



MercuryPharma

Package leaflet: Information for the patient
Econac® XL 100mg Tablets
diclofenac sodium

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 any further questions, 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.

The name of your medicine is Econac XL 100mg Tablets. It will be referred to as Econac Tablets for ease here after.

What is in this leaflet

1. What Econac Tablet is and what it is used for
2. What you need to know before you take Econac Tablets
3. How to take Econac Tablets
4. Possible side effects
5. How to store Econac Tablets
6. Contents of the pack and other information

1. WHAT ECONAC TABLET IS AND WHAT IT IS USED FOR

Econac Tablets contain diclofenac and belong to a group of medicines called non-steroid anti-inflammatory drugs (NSAIDs). These medicines reduce pain and inflammation, and bring down a high temperature. Econac Tablets are used to treat a number of painful conditions affecting the joints such as arthritis and muscles sprains, fractures, dislocation, back pain, dental and other minor surgeries. Econac Tablets are specially formulated to release diclofenac slowly, over several hours.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ECONAC TABLETS

Do not take Econac Tablets

- If you think you may be allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of Econac Tablets. (These are listed at the end of the leaflet.) Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, chest pain, runny nose, skin rash or any other allergic type reaction.
- If you have or previously have had a peptic ulcer bleeding or perforation in your stomach or intestines
- If you have established heart disease and/or cerebrovascular disease e.g. if you have had a heart attack, stroke, ministroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages
- If you have severe heart, kidney or liver failure or cerebrovascular bleeding (bleeding in your brain)
- If you have or have had problems with your blood circulation (peripheral arterial disease)
- If you have had stomach or bowel problems after taking other NSAIDs
- If you are in your last three months of pregnancy.

Tell your doctor or pharmacist if you are not sure if any of the conditions above apply to you.

Econac Tablets are **not recommended for children**.

Warnings and precautions

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

- If you have had an ulcer or some other problem affecting your stomach or intestines (ulcerative colitis, Crohn's disease)
- If you have asthma or wheezing attacks (or if you have had asthma in the past)
- If you have any heart, liver or kidney problems
- If you are elderly
- If you have low body weight
- If you have mixed connective tissue disorders and systemic lupus erythematosus -SLE (which results in joint pain, skin change and disorders of other organs)
- If you have a condition called porphyria
- If you have recently undergone major surgery
- If you are particularly prone to infections (diclofenac may suppress the signs and symptoms of an infection)
- If you have experienced stomach discomfort, had heartburn or felt nauseous after taking aspirin or any other nonsteroidal anti-inflammatory drugs
- If you have a bleeding/blood disorder
- If you smoke
- If you have diabetes

- If you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides
- If you had a previous episode of vomiting blood or blood in stools
- If you experience skin rash, itching, painful red areas, peeling or blistering of the skin or any other allergic reaction within the first few days of treatment with diclofenac
- If you are planning to be pregnant or planning on becoming pregnant.

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

If you are having a medical examination, tell the doctor that you are taking Econac Tablets as they reduce the signs of infection, fever and inflammation which would otherwise be noticed.

Medicines such as Econac Tablets may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with higher doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

If you have heart problems or suffered from a previous stroke or think that you may 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.

Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before taking Econac Tablets, as Econac Tablets can sometimes worsen wound healing in your gut after surgery.

Long term use with diclofenac is not recommended, however it is advised to undergo routine blood tests if diclofenac is indicated for long term treatment.

Other medicines and Econac Tablets

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

Econac Tablets may affect or be affected by the following medicines

- Anticoagulant tablets (to prevent blood clots, e.g. warfarin)
- Medicines for the treatment of high blood pressure (diuretics, beta-blockers and ACE inhibitors)
- Diuretics (to make you pass more water e.g. spironolactone, amiloride and triamterene)
- Lithium (for depression)
- Medicines for the treatment of heart conditions (e.g. digoxin)
- A corticosteroid (e.g. for asthma and various inflammatory conditions)
- Antibiotics such as quinolone (for an infection e.g. quinolones like ciprofloxacin, nalidixic acid, norfloxacin)
- Any other NSAID (for painful or inflammatory conditions e.g. aspirin, ibuprofen, naproxen etc)
- Mifepristone (used as an emergency contraceptive or to induce abortion or labour)
- Ciclosporin or Tacrolimus (used to suppress the body's immune system, e.g. following transplants or in diseases such as psoriasis and rheumatoid arthritis)
- Zidovudine (an anti-viral drug)
- Medicines of the class SSRIs (Selective Serotonin Reuptake Inhibitors) to treat depression such as fluoxetine or sertraline (for depression)
- Medicines used to treat diabetes
- Phenytoin (medicines to treat epilepsy)
- Colestipol and cholestyramine (medicines to lower cholesterol level)
- CYP2C9 inhibitors: e.g. Sulfinapyrazone and voriconazole
- Methotrexate (used to treat cancer)
- Anti-platelet drugs which affect the clotting of blood which may increase the risk of bleeding.

Pregnancy, breast-feeding and fertility

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

Pregnancy

Do not take Econac Tablets if you are pregnant (or think you may be) or breast-feeding unless your doctor has decided that it is in your best interests. You should NOT take these tablets during the last three 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 Econac Tablets 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 few days from 20 weeks of

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AMS Component No.	AW-LF-0001541 (v0.2)
Product Description:	Econac XL 100mg Tablets
Component:	Leaflet
Product Code:	100103
Country:	UK
Vendor Name:	Intas Pharmaceuticals Ltd
Proof Number:	0.2
Revision Date:	19-Aug-2025
Revised by:	PAT

Dimension:	160 x 270 mm
Commodity No.:	N/A
Pharma Code:	N/A
Print Colours:	Black
Non-Print Colours:	Cutter
Min. Font Size:	8 pt

pregnancy onward, Econac Tablets 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.

