

## **Package Leaflet: Information for the user**

### **Barcan 100 mg film-coated tablets** Aceclofenac

**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.

#### **What is in this leaflet**

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

#### **1. What Barcan is and what is used for**

Barcan belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These drugs have anti-inflammatory and painkiller properties. The active ingredient of Barcan is aceclofenac.

Barcan is used to relieve pain and inflammation if you suffer from different types of inflammation of the joints (rheumatic diseases such as: osteoarthritis, rheumatoid arthritis or ankylosing spondylitis).

#### **2. What you need to know before you take Barcan**

##### **Do not take Barcan:**

- if you are allergic to aceclofenac or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic 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
  - bronchospasm
  - 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
- if you have active bleeding or bleeding disorders.
- 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 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).
- if you suffer from severe liver failure.
- if you are in the last three months of pregnancy.

### **Warnings and precautions**

Talk to your doctor before taking Barcan:

- if you suffer from any form of kidney or liver disease or if you have a tendency to fluid retention or you are being treated with diuretic medication.
- if you have any of the following disorders, as they may worsen:
  - gastrointestinal disorders of the upper or lower tract
  - inflammatory bowel disease (ulcerative colitis)
  - chronic inflammatory bowel disease (Crohn's disease)
  - a history suggestive of stomach ulcer, bleeding or perforation - blood disorders
- if you have, or have ever had problems with the circulation of the blood to your brain.
- if you suffer from a metabolic disorder known as porphyria.
- if you suffer from systemic lupus erythematosus, SLE (a chronic skin and connective tissue disease, typically involving rash on the bridge of the nose and cheeks).
- if you smoke
- if you have diabetes
- if you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides
- if you are receiving at the same time medicines that can increase the risk of ulcers or digestive bleeding, e.g., oral corticosteroids, anticoagulants such as warfarin, antidepressants that belong to the group of the serotonin reuptake inhibitors, or platelet aggregation inhibitors such as aspirin.
- if you have suffered in the past /or still suffer from bronchial asthma.
- if chicken pox occurs, the use of this medicine should be avoided because of rare serious infections of the skin related to this use.

Medicines such as Barcan may be associated with an increase risk of ulcers and digestive bleeding (combination therapy with protective agents should be considered) and/or an increased risk of heart attack ("myocardial infarction"). Side effects may be minimised by using the lowest effective dose for the shortest duration necessary. Do not exceed the recommended dose or duration of the treatment.

Hypersensitivity reactions, including angioedema (skin swelling mainly around eyes and lips), can occur without earlier exposure to the drug. Serious skin reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported very rarely in association with the use of medicines like Barcan. The risk is higher in the first month of treatment. Stop the treatment and tell your doctor immediately at the first onset of a skin rash, injuries of mucous membrane or any signs of hypersensitivity (see section 4).

If you are elderly, you are more likely to experience serious side-effects, especially gastrointestinal bleeding or a puncture (perforation). If your doctor prescribes Barcan for you, you will be given the lowest effective dose over the shortest duration.

### **Children and adolescents**

Do not give Barcan to children and adolescents.

## Other medicines and Barcan

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:

- any other non-steroidal anti-inflammatory drugs (**NSAID**) (such as aspirin, ibuprofen, naproxen)
- medicines used to treat **depression** (such as selective serotonin-reuptake inhibitors, so-called SSRIs ) or manic depression (lithium)
- medicines used to treat **heart** failure and irregular heart beats (digoxin)
- medicines used to treat high blood pressure (antihypertensives)
- drugs used to increase the rate of **urine excretion** (diuretics) which are also used to treat high blood pressure
- medicines that stop **blood** clotting (anticoagulants) such as warfarin
- methotrexate which is used to treat **cancer** and **autoimmune** disorders (eg. psoriasis and rheumatism)
- 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)

## Barcan with food and drink

Barcan can be taken with food.

## 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.

### 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.

### Pregnancy

Do not take Barcan 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 Barcan 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, Barcan 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.

