epigastric pain, gastrointestinal liritation, gastrointestinal bleeding, rarely diarrhoea, disorientation, excitation, common, drowsiness, disziness, limitus, phycelension, crea, preprietarry depression, fainting, occasionally and convulsions. In cases of significant poisoring acute renal failure and plev dramage are possible. b) Therapeutic measure

### Patients should be treated symptomatically as required

Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within one hour of ingestion of a potentially considered within one hou life-threatening overdose.

Specific therapies such as dialysis or haemoperfusion are probable of no help in eliminating NSAIDs due to their high rate of protein binding and extensive metabolism.

Good urine output should be ensured. Renal and liver function should be closely monitored

Patients should be observed for all least four hours after ingestion of potentially toxic amounts. In case of frequent or prolonged convulsions, patients should be treated with intravenous diazepam.

Other measures may be indicated by the patient's clinical condition.

Management of acute poisoning with oral aceclofenac essentially consists of supportive and symptomatic measures for complications such as hypotension, renal fallure, convulsions, gastro-intestinal irritation, and respiratory decression.

### PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties
Pharmacotherapeutic group: Antiinflammatory and
Antiinheumatic products, non-steroids; Acetic acid
derivatives and related substances
ATC Code: M01AB16

# Pharmacodynamic properties Aceclofenac is a non-steroidal agent with marked antiinflammatory and analgesic properties.

The mode of action of accelofenac is largely based on the inhibition to prostaglandin synthesis. Accelofenac is a potent inhibitor of the enzyme cyclo-oxygenase, which is involved in the production of prostaglandins.

Pharmacokinetic properties
After oral administration, accidenac is rapidly and complistly absorbed as unchanged drug. Peak plasma concentrations are reached approximately 12 to 3.00 hours following imagestion. Accidence ponentials into the synovial fluid, where the concentrations reach approximately 57% of those in plasma. The volume of distribution is approximately 57% of the six plasma. The volume of distribution is approximately 55%.

The mean plasma elimination half-life is around 4 hours. Acedofenac is highly protein-bound (1995). Acedofenac icriculates mainly as unchanged drug, and 4- Hydroxyacedofenac is the main metabolite detected in plasma. Approximately two- thirds of the administered dose is excreted via the urine, mainly as hydroxymetabolites.

No changes in the pharmacokinetics of acedofenac have been detected in the elderly.

Preclinical safety data
The results from preclinical studies conducted with acceptenace are consistent with those expected for NSAIDs. The principal target organ was the gastro-intestinal tract. No unexpected findings were recorded.

Acedofenac was not found to be carcinogenic in either

Animal studies indicate that there was no evidence of teratogenesis in rats although the systemic exposure was low and in rabbits, treatment with aceclofenac (10 mg/kg/day) resulted in a series of morphological changes in some fetuses.

### PHARMACEUTICAL PERTICULARS

### Shelflife: 24 months

Storage Condition : Do not store above 30°C.

Name and Contents of Container 10 tablets in Alu-Alu blister pack, 2 such blisters in a printed carton along with Pack Insert.

Manufacturing Authorization Holder	Manufacturer
Ajanta Pharma Limited Ajanta House, Charkop Kandrif (West) Mumbal - 400 087, India. Tal: +91-22-9508 1000 Fax: (0011) 22-95081200/ 300 Email: info@sjantahams.com	Ajanta Pharma Limited Mirza, Palashbari Road, VII-Kokhar, Kamrup, Assam India

### Version No : 00

Last Revision Date: Oct 20, 2020

RELEASE TABLETS 200 MG

Distribution Category: Prescription Only Medicine or

# 1. What Actinac ER 200 is and what it is used for What Actinac ER 200 is and what It is used for Actinac ER 200 belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). They have anti-inflammatory and painkiller properties causing a lowering of swelling, redness (inflammation) and pain. The medicine/active ingredient of Actinac ER 200 is accolorence.

Actinac ER 200 works by blocking the production of hormone-like substances called prostaglandins

- - connective tissue disorders.

    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.

