

PACKAGE LEAFLET: INFORMATION FOR THE USER

PRESERVEX™ 100MG TABLETS (aceclofenac)

Your medicine is available using the name Preservex 100mg Tablets but will be referred to as Preservex throughout this leaflet.

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 also section 4.

What is in this leaflet:

- What Preservex is and what it is used for
- What you need to know before you take Preservex
- How to take Preservex
- Possible side effects
- How to store Preservex
- 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). These drugs have anti-inflammatory and painkiller properties. The active ingredient of Preservex is aceclofenac.

Preservex works by blocking the production of hormone-like substances called prostaglandins. Prostaglandins are released at the sites of injury, tissue damage and immune reactions. Prostaglandins play an important role in both the inflammatory response of the body and stimulating the re-absorption of bone in diseases.

Preservex is 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 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
 - 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 have or have ever had a severe heart failure (heart attack).
- if you suffer from, or suspect that you have severe liver failure.
- if you suffer from bleeding or bleeding disorders.
- if you are pregnant (unless considered essential by your doctor).

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:
 - gastrointestinal disorders of the upper or lower tract
 - inflammatory bowel disease (ulcerative colitis)
 - chronic inflammatory bowel disease (Crohn's disease)
 - ulceration, 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 asthma or any other breathing problems.
- if you suffer from **porphyria**.
- if you have heart problems, previous stroke or think that you might be at risk of these conditions (for example, if you have high blood pressure, diabetes, high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.
- 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.

Preservex should be discontinued at the first onset of a skin rash, injuries of mucous membrane or any signs of hypersensitivity.

Medicines such as Preservex may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

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 **depression** (selective serotonin-reuptake inhibitors) 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)
- 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
- 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

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 are planning to become pregnant or 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 has not been established. It is not recommended for use in pregnancy unless considered essential by your doctor.

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 breastfeeding unless considered essential by your doctor.

Driving and using machines

If you are taking Preservex and you experience dizziness, drowsiness, vertigo, tiredness or any visual disturbances, you must not drive or use machinery.

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 200 mg (two Preservex tablets). One 100 mg 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.

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.
- medicines such as Preservex 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 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 (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 (may affect up to 1 in 1,000 people):

- hypersensitivity (allergic reaction)
- visual disturbance
- cardiac failure
- hypertension
- shortness of breath
- gastrointestinal haemorrhage
- gastrointestinal 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 (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)
- injury of the liver (including hepatitis)
- yellowing of the skin (jaundice)
- spontaneous bleeding into the skin (appears as a rash)
- nephrotic syndrome
- 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, Website: 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 Preservex

Keep out of the sight and reach of children.

The box is marked by a "use by date". Do not take the tablets after this date. The expiry date 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 store above 30°C.

If your tablets appear to be discoloured or show any signs of deterioration, please return them to your pharmacist who will advise you.

If your doctor tells you to stop taking the tablets, please take them back to the pharmacist. Only keep the tablets if your doctor tells you to.

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 ingredient in Preservex is aceclofenac. Each film-coated tablet contains 100mg of aceclofenac.

Preservex also contains the following inactive ingredients used to bind and coat the tablets, these are: microcrystalline cellulose, sodium croscarmellose polyvidone, glycerol palmitostearate, and the film coat, containing partially substituted hydroxypropyl methylcellulose, polyoxyethylene 40 stearate and titanium dioxide.

What Preservex looks like and contents of the pack

Preservex are white round film-coated tablets, 8mm in diameter, without any markings.

Preservex are available in blister strips of 20, 40 and 60 tablets.

Manufacturer

Preservex are manufactured by: Industrias Farmacéuticas Almirall, S.A., Ctra. Nacional II, Km. 593, 08740 Sant Andreu de la Barca - Barcelona, Spain.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

Product Licence holder: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

PL No: 04423/0339

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Leaflet revision date: 09.06.16

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ACECLOFENAC 100MG TABLETS

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What is in this leaflet:

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- What you need to know before you take Aceclofenac
- How to take Aceclofenac
- Possible side effects
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- Contents of the pack and other information

1. What Aceclofenac is and what it is used for

Aceclofenac 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 Aceclofenac is aceclofenac.

Aceclofenac works by blocking the production of hormone-like substances called prostaglandins. Prostaglandins are released at the sites of injury, tissue damage and immune reactions. Prostaglandins play an important role in both the inflammatory response of the body and stimulating the re-absorption of bone in diseases.

Aceclofenac is 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

Do not take Aceclofenac:

- 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).
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 - 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 have or have ever had a severe heart failure (heart attack).
- if you suffer from, or suspect that you have severe liver failure.
- if you suffer from bleeding or bleeding disorders.
- if you are pregnant (unless considered essential by your doctor).

Aceclofenac is not recommended for use in children.

Warnings and precautions

Before you start taking Aceclofenac, tell your doctor:

- if you suffer from any other form of kidney or liver disease.
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 - gastrointestinal disorders of the upper or lower tract
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 - chronic inflammatory bowel disease (Crohn's disease)
 - ulceration, 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 asthma or any other breathing problems.
- if you suffer from **porphyria**.
- if you have heart problems, previous stroke or think that you might be at risk of these conditions (for example, if you have high blood pressure, diabetes, high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.
- 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 should be discontinued at the first onset of a skin rash, injuries of mucous membrane or any signs of hypersensitivity.

Medicines such as Aceclofenac may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

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

Do not exceed the recommended dose or duration of treatment.

Other medicines and Aceclofenac

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

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- 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
- 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 with food and drink

Aceclofenac 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 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 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 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 breastfeeding unless considered essential by your doctor.

Driving and using machines

If you are taking Aceclofenac and you experience dizziness, drowsiness, vertigo, tiredness or any visual disturbances, you must not drive or use machinery.

3. How to take Aceclofenac

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 200 mg (two Aceclofenac tablets). One 100 mg 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 for you, you will be given the lowest effective dose over the shortest duration.

If you take more Aceclofenac 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

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

Do not stop taking Aceclofenac 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.
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- meningitis. The symptoms include high fever, headache, vomiting, blotchy red rashes, neck stiffness, sensitivity and intolerance to light.
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- kidney failure.

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- constipation
- vomiting
- mouth ulcers
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- inflammation of the skin (dermatitis)
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- increase in blood urea levels
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Rare (may affect up to 1 in 1,000 people):

- hypersensitivity (allergic reaction)
- visual disturbance
- cardiac failure
- hypertension
- shortness of breath
- gastrointestinal haemorrhage
- gastrointestinal 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 (tremor)
- drowsiness
- headaches
- abnormal taste in the mouth
- sensation of spinning when standing still
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