### Breast-feeding

It is not known if this medicine passes into breast milk. It is not recommended for use during breastfeeding unless considered essential by your doctor.

### **Driving and using machines**

Do not use any tools or machines if you experience dizziness, drowsiness, tiredness or any visual disturbances while taking this medicine.

### **Sodium**

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

## **3. How to take Barcan**

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

You will be prescribed the lowest effective dose over the shortest duration to reduce side effects. Do not exceed the stated daily dose.

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

For patients with liver impairment the recommended initial dose is 100 mg.

Tablets should be swallowed whole with a glass of water and can be taken with food.

### **If you take more Barcan than you should**

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

Symptoms of an overdose can include nausea, vomiting, stomach pain, dizziness, drowsiness and headache.

### **If you forget to take Barcan**

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 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.

If you experience any of the following side effects, stop the treatment and tell your doctor **immediately**:

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

- swelling of the face, tongue or throat, difficulty swallowing (angioedema), visual disturbances, high blood pressure, worsening of high blood pressure, heart failure, shortness of breath
- severe stomach pain or any sign of bleeding in the stomach or intestines, bleeding of the gastrointestinal tract (blood in the stools or black coloring of the stools)

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

- yellowing of the skin and eyes, occasionally with high fever or swelling and sensitivity of the upper abdomen (hepatitis and/or pancreatitis)
- vomiting of blood
- detachment of the skin and/or mucous membrane (Stevens-Johnson syndrome, a condition with red blistered, eroded, bloody or crusted skin, and toxic epidermal necrolysis, a disease with blistering and peeling of the top layer of the skin).
- bronchospasm

Stop taking the medicine and *tell your doctor as soon as possible if you experience:*

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

- indigestion or heartburn
- stomach pain or other abnormal stomach symptoms.

The following side effects have also been reported:

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

- dizziness
- feeling sick
- diarrhoea
- increased liver enzymes in the blood

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

- wind
- 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 (may affect up to 1 in 1,000 people):

- low count of red blood cells (anemia)
- severe allergic reactions including so-called anaphylactic shock
- hypersensitivity (allergic reaction)

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

- decrease in blood cell counts (bone marrow depression)
- changes in blood cells levels
- abnormal breakdown of red blood cells (haemolytic 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
- buzzing in the ears (tinnitus)
- heart pounding or racing (palpitations)
- hot flushes
- vascular inflammation
- bronchospasm
- inflammation of the mouth
- stomach ulcer
- intestinal perforation
- worsening of ulcerative colitis and Crohn's disease
- a number of small bleedings in the skin (appears as a rash)
- increased blood alkaline phosphatase levels
- skin irritation (eczema)
- disturbances in renal function
- water retention and swelling
- tiredness
- leg cramps
- weight gain

In rare cases, serious skin infections occur in association with chickenpox.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Barcan**

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 outer carton and blister after "EXP". The expiry date refers to the last day of that month.

Do not store above 30°C.

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. Contents of the pack and other information**

### **What Barcan contains**

The active substance is aceclofenac 100 mg.

The other ingredients (excipients) are:

Tablet core: microcrystalline cellulose, croscarmellose sodium, povidone and glyceryl palmitostearate.

Coating material: hypromellose, microcrystalline cellulose, macrogol 40 stearate and titanium dioxide.

**What Barcan looks like and contents of the pack**

Barcan 100 mg film-coated tablets are white, round film-coated tablets with a diameter of 8 mm

Barcan tablets are available in blister packs containing 10, 20, 30, 50, 60, 100 or 600 (30 x 20) tablets. Each strip contains 10 or 15 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder: Almirall

S.A.

General Mitre 151

08022 Barcelona

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Manufacturer:

Industrias Farmacéuticas Almirall, S.A.

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**This medicinal product is authorised in the Member States of the EEA under the following names:**

|         |                                    |
|---------|------------------------------------|
| France  | Cartrex 100 mg comprimé pelliculé  |
| Germany | Beofenac 100 mg Filmtablette       |
| Sweden  | Barcan 100 mg filmdragerad tablett |

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