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

Breast-feeding

Diclofenac is known to pass into milk into small amounts and hence should be avoided by nursing mothers.

Fertility

Econac 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.

Driving and using machines

If you feel dizzy, sleepy or experience visual disturbances when you start to use Econac Tablets, do not drive or use machines until the effect has worn off.

Econac Tablets contain lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE ECONAC TABLETS

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Econac Tablets should be taken with or after food. The tablets should be swallowed whole with a glass of water.

The recommended dose is

Adults: The usual dose is one tablet each day with a maximum daily dose of 150 mg. As a general principle, the smallest effective dose should be used.

Elderly population: If you are elderly, your doctor may want to reduce the usual adult dose and check that the medicine is suiting you, especially during the first four weeks of treatment. Be sure to follow your doctor's instructions carefully and to keep your appointments.

Use in Children:

Econac Tablets are not recommended for use in children.

If you take more Econac Tablets than you should

If you (or someone else) take too many of these tablets, contact your doctor or hospital immediately for advice. Bring the pack with any remaining tablets with you.

If you forget to take Econac Tablets

If you miss a dose, leave it out and take the next dose whenever it is due. After that, just carry on as before. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects can be serious.

Stop taking Econac Tablets and tell your doctor straight away if you notice any of the side effects:

- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Econac Tablets and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain (frequency not known, cannot be estimated from the available data)
- Stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick)
- Any sign of bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit or black, tarry faeces
- A serious allergic skin reaction which may include large widespread red and/or dark patches, swelling of the skin, blisters, itching (Generalised bullous fixed drug eruption), swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- Painful red areas, peeling or blistering
- Yellowing of your skin or the whites of your eyes
- Persistent sore throat or high temperature
- An unexpected change in the amount of urine produced and/or its appearance
- Sudden and crushing chest pains (signs of myocardial infarction or heart attack)
- Breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of heart failure)
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

If you notice that you are bruising more easily than usual or have frequent sore throats or infections, tell your doctor.

Other side effects

Common: may affect up to 1 in 10 people

- headache, dizziness, spinning of head, feeling sick (nausea), being sick (vomiting), diarrhea, indigestion, pain in your stomach, wind, loss of appetite, raised liver enzymes and rash.

Rare: may affect upto 1 in 1000 people

- allergic reactions, skin rashes, sleeplessness, asthma, difficulty in breathing, gastritis, indigestion, stomach ache, inflammation of liver (hepatitis), jaundice and liver disorder general swelling of the body.

Very rare: may affect up to 1 in 10,000 people

- reduction in the number of blood platelets (increase chance of bleeding or bruising)
- deficiency of red cells or of haemoglobin in the blood
- deficiency of granulocytes in the blood, causing increased chances of infection
- fluid retention in body and face characterised by swelling of the skin
- disorientation, depression, sleeplessness, nightmare, irritability, psychotic disorder, nervousness, abnormal sensation typically tingling or pricking, memory impairment, convulsions (sudden, violent movements of the body), dysfunction of the sense of taste, hallucinations (seeing or hearing things that are not really there), sensory disturbance
- visual disturbance, blurred vision, double vision
- ringing in the ears, impaired hearing
- palpitations (awareness of your heartbeat), chest pain, abnormally low blood pressure (hypotension), abnormally high blood pressure (hypertension), inflammation of blood vessels, colitis (inflammation of the lining of the colon), constipation, mouth ulcers, inflammation of intestines (Crohn's disease), inflammation of pancreas, hepatitis and liver failure
- inflammation of skin with blisters containing fluid, flu-like symptoms with painful red or purplish rashes and blisters on skin (Stevens-Johnson syndrome), increase in reactivity of the skin to sunlight, itching and bleeding of skin, baldness, inflammation of small blood vessels (Henoch-Schonlein purpura)
- kidney failure and presence of blood in urine.

Not known: frequency cannot be estimated from the available data

Confusional state, Hallucinations (seeing or hearing things that are not really there), sensory disturbances, Inflammation of the nerves in the eye, feeling of discomfort and erectile dysfunction. Medicines such as Econac may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. An allergic skin reaction, that may include round or oval patches of redness and swelling of the skin, blistering, and itching (Fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur. Fixed drug eruption usually reoccurs at the same site(s) if the medication is taken again.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ECONAC 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 after 'Exp.' The Expiry date refers to last day of that month. Do not store above 25°C. Keep in original container/package in order to protect from light.

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. CONTENTS OF THE PACK AND OTHER INFORMATION

What Econac Tablets contains

- The active substance is Diclofenac Sodium. Each prolonged release tablet contains 100mg Diclofenac Sodium.
- The other ingredients are lactose monohydrate, magnesium stearate, hydrogenated vegetable oil Type I, povidone K 30, talc.

What Econac Tablets looks like and contents of the pack
Econac Tablets are white circular, biconvex, tablets engraved with "DSR" on one side. Each tablet contains 100mg diclofenac sodium. They are packed in either aluminium blister packs (20, 21, 28, 30 tablets), tubes with plastic caps (56, 100, 250, 500 tablets) or plastic bottles with screw caps (56, 100, 250, 500 tablets). Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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