

**PACKAGE LEAFLET**

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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

#### **1. What Preservex is and what it is used for**

Preservex 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 Preservex is aceclofenac.

Preservex works by blocking the production of hormone-like substances called prostaglandins. Prostaglandins have many functions in the body including an important role in both the way the body responds to inflammation and also the reabsorption of calcium in some diseases of the bone.

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

- Osteoarthritis - 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 spine/backbone which can lead to the joints fusing together.

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

##### **Do not take Preservex**

- 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 causing tightness in the chest wheezing and difficulty breathing.
  - runny nose, itching and/or sneezing (irritation of the nose).
  - raised red circular patchy rash on the skin which may have felt itchy 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 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).

- 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, or suspect that you have severe liver failure.
- if you suffer from bleeding or any type of blood clotting disorders.
- if you are pregnant (unless your doctor considers it essential for you to continue to take this medicine)

Preservex is not recommended for use in children.

### Warnings and precautions

Before you start taking Preservex, tell your doctor:

- if you suffer from any other form of kidney or liver 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 or bowel
- if you have, or have ever had problems with the circulation of the blood to your brain.
- if you suffer from asthma or any other breathing problems.
- if you suffer from a rare inherited disorder known as **porphyria**.
- if you smoke
- if you have diabetes
- if you have angina, blood clots, high blood pressure, raised cholesterol or other raised body fats such as triglycerides
- if you suffer from an autoimmune condition known as systemic lupus erythematosus or other 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 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. Preservex should be stopped immediately at the first onset of symptoms such as tightness of the chest, breathing difficulties, fever, skin rashes, soreness of the skin lining the mouth and other mucous membranes causing ulcers, or any signs of hypersensitivity.

Medicines such as Preservex may be associated with a small increased risk of heart attack ("myocardial 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 Preservex

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 **depression** (selective serotonin-reuptake inhibitors (SSRIs) such as citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine and sertraline) or manic depression (lithium)
- medicines used to treat **heart** failure and irregular heart beats (cardiac glycosides such as digoxin)
- medicines used to treat high blood pressure (antihypertensives: ACE inhibitors such as enalapril, lisinopril; angiotensin II receptor antagonists such as losartan, candesartan; also hydralazine, methyldopa, clonidine, moxonidine, propranolol)

- medicines to treat infection (**quinolone antibiotics** such as ciprofloxacin, ofloxacin, levofloxacin, moxifloxacin)
- drugs used to increase the rate of **urine excretion** (diuretics such as thiazides, furosemide, amiloride hydrochloride)
- medicines that stop **blood** clotting (anticoagulants) such as warfarin, heparin
- methotrexate which is used to treat **cancer** and **autoimmune** disorders such as arthritis and skin conditions
- mifepristone
- any **steroids** for the treatment of swelling and inflammation (glucocorticoids such as hydrocortisone, prednisolone,)
- medicines used to suppress the **immune** system after organ transplant (cyclosporin or tacrolimus)
- medicines used to treat HIV (zidovudine)
- medicines used to lower blood **sugar** levels in diabetes (antidiabetics such as glibenclamide, glicazide, tolbutamide)
- any other painkiller **NSAID** drugs (aspirin, ibuprofen, naproxen, COX-2 inhibitors such as celecoxib and etoricoxib)
- antiplatelet drugs such as clopidogrel.

### **Preservex with food and drink**

Preservex must be taken preferably with or after 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.

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

Do not take Preservex 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 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.

Preservex 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.

### **Driving and using machines**

If you are taking Preservex and you experience dizziness, drowsiness, vertigo, tiredness or any difficulty with your eyesight, 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 Preservex**

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 to reduce side effects. Check with your doctor or pharmacist if you are not sure.

The recommended dose in adults is 200mg (two Preservex 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 Preservex for you, you will be given the lowest effective dose over the shortest duration of treatment.

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

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

#### **If you forget to take Preservex**

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 Preservex**

Do not stop taking Preservex unless your doctor advises you.

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.

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.
- 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

- dizziness
- nausea (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
- constipation
- vomiting
- mouth ulcers
- itching
- rash
- inflammation of the skin 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):

- hypersensitivity (allergic reaction)
- problems with eyesight
- heart failure
- high blood pressure/shortness of breath
- bleeding 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 numbness of skin
- uncontrollable shaking
- drowsiness
- headaches
- abnormal taste in the mouth
- sensation of spinning when standing still
- 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 pancreas
- injury of the liver (including hepatitis)
- yellowing of the skin

- spontaneous bleeding into the skin (appears as a rash)
- nephrotic syndrome: a condition which indicates kidney damage and includes large amounts of protein in the urine, low blood albumin levels, high blood cholesterol levels and swelling of the legs, feet or ankles
- 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
- worsening of 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, Website: [www.mhra.gov.uk/yellowcard](http://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 Preservex**

Keep this medicine out of the sight and reach of children.

Store below 30°C.

Do not use this medicine after the expiry date which is stated on the outer carton. The expiry date refers to the last day of that month. It is recommended that you store Preservex in the original box.

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 Preservex contains**

The active substance is aceclofenac 100mg.

The other ingredients (excipients) are:

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

Coating Material - partially substituted hydroxypropyl methylcellulose, microcrystalline cellulose, polyoxyethylene 40 stearate and titanium dioxide (E171).

### **What Preservex looks like and contents of the pack**

Preservex 100 mg film-coated tablets are white, round tablets.

Preservex tablets are available in boxes of either 10 or 60 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder:

Almirall S.A.  
General Mitre 151  
08022 Barcelona  
Spain

Manufacturer:

Industrias Farmacéuticas Almirall, S.A.  
Ctra. de Martorell 41-61,  
08740 Sant Andreu de la Barca  
Barcelona  
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