

A photograph of an ice climber in a dark jacket, red pants, and an orange helmet, using two ice axes to ascend a vertical ice wall. The climber is positioned on the right side of the frame. The background shows a dark rock face with icicles hanging from the top left corner. A large blue rectangular overlay covers the bottom half of the image, containing text and a logo.

Aceclofenac Film coated tablets

www.qualixpharma.com

 Qualix Pharma



Natural Park Maladeta-Posets, Pyrenees, Spain
(Photography: Dani Vega)



adm@qualixpharma.com

**ACECLOFENAC 100MG
FILM COATED TABLETS**
**ANTIINFLAMMATORY AND
ANTIRHEUMATIC NON-STERIODS**
LICENSE AND COMMERCIAL TERMS


PRODUCT: ACECLOFENAC
100MG
FILM COATED TABLETS



PACK SIZE: 20, 40
AND 80 TABLETS



MANUFACTURER:
EUROPEAN
(GMPS-EU)



SHELF-LIFE: 3 YEARS



DO NOT STORE
ABOVE 30°C.

BE

BE STUDY: YES



TYPE OF AGREEMENT:
LICENSE AND SUPPLY
AGREEMENT



TERRITORIAL SCOPE:
TO BE AGREED

TM

TRADEMARK:
TO BE AGREED



LICENSE FEE:
TO BE AGREED



DOSSIER FORMAT:
EU-CTD



DOSSIER STATUS:
AVAILABLE



STABILITY:
CLIMATIC ZONE II



CERTIFICATE OF
PHARMACEUTICAL PRODUCT
CPP: AVAILABLE

TECHNICAL INFORMATION:

The group of non-steroidal anti-inflammatory drugs (NSAIDs) are a group of medicines that relieve pain and fever and reduce inflammation. They are comparable from efficacy and potential adverse effects point of view, but having a high variability in response. The variability between individuals in the response to NSAIDs may influence both their efficacy and safety.

Aceclofenac is a non-steroidal anti-inflammatory drug (NSAID) that inhibits the prostaglandin synthesis.

The drugs belonging to this group, used at equipotent doses, usually are considered to have similar efficacy in inflammation or pain treatment. However, it has been shown, differences in hepatic, gastrointestinal and haematological toxicity.

Diclofenac may cause severe gastric ulcer if taken in improper way. The fact, Diclofenac tablets need to have a gastro-resistant coating in order to protect the stomach and reduce the adverse effects.

Aceclofenac is a better choice of drug in managing pain with better efficacy and tolerability. Patients experienced more number of adverse events (AEs) with Diclofenac when compared with Aceclofenac.

1. WHAT ACECLOFENAC IS AND WHAT IT IS USED FOR

Aceclofenac is a pain-relieving, anti-inflammatory and antirheumatic medicine. Aceclofenac is used for the treatment of chronic joint disorders with chronic pain and inflammation: such as osteoarthritis, rheumatoid arthritis and spondylarthritis ankylopoetica.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACECLOFENAC

You will be prescribed the lowest effective dose over the shortest duration to reduce side effects.

Do not take Aceclofenac Tablets

- If you are in the last 3 months of pregnancy.
- If you are allergic to aceclofenac or any of the other ingredients of this medicine.
- If you have had asthma, acute rhinitis, skin rash or other allergic reactions following the ingestion of acetylsalicylic acid or other nonsteroidal anti-inflammatory drug.
- If you are / were suffering from stomach or intestinal ulcer or gastrointestinal bleeding.
- If you have active bleeding or bleeding disorders.
- If you are suffering from severe liver or kidney disease.
- 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).

Warnings and precautions

Before you start taking Aceclofenac tablets, tell your doctor or pharmacist:

- If you have disorders of the stomach or gut/bowel, inflammatory bowel disease (ulcerative colitis), chronic inflammatory bowel disease (Crohn's disease), ulceration, bleeding or perforation of the stomach or bowel
- If you suffer from any other form of kidney or liver disease.
- If you have, or have ever had problems with the circulation of the blood to your brain.
- If you smoke
- If you have diabetes
- If you have angina, blood clots, high blood pressure, raised cholesterol or other raised body fats such as triglycerides
- If you suffer from a blood disorder known as porphyria.
- If you are recovering from major surgery.
- If you suffer from asthma or any other breathing problems.
- If you are infected with chicken pox, the use of this medicine should be avoided because a rare serious infection of the skin may develop.
- Hypersensitivity reactions can occur and very rarely, very serious allergic reactions are appearing. The risk is higher in the first month of treatment. Aceclofenac Tablets should be stopped immediately at the first onset of symptoms such as skin rashes, soreness of the skin lining the mouth and other mucous membranes causing ulcers, or any signs of hypersensitivity.

