

PACKAGE LEAFLET: INFORMATION FOR THE USER

Aceclofenac 100 mg film-coated Tablets **Aceclofenac**

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 further questions, please ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Aceclofenac Tablets is and what it is used for
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1. What Aceclofenac Tablets is and what it is used for

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

Aceclofenac Tablets is used to relieve pain and inflammation in patients suffering from:

- arthritis of the joints (osteoarthritis). This commonly occurs in patients over the age of 50 and causes the loss of the cartilage and bone tissue next to the joint.
- autoimmune disease that causes chronic inflammation of the joints (rheumatoid arthritis).
- arthritis of the spine which can lead to the fusion of the vertebrae (ankylosing spondylitis).

2. What you need to know before you take Aceclofenac Tablets

Do not take Aceclofenac Tablets:

- if you are allergic to aceclofenac or any of the other ingredients of Aceclofenac Tablets
- if you are pregnant (unless considered essential by your doctor).
- if aspirin or other NSAIDs have caused asthma, rhinitis (running nose) or urticaria (skin rash) or other allergic reaction.
- if you have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation.
- if you have severe kidney disease
- if you have severe heart disease or congestive heart failure (NYHA class, II-IV)
- if you have severe liver disease
- if you have history of active bleedings 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)

Warning and precautions:

Talk to your doctor, pharmacist or nurse before taking Aceclofenac tablets:

- if you have ever experienced stomach discomfort or pain, vomiting of blood or heartburn after taking aspirin or other nonsteroidal anti-inflammatory drugs.
- if you suffer from any other form of kidney or liver disease.
- if you suffer from asthma or any other breathing problems.
- if you have suffered from any blood-clotting problem (if you bleed easily).
- if you have recently undergone major surgery.
- if you are breast-feeding.
- if you are suffering from Crohn's disease (chronic inflammatory bowel disease) or ulcerative colitis (inflammatory bowel disease).
- if you suffer from a blood disorder known as porphyria.
- if you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.
- if you smoke
- if you have diabetes
- if you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides

Medicines such as Aceclofenac Tablets may be associated with an increased risk of heart attack ("myocardial infarction").

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.

Aceclofenac Tablets 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.

Other medicines and Aceclofenac Tablets:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

- Anticoagulants (drugs that alter the rate of blood clotting) like warfarin.
- Diuretics (drugs used to increase the rate of urine excretion) such as furosemide, hydrochlorothiazide or triamterene.
- Antidiabetic drugs (medicines used to lower blood sugar levels).
- Methotrexate (used to treat cancer, arthritis)
- Steroids.
- Ciclosporin and Tacrolimus (drugs used to suppress the immune system)
- Anti-infectives (Such as quinolone antibiotics)
- Zidovudine (drug used to treat HIV)
- Other non-steroidal anti-inflammatory agents (NSAIDs) like aspirin, ibuprofen
- SSRIs and lithium (used to treat depression or manic depression)
- Medicines used to treat high blood pressure (antihypertensives)
- Cardiac glycosides like digoxin (used to treat heart failure and irregular heart beats)

You should not take Aceclofenac Tablets for 8-12 days after taking mifepristone (drug used to terminate pregnancy).

Taking Aceclofenac Tablets with food and drink:

Aceclofenac Tablets should be taken preferably with or after food.

Pregnancy, breast-feeding and fertility:

Do not take Aceclofenac Tablets if you plan to become pregnant, are pregnant or breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:

As a precaution, you should refrain from driving or operating machinery if you feel dizzy or sleepy when you take Aceclofenac Tablets. Do not perform any of these actions until the effects wear off.

3. How to take Aceclofenac Tablets

Always take Aceclofenac Tablets exactly as your doctor has told you. You will be prescribed the lowest effective dose over the shortest duration to reduce side effects. You should check with your doctor or pharmacist if you are not sure.

Adults:

The recommended dose in adults is 200 mg a day. One 100mg tablet should be taken in the morning and one in the evening (1 tablet every 12 hours).

Children:

Aceclofenac Tablets is not recommended for use in children under the age of 18.

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 Tablets for you, you will be given the lowest effective dose over the shortest duration.

Method and route of administration:

Swallow the tablet whole with a glass of water. Do not crush or chew the tablets. Never change the dose of your medicine without talking to your doctor first. Continue to take your tablets for as long as your doctor recommends.

If you take more Aceclofenac Tablets than you should:

If you take more Aceclofenac tablets than you have been told to take, or if someone else accidentally takes your medicine, immediately see a doctor or go to a hospital straight away.

If you forget to take Aceclofenac Tablets:

If you forget to take your medicine at any time, take it as soon as you remember; then continue to take it at the usual times. Do not take a double dose to make up for a forgotten dose.

