

# ACECOL 100mg (Aceclofenac) TABLETS

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

## USES:

**Aceclofenac 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).

## PRECAUTIONS:

Talk to your doctor, pharmacist or nurse before taking Aceclofenac tablet: if you have ever experienced stomach discomfort or pain, vomiting of blood or heartburn after taking aspirin or other non-steroidal 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 suffer from any blood-clotting problem (if you bleed easily).

If you have recently under gone major surgery.

If you are breast - feeding.

If you suffer 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 problem, 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.

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 minimized by using the lowest effective dose for the shortest duration necessary. Do not exceed the recommended dose or duration of treatment.

## DRUG INTERACTION:

Tell your doctor or pharmacist if you are taking, have recently taken or might have taken 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 (drugs used to terminate pregnancy).

## 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 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.

## DOSAGE:

### 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 Tablet 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 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 tablet. 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 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 TABLET:

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 double dose to make up for a forgotten dose.

## IF YOU STOP TAKING ACECLOFENAC TABLET:

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.

## POSSIBLE SIDE EFFECTS:

**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 stools/motions. Pass black tarry stools. Vomit any blood or dark particles that look like coffee ground. 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 ABDOMINAL PAIN:

Dizziness, Indigestion, Nausea (feeling sick), Diarrhoea, increased liver enzymes in the blood.

## UNCOMMON:

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:

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:

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 flushers, 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) blister, 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)

## 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 kidney.

## STORAGE:

Store in a cool and dry place.

Protect from heat , light and moisture.

Keep all medicines out of the reach of children.

To be sold on prescription only.

## HOW SUPPLIED:

Acecol 100mg tablets. Supplied in a blister Pack of 1 x 10's

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100 ملی گرام  
ٹیبلیٹس  
اسیکلو فینک

خوراک : ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

ہدایات : خشک اور ٹھنڈی جگہ پر رکھیں۔

گرمی، روشنی اور نمی سے بچائیں۔

تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

Manufactured by:  
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