Other medicines and Aceclofenac

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Please tell your doctor if you are taking lithium, digoxin, diuretics, antihypertensives, anticoagulants, platelet aggregation inhibitors, antidiabetics, methotrexate, corticoids, acetylsalicylic acid and any other NSAID drugs, selective serotonin-reuptake inhibitors (SSRIs), ciclosporin, tacrolimus or zidovudine.

Aceclofenac with food and drink

Aceclofenac tablets must be taken with or without food.

Pregnancy, breast-feeding and fertility

Do not take this medicine if you are pregnant, think that you may be pregnant or intend to become pregnant whilst taking these tablets or are breast-feeding or planning to breast-feed.

Aceclofenac tablets should not be used if you are breast-feeding.

Driving and using machines

If you are taking Aceclofenac tablets and you experience dizziness, drowsiness, tiredness or any visual disturbances, you must not drive or use machinery.



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.

Film-coated tablets should be swallowed in whole with a sufficient quantity of liquid.

POSOLGY

The recommended dose in adults is 200 mg, i.e. one 100mg tablet should be taken in the morning and one in the evening (one film-coated tablet or sachet every 12 hours).

If you think the effect of Aceclofenac is too strong or weak, consult your doctor or pharmacist.

Use in children

It is not recommended the use in children.

Elderly

The dosage will be determined by your doctor and periodic control visit is necessary.

Kidney - and heart disease

The dosage will be determined by your doctor and periodic control visit is necessary.

Liver disease

The recommended initial daily dose should be reduced to one film-coated tablet.

Long-term treatment

If you receive long-term treatment with Aceclofenac, your doctor will perform control laboratory tests (liver and kidney function, blood-counts) at regular intervals.

4. POSSIBLE SIDE EFFECTS

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

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

- Dyspepsia (upset stomach or indigestion), abdominal pain, nausea and diarrhoea
- Dizziness
- Increased liver enzymes in the blood

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

- Wind (flatulence), inflammation or irritation of the lining of the stomach (gastritis), constipation, vomiting, mouth ulcer.
- 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 (may affect up to 1 in 1,000 people):

- Gastrointestinal haemorrhage, gastrointestinal ulceration.
- Cardiac failure, hypertension.
- Anaemia.
- Hypersensitivity (allergic reaction).
- Visual disturbance.
- Shortness of breath.

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

- Inflammation of the mouth, inflammation of the pancreas (pancreatitis), perforation of either the stomach, large intestine or bowel wall.
- Exacerbation of colitis and Crohn's disease.
- Purpura.
- Stevens Johnson's syndrome.
- Heart pounding or racing (palpitations), uncontrollable shaking (tremor) hot flushes,
- Inflammation of the liver (hepatitis), increased blood alkaline phosphatase levels.
- Abnormally low number of white blood cells and platelets in the blood.
- High levels of potassium in the blood.
- Depression, sleep disturbances, abnormal dreams.
- Tingling, pricking or numbness of skin, drowsiness, headaches, abnormal taste.
- Sensation of spinning when standing still, ringing in the ears (tinnitus).
- High pitched noise when breathing, difficulty breathing.
- Leg cramps.
- Disturbance of renal function, renal failure.
- Water retention and swelling.
- Weight gain.
- Exceptionally, serious skin infections occur in association with chickenpox.



5. HOW TO STORE ACECLOFENAC

Keep this medicine out of the sight and reach of children
Do not store above 30°C.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Aceclofenac looks like and contents of the pack

Aceclofenac 100mg film coated tablets: white, round, biconvex film coated tablets packed in Al/Al blister.

Pack size: 20, 40 or 60 film coated tablets.

