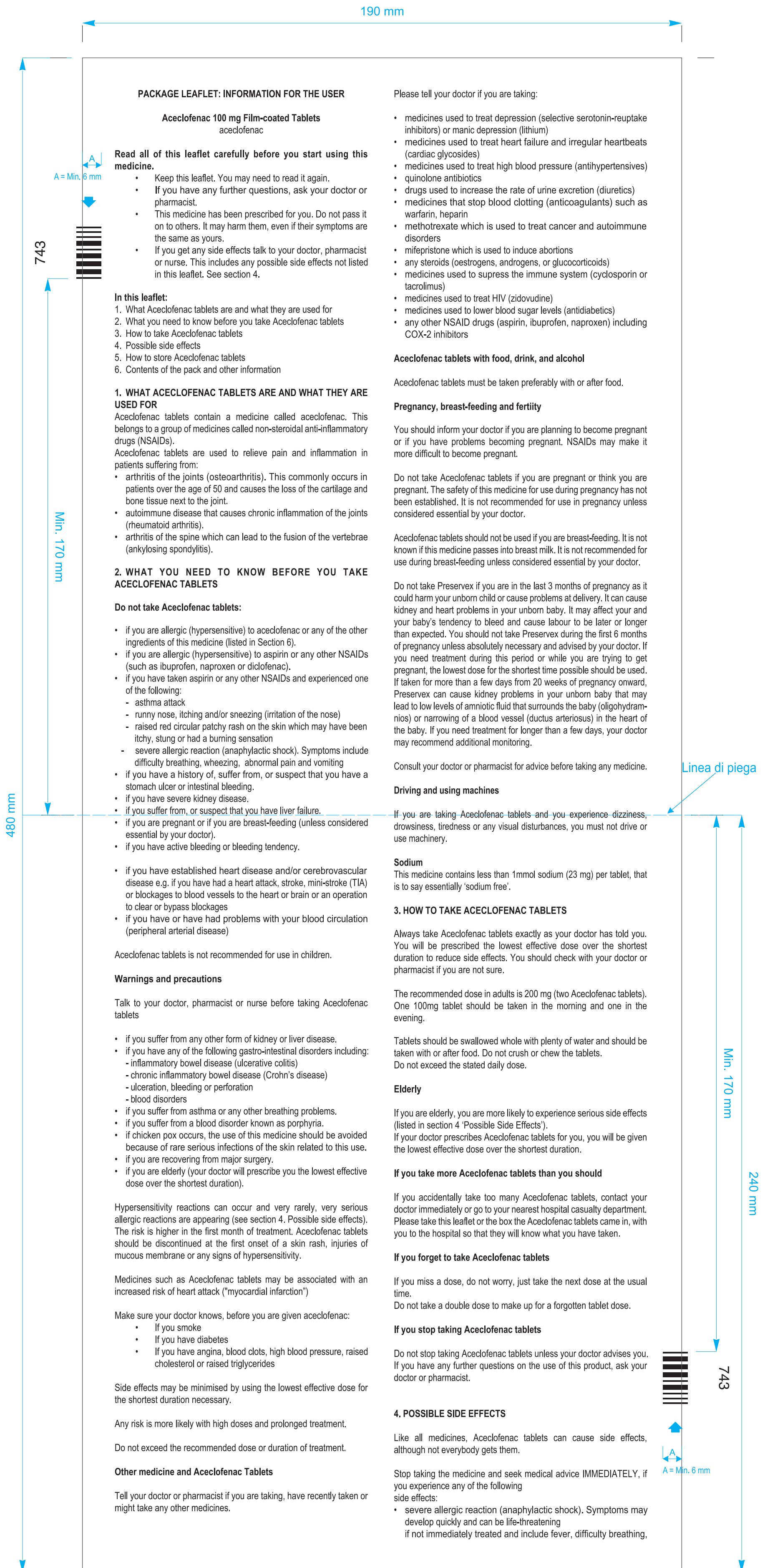


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Aceclofenac 100 mg Film-coated Tablets Leaflet Fto: 190x 480 mm

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Aceclofenac 100 mg Film-coated Tablets
aceclofenac

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms 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.

In this leaflet:

1. What Aceclofenac tablets are and what they are used for
2. What you need to know before you take Aceclofenac tablets
3. How to take Aceclofenac tablets
4. Possible side effects
5. How to store Aceclofenac tablets
6. Contents of the pack and other information

1. WHAT ACECLOFENAC TABLETS ARE AND WHAT THEY ARE USED FOR

Aceclofenac tablets contain a medicine called aceclofenac. This belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

Aceclofenac tablets are 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 (hypersensitive) to aceclofenac or any of the other ingredients of this medicine (listed in Section 6).
- if you are allergic (hypersensitive) to aspirin or any other NSAIDs (such as ibuprofen, naproxen or diclofenac).
- if you have taken aspirin or any other NSAIDs and experienced one of the following:
 - asthma attack
 - runny nose, itching and/or sneezing (irritation of the nose)
 - raised red circular patchy rash on the skin which may have been itchy, stung or had a burning sensation
 - severe allergic reaction (anaphylactic shock). Symptoms include difficulty breathing, wheezing, abnormal pain and vomiting
- if you have a history of, suffer from, or suspect that you have a stomach ulcer or intestinal bleeding.
- if you have severe kidney disease.
- if you suffer from, or suspect that you have liver failure.
- if you are pregnant or if you are breast-feeding (unless considered essential by your doctor).
- if you have active bleeding or bleeding tendency.
- 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)

Aceclofenac tablets is not recommended for use in children.