    If you are converted from mail for surroup. ....econor or use sion may develop.
    If you are recovering from major surgery,
    If you are elderly (your doctor will prescribe you the
    lowest effective dose over the shortest duration).

# 2. What you need to know before you take Actinac ER 200 Do not take Actinac ER 200

if you are allergic to aceclofenac or any of the other ingredients of this medicine, if you are allergic to aspirin or any other NSAIDs (such as ibuprofer, naproxen or dicjofenac).

### **ACTINAC ER 200**

ACECLOFENAC EXTENDED

# the nose), raised red circular patchy rash on the skin which may have feltitchy or like a sting or burn. a severe allergic reaction known as anaphylactic shock. The symptoms may be life threatening and include difficulty breathing, wheezing, abdominal pain and weight.

- PATENT THE ORBATION LEALET

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

  Keep this leifest. You may need to read it again:

  Keep this leifest. You may seed to read it again:

  This medicine has been prescribed for you oely. Or the start of the prescribed for you oely. Or the start of the prescribed for you oely. Or the start of pain and vomiting if you have a history of, suffer from, or suspect that you have a stomach ulcer or have vomited blood or passed blood in your faeces (black tarry stools). passed blood in your faeces (black tarry stools). If you have sever kidney disease. If you have established heart disease and for cerebrovascular disease e.g. if you have had a heart attack, stroke, min-stroke (TLA) or blockages to blood vessels to the heart or brain or an operation to dear or bypess blockages.
- What is in this leaflet:

  1. What Actinae ER 200 is and what it is used for 2. What you need to know before you take Actina
- 200
  3. How to take Actinac ER 200
  4. Possible side effects
  5. How to store Actinac ER 200
  6. Contents of the pack and other information

staglandins have many functions in the body staglandins have many functions in the body sting an important role in both the way the body sends to inflammation and also the reabsorption or

Actinac ER 200 is used to relieve pain and reduce redness and swelling (inflammation) in patients suffering from:

- Ostecarthritis inflammation of the joints. This is a common condition in patients over the age of 50 and causes damage to the tissues and bones in the
- joints.

  Rheumatoid arthritis long term inflammation of the joints caused by the body's own immune system
- (autoimmune response).
  Ankylosing spondylitis inflammation of the soine/backbone which can lead to the joints fusing

If you have taken aspirin or any other NSAIDs and experienced one of the following: asthma attack causing lightness in the chest wheezing and difficulty breathing. runny nose, litching and/or sneezing (irritation of the nose). skin rashes, soreness of the skin lining the mouth ther mucous membranes causing ulcers, or any

clotting disorders.

If you are pregnant (unless your doctor considers it essential for you to continue to take this medicine)

Actinac ER 200 is not recommended for use in children

Warnings and precautions
Before you start taking Actinac ER 200, tell your doctor:
If you suffer from any other form of kidney or liver disease.

disease. If you have any of the following disorders, as they

may worsen:
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

if you have, or have ever had problems with the

if you have, or have ever had problems with the cruciation of the decoded you brain. Cruciation of the decoded you brain. problems. Come askine or any other broathing problems. If you suffer from a rare inherited discorder known as if you have any other than the company of you have discharged in your brain and body fast such as thighcorrection of or other raised body fast such as thighcorrection of or other raised body fast such as thighcorrection of or other raised body fast such as thighcorrection of if you suffer from an audiormismae condition known as systemic layers enythematisms or or their such problems.

Hypersensitivity reactions can occur and very rarely, very serious allergic reactions are appearing (see section-4) resolite side effects). The risk in higher in the first month of treatment. Actinac ER 200 should be stopped immediately at the first onest of symptoms such as lightness of the chest, breathing difficulties,

Medicines such as Actinac ER 200 may be as with a small increased risk of heart attack ("m wour a small increased risk of heart attack (myocardia) infarction"). Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