If you stop taking Aceclofenac Tablets:

Do not stop taking your tablets even if you are feeling well, unless your doctor tells you. If you have any further question on the use of the product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Aceclofenac tablets can cause side effects, although not everybody gets them.

If you experience any of the following side effects, tell your doctor immediately:

- medicines such as Aceclofenac tablets may be associated with a small increased risk of heart attack, ("myocardial infarction") or stroke
- severe allergic reaction (anaphylactic shock). Symptoms may include difficulty breathing, wheezing, abnormal pain and vomiting, **skin rash**, flaking skin, boils or **sore lips and mouth**
- very rarely signs may include sudden wheeziness **fluttering or tightness in the chest** and collapse.
- swelling of the face
- kidney failure

If you suffer from any of the following at any time during your treatment stop taking the medicine and seek immediate medical help:

- Pass blood in your faeces (stools/motions)
- Pass black tarry stools

- Vomit any blood or dark particles that look like coffee grounds.

Stop taking the medicine and tell your doctor if you experience:

- Indigestion or heartburn
- Abdominal pain (pains in your stomach) or other abnormal stomach symptoms.

If any of the below side effects get serious, or if you notice any other side effects not listed in this leaflet, please tell your doctor or pharmacist.

Common (occur in more than 1 in 100 patients but in less than 1 in 10 patients):

- dizziness
- indigestion
- abdominal pain
- nausea (feeling sick)
- diarrhoea
- increased liver enzymes in the blood

Uncommon (occur in more than 1 in 1,000 patients but in less than 1 in 100 patients):

- wind (flatulence)
- inflammation or irritation of the lining of the stomach (gastritis)
- constipation
- vomiting
- mouth ulcers
- itching
- rash
- inflammation of the skin (dermatitis)
- raised circular red itchy, stinging or burning patches on the skin (hives)
- increase in blood urea levels
- increase in blood creatinine levels

Rare (occur in more than 1 in 10,000 patients but in less than 1 in 1,000 patients):

- low levels of iron in the blood
- hypersensitivity (allergic reaction)
- swelling
- visual disturbance
- shortness of breath
- heart failure
- high blood pressure
- gastrointestinal (stomach) bleeding
- gastrointestinal (stomach) ulcer

Very Rare (occur in less than 1 in 10,000 patients):

- low white blood cells levels
- low platelets levels in the blood
- decreased bone marrow function
- abnormal breakdown of red blood cells (anemia)
- high potassium levels in the blood
- depression
- strange dreams
- inability to sleep
- tingling, pricking or numbness of skin
- uncontrollable shaking (tremor)
- drowsiness
- headaches

- abnormal taste in the mouth
- sensation of spinning when standing still
- heart pounding or racing (palpitations)
- hot flushes
- difficulty breathing
- high pitched noise when breathing
- inflammation of the mouth
- stomach ulcer
- inflammation of the pancreas (pancreatitis)
- inflammation of the liver (hepatitis)
- yellowing of the skin (jaundice)
- spontaneous bleeding into the skin (appears as a rash)
- blisters
- water retention and swelling
- tiredness
- leg cramps
- increased blood alkaline phosphatase levels
- weight gain
- sound or ringing in the ears
- swelling, redness, and pain in a blood vessel
- Crohn's disease (inflammation of the lining of the digestive system)
- Kidney failure

If any of the below side effects get serious, please tell your doctor or pharmacist.

Other side effects that have been reported with this type of drug (NSAIDs) are:

- bone marrow failure
- hallucinations
- confusion
- blurred, partial or complete loss of vision
- painful movement of the eye
- ringing in the ears
- aggravated asthma
- ulcers
- perforation of either the stomach, large intestine or bowel wall
- blistering and peeling of the top layer of skin
- mild, itchy pink/redness of the skin
- reddening or scaling of skin
- skin irritation (eczema)
- skin reaction to sunlight
- inflammation of the kidneys
- generally feeling unwell
- aseptic meningitis
- exacerbation of colitis and Crohn's disease
- hypertension (high blood pressure)
- cardiac failure
- bone marrow depression

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Tablets

- Keep this medicine out of the sight and reach of children.
- 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.
- Store below 25°C
- 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. Content of the pack and other information

What Aceclofenac Tablets contain:

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

The other ingredients are:

Core tablet: cellulose microcrystalline, croscarmellose sodium, povidone K-30, glyceryl palmitostearate.

Film-coating: Hypromellose 15 cps, macrogol 400 and titanium dioxide (E171).

What Aceclofenac Tablets looks like and contents of the pack:

Aceclofenac Tablets are white to off-white, round shaped, biconvex, film-coated tablet debossed with “100” on one side and plain on the other side.

Aceclofenac Tablets are available in boxes of 10, 20, 30, 40, 60 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Accord Healthcare Limited,
Sage House,
319 Pinner road,
North Harrow,
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