associated with a small increased risk of heart attack ("myocardial infarction"), a decrease in blood flow to the heart or stroke.
- Stiff neck, extreme sensitivity to bright light with fever, headache, feeling sick or being sick. These may be signs you have meningitis.
- Sudden dimming, blurring or loss of vision.
- Hallucinations or confusion.

If any of the following side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist:

Common (may affect up to 1 in 10 people):

- Dizziness.
- Indigestion, stomach pain.
- Feeling sick.
- Diarrhoea.
- Increased liver enzymes in the blood.

Uncommon (may affect up to 1 in 100 people):

- Constipation, wind.
- Being sick.
- Mouth ulcers.
- Itchy skin, rash.
- Increase in blood urea levels.
- Increase in blood creatinine levels.
- Inflammation or irritation of the lining of the stomach (gastritis).

- Inflammation of the skin (dermatitis).
- Raised circular red itchy, stinging or burning patches on the skin (hives).

Rare (may affect up to 1 in 1,000 people):

- Low red blood cell count which can be seen in a blood test.
- Other problems with your sight.
- Breathlessness or difficulty breathing.
- Raised blood pressure.

Very rare (may affect up to 1 in 10,000 people):

- Reduction in blood platelets which increases the risk of bleeding or bruising.
- High potassium levels in the blood.
- Depression.
- Increased blood alkaline phosphatase levels.
- Swelling of blood vessels (vasculitis).
- Difficulty sleeping or falling asleep.
- Unusual dreams.
- Uncontrollable shaking (tremor).
- Sleepiness.
- Headache.
- Disturbance or loss of taste.
- Inflammation of the mouth.
- Worsening of pre-existing conditions like inflammation of the intestine which causes abdominal pain or diarrhoea (colitis and Crohn's disease).
- Ringing in the ears (tinnitus).
- Tingling, pricking or numbness of skin.
- Unusual bleeding or bruising under the skin (purpura).
- Feeling of spinning (vertigo).
- Irregular and/or forceful heart beat (palpitations).
- Flushing or hot flushes.
- Wheezing, difficulty breathing, high pitched noise when breathing.
- Water retention and swelling.
- Cramp in the legs.
- Tiredness.
- Weight increase.

Not known (cannot be estimated from the available data):

- Generally feeling unwell.
- Sensitivity of skin to light.

Taking Aceclofenac can affect the results of various blood tests you may have done. This effect is generally not serious and the results should return to normal when you stop taking Aceclofenac.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aceclofenac

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Aceclofenac contains

The active substance is aceclofenac. Each tablet contains 100 mg aceclofenac.

The other ingredients are: cellulose microcrystalline, povidone, stearic acid, croscarmellose sodium and magnesium stearate. The film-coating also contains: titanium dioxide, hypromellose, macrogol and polysorbate 80 (E433).

What Aceclofenac looks like and contents of the pack

Aceclofenac film-coated tablets are round white or off-white with two sides that curve out marked "G" on one side.

Aceclofenac is available in blister packs containing 10, 20, 30 and 60 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer

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