# Other medicines and Actinac ER 200

- 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: medicines used to treat mental health problems like
- nuoxetine, fluvoxamine, paroxetine and sertraline) or manic depression (lithium) nedicines used to treat heart failure and irregular to clear or bypass blockages.
  If you have or have had problems with your blood cruption (periphenal attential disease).
  If you suffer from, or suspect that you have severe liver failure.
  If you suffer from bleeding or any type of blood dotting diseases. heartbeats (cardiac glycosides such as digoxin) medicines used to treat high blood pressure (antihypertensives: ACE inhibitors such as enalopril. Ilsimopril: angiotensin III receptor antagonists such as losartan, candesartan; also hydralazine, methyldopa, donidine, moxonidine, propramatol)
  - oprana(o)) edicines to treat infection (quinolone antibiotics ach as ciprofloxacin, ofloxacin, levofloxacin
  - noxitioxacin) rugs used to increase the rate of urine excretion fluretics such as thiazides, furosemide amiloride
  - inyurochloride) medicines that stop blood clotting (anticoagulants) such as warfarin, heparin methotrexate which is
  - has warfarin, heparin hotrexate which is used to treat cancer and bimmune disorders such as arthritis and skin

  - conditions integrations of the teachest of sending and inflammation (glucoporticoids such as hydrocordison-perdisobne), medicines used to suppress the immune system medicines used to suppress the immune system medicines used for suppress the immune system medicines used for teach IVI (zdovudne) immune medicines used to flower blood supple levels in medicines used to flower blood supple levels in discussion to the control of the control o

# Actinac ER 200 with food and drink Actinac ER 200 must be taken preferably with or after

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

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

Do not take Actinac ER 200 if you are pregnant or think you are pregnant. The safety of this medicine for use during pregnancy is not known. It is not recommended for use in pregnancy unless considered essential by your do

Actinac ER 200 should not be used if you are breast-feeding. It is not known if this medicine passes into breast mik. It is not recommended for use during breast-feeding unless considered essential by your

Driving and using machines
If you are taking Actinac ER 200 and you experience
dizzinoss, drowsinoss, vertigo, tiredness or any
difficulty with your eyesight, you must not drive or use
machinery.

3. How to take Actinac ER 200
Always take this medicine exactly as your doctor or pharmacist has told you. You will be prescribed the lowest effective dose over the shortest duration it reduce side effects. Check with your doctor or pharmacist (you are not sure.)

Tablets should be swallowed whole with plenty of water and should be taken with or after food. Do not crush or chew the tablets.

Do not exceed the stated daily dose

### If you stop taking Actinac ER 200

o not stop taking Actinac ER 200 unless your doctor

## STOP TAKING the medicine and seek medical advice if

# Elderly If you are elderly, you are more likely to experience sorious side-effects (listed in section "Possible Side Elfects"). If your doctor prescribes Actinac ER 200 for you, you will be given the lowest effective dose over the shortest duration of treatment.

If you take more Actinac ER 200 than you should If you accidentally take too many Actinac ER 200 tablets, contact your doctor immediately or go to your nearest hospital casually department. Please take this leaflet or the box the Actinac ER tablets came in, with you to the hospital so that they will know what you have

# If you have any further questions on the use of this

- 4. Possible side effects
  Like all medicines, this medicine can cause side effects.
- severe allergic reaction (anaphylactic shock). Symptoms may develop quickly and can be life-threatening if not immediately treated and include fever, difficulty breathing, wheezing, abdominal pain, vomiting, swelling of the face and throat, severo skin rashes auch as Stevene-Johnnson Syndrome and Toxic Epidemal Necrolysis. These

- are potentially life-threatening and develop quickly forming large blaters and the skin to peel away. The rash can also appear in the mouth, throat or eyes. Fever, headsche and aching of the joints usually cocur at the same time.

  meninglist. The symptoms include high fever, headache, vontiling, olytelny red rashes, neck stiffness, senativity and intolprance to [gith.]