Warnings and precautions

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

- if you suffer from any other form of kidney or liver disease.
- if you have any of the following gastro-intestinal disorders including:
 - inflammatory bowel disease (ulcerative colitis)
 - chronic inflammatory bowel disease (Crohn's disease)
 - ulceration, bleeding or perforation
 - blood disorders
- if you suffer from asthma or any other breathing problems.
- if you suffer from a blood disorder known as porphyria.
- if chicken pox occurs, the use of this medicine should be avoided because of rare serious infections of the skin related to this use.
- if you are recovering from major surgery.
- if you are elderly (your doctor will prescribe you the lowest effective dose over the shortest duration).

Hypersensitivity reactions can occur and very rarely, very serious allergic reactions are appearing (see section 4. Possible side effects). The risk is higher in the first month of treatment. Aceclofenac tablets should be discontinued at the first onset of a skin rash, injuries of mucous membrane or any signs of hypersensitivity.

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

Make sure your doctor knows, before you are given aceclofenac:

- If you smoke
- If you have diabetes
- If you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

Any risk is more likely with high doses and prolonged treatment.

Do not exceed the recommended dose or duration of treatment.

Other medicine and Aceclofenac Tablets

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 depression (selective serotonin-reuptake inhibitors) or manic depression (lithium)
- medicines used to treat heart failure and irregular heartbeats (cardiac glycosides)
- medicines used to treat high blood pressure (antihypertensives)
- quinolone antibiotics
- drugs used to increase the rate of urine excretion (diuretics)
- medicines that stop blood clotting (anticoagulants) such as warfarin, heparin
- methotrexate which is used to treat cancer and autoimmune disorders
- mifepristone which is used to induce abortions
- any steroids (oestrogens, androgens, or glucocorticoids)
- medicines used to suppress the immune system (cyclosporin or tacrolimus)
- medicines used to treat HIV (zidovudine)
- medicines used to lower blood sugar levels (antidiabetics)
- any other NSAID drugs (aspirin, ibuprofen, naproxen) including COX-2 inhibitors

Aceclofenac tablets with food, drink, and alcohol

Aceclofenac tablets must be taken preferably with or after food.

Pregnancy, breast-feeding and fertility

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

Do not take Aceclofenac tablets 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 tablets 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.

Do not take Preservex if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take Preservex during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Preservex can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Consult your doctor or pharmacist for advice before taking any medicine.

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.

Sodium

This medicine contains less than 1mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

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.

The recommended dose in adults is 200 mg (two Aceclofenac tablets). One 100mg tablet should be taken in the morning and one in the evening.

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.

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.

If you take more Aceclofenac tablets than you should

If you accidentally take too many Aceclofenac tablets, contact your doctor immediately or go to your nearest hospital casualty department. Please take this leaflet or the box the Aceclofenac tablets came in, with you to the hospital so that they will know what you have taken.

If you forget to take Aceclofenac tablets

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.

If you stop taking Aceclofenac tablets

Do not stop taking Aceclofenac tablets unless your doctor advises you. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Stop taking the medicine and seek medical advice IMMEDIATELY, if you experience any of the following 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.
- severe skin rashes such as Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis. These are potentially life-threatening and develop quickly forming large blisters and the skin to peel away. The rash can also appear in the mouth, throat or eyes. Fever, headache and aching of the joints usually occur at the same time.
- meningitis. The symptoms include high fever, headache, vomiting, blotchy red rashes, neck stiffness, sensitivity and intolerance to light.
- passing blood in your faeces (stools/motions).
- passing black tarry stools. Vomit any blood or dark particles that look like coffee grounds.
- medicines such as Aceclofenac tablets may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.
- kidney failure.

STOP TAKING the medicine and seek medical advice if you experience:

- indigestion or heartburn.
- abdominal pain (pains in your stomach) or other abnormal stomach symptoms.
- blood disorders such as reduced production of blood cells, abnormal breakdown of red blood cells known as haemolytic anaemia, low content of iron in the blood, low level of white blood cells, low number of platelet cells, increased blood potassium levels which can irritate the blood vessels causing inflammation known as vasculitis. These disorders can cause you to feel extremely tired, breathless, aching of the joints and be prone to repeated infections and bruising.

If any of the **below** side effects get serious, or if you notice any 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
- 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)
- visual disturbance
- cardiac failure
- hypertension
- shortness of breath
- gastrointestinal haemorrhage
- gastrointestinal ulceration

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

- 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
- ringing in the ears (tinnitus)
- heart pounding or racing (palpitations)
- hot flushes
- difficulty breathing
- high pitched noise when breathing
- inflammation of the mouth
- perforation of either the stomach, large intestine or bowel wall
- exacerbation of colitis and Crohn's disease
- 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

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

- hallucinations
- confusion
- blurred, partial or complete loss of vision
- painful movement of the eye
- aggravated asthma
- skin reaction to sunlight
- inflammation of the kidneys
- generally feeling unwell

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. 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 this medicine after the expiry date which is stated on the carton and the blister foil. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions

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 to protect the environment.

6. FURTHER INFORMATION

What Aceclofenac tablets contain

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

The other ingredients are: microcrystalline cellulose (E460i), croscarmellose sodium, copovidone, talc (E553b), silica colloidal anhydrous, glycerol distearate.

The film coating contains: HPMC 2910/Hypromellose, Microcrystalline Cellulose, Titanium dioxide (E171), Polyoxyl 40 (Macrogol) stearate.

What Aceclofenac tablets look like and contents of the pack

Aceclofenac 100 mg tablets are white, round, biconvex film-coated tablets.

They are available in Aluminium/Aluminium blister packs of 20, 30, 40, 60, 90, 100 or 180 tablets.

Not all pack sizes may be marketed

Marketing authorisation holder and Manufacturer

Marketing Authorisation Holder

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100 Bishopsgate
London
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United Kingdom

Manufacturer

Rivopharm UK Ltd.
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