# indigestion or heartburn, abdominal pain (pains in your stomach) or other

- adoptimisk penning you sounder, or other blood disorders such as reduced production of blood cells, ahnormal breakdown of red blood cells known as heamolytic aneamis, low content of from in the blood, low level of white blood cells, low number of platelet cells, increased blood potassis, lowed which can irritate the blood vessels causing inflammation known as vasculist. These disorders can cause you to feel externely tred, breathless, solding of the joints and be prone to repeated could be considered.
- If any of the below side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell notice any side effects not listed in this leafle your doctor or pharmacist. Common (may affect up to 1 in 10 people): dzziness nausea (feeling sick) diarrhoea increased liver enzymes in the blood

- Uncommon (may affect up to 1 in 100 people):
- inflammation or irritation of the lining of the stomach constipation
- omiting mouth ulcers
- If you forget to take Actinac ER 200
  If you miss a dose, do not worry, just take the next dose
  at the usual time. Do not take a double dose to make up
  for a forgotten tablet dose.
  - mation of the skin raised circular red itchy, ng or burning patches on the skin (hives) stinging or burning patches on the s increase in blood urea levels increase in blood creatinine levels
  - Rare (may affect up to 1 in 1,000 people):
  - hypersensitivity (allergic reaction)
    problems with eyesight
    heart failure
    high blood pressure, shortness of breath
    bleading from the stomach or bowel
    stomach or bowel ulceration
  - Very Rare (may affect up to 1 in 10,000 people):
  - depression strange dreams inability to sleep tingling, pricking or numb uncontrollable shaking uncontrollable shaking drowsiness headaches abnormal taste in the mouth sensation of spinning when standing still dealing in the cours
  - ringing in the ears heart pounding or racing

- hot flushes difficulty breathing high pitched noise when breathing inflammation of the mouth perforation of either the stomach, large intestine or bowel wall worsening of colitis and Crohn's disease inflammation of the
  - inflammation of the pancreas injury of the liver (including hepatitis) yellowing of the skin spontaneous bleeding into the skin (appears as a conth.)
    - rash) nephrotic syndrome: a condition which indicates kidney damage and includes large amounts of protein in the urine, low blood albumin kevels, high blood cholesterol levels and swelling of the legs, feet or ankles water retention and swelling
    - water retermion. .... thredness leg cramps increased blood alkaline phosphatase levels

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

    - insillucinations confusion in sillucinations confusion blurred, partial or complete loss of vision painful movement of the eye worsening of asthma skin reaction to sunlight inflammation of the kidneys generally feeling unwall

    - Exceptionally, serious skin infections occur in association with chickenpox 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. By reporting side-effects, you can help provide more information on the safety of

- How to store Actinac ER 200
   Keep this medicine out of the sight and reach of
- How to this return of the sight and reach of children. Do not store above 30°C. Do not store the modern eather the expiry date which so not use the modern eather the expiry date which so the store above 30°C. The expiry date which so the store above 30°C and the store of the store of the product of the store of the store of the store of you store Actions ER 200 in the original blox. Do not throw away any medicines via vesterwater or to causeful which. Ask, your plannascal those to measures will help protect the environment. These measures will help protect the environment.

### 6. Contents of the pack and other information What Actinac ER 200 contains The active ingredient is Aceclofenac BP 200 mg

List of Excipients:
Microcrystalline callulose, Hypromellose (K100
Premium LVCR), Povidone (P.V.P.K.30), Punfied Talc,
Magnesium Stearate, Lactose (Monohydrate),
Isopropyl Alcohol, Hypromellose (Methocel E3
Pammium IV), Dichrormethane (Methylene Chiodde)

What Actinac ER looks 200 like and contents of the

Plack
White to off-white coloured, circular, biconvex, film
coated tablets, plain on both sides.

10 tablets in Alu-Alu blistor pack, 2 such blisters in a
printed carton along with Pack Insert.

Manufacturing Authorization Holder	Manufacturer
Ajanta Pharma Limbed Ajanta House, Charkop Kandiki (West) Mumbal - 400 067, India. Tal : +91-22-8606 1000 Fax: (0091) 22-86061200 300 Email : info@ajantapharma.com	Ajanta Pharma Limbod Mirza, Palashberi Road, Vill-Kokihar, Kamrup, Assam, India

For any information about this medicinal product, please contact Manufacturing Authorization Holder.

DATE OF PUBLICATION OR REVISION