

ALMIRAL SUPPOSITORIES

Diclofenac Sodium (100mg)

What is in this leaflet

1. What Almiral Suppositories is used for
2. How Almiral Suppositories works
3. Before you use Almiral Suppositories
4. How to use Almiral Suppositories
5. While you are using it
6. Side effects
7. Storage and disposal of Almiral Suppositories
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Almiral Suppositories is used for

Almiral Suppositories relieve pain, reduce swelling and ease inflammation in conditions affecting the joints, muscles and tendons.

How Almiral Suppositories works

Almiral Suppositories contains diclofenac sodium which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs relieve the symptoms of inflammation, such as pain and swelling, by blocking the production of the molecules (prostaglandins) responsible for pain and inflammation.

Before you use Almiral Suppositories

- When you must not use it

Do not use Almiral Suppositories if you:

- are allergic to diclofenac sodium, aspirin, ibuprofen, other NSAID, or any of the other ingredients of this medicine (listed in section 6). Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, runny nose, skin rash or any other allergic type reaction.
- have ulcer in stomach or digestive tract.
- have had stomach or bowel problems after you have taken other NSAIDs.
- have severe heart, kidney or liver failure.
- have any heart problem or blood vessel blockage
- have or have had problems with your blood circulation (peripheral arterial disease).
- are more than six months pregnant.
- have rectal inflammation.

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

Pregnancy and Lactation

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 not use Almiral Suppositories during the last 3 months of pregnancy as it may affect the baby's circulation.

Using Almiral Suppositories may make it more difficult to conceive. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.

- Before you start to use it

Talk to your doctor or pharmacist before using Almiral Suppositories if you:

- Have any stomach or bowel disorders including ulcerative colitis or Crohn's disease.
- Have kidney or liver problems, or you are elderly.
- Have a condition called porphyria (liver disorder that affects skin and nervous system).
- Have any blood or bleeding disorder.
- Have had asthma.
- Have heart problems, or you have had a stroke, or you think you might be at risk of these conditions (for example, if you have high blood pressure, diabetes or high cholesterol or are a smoker).
- Have diabetes.
- Smoke.
- Have Lupus (SLE) or any similar condition.
- Recently had or you are going to have a surgery of the stomach or intestinal tract before receiving/taking/using Almiral Suppositories, as Almiral suppositories can sometimes worsen wound healing in your gut after surgery.

- Taking other medicines

Tell your doctor or pharmacist if you are

using, have recently used or might use any other medicines.

Some medicines can interfere with your treatment. Tell your doctor or pharmacist if you are taking any of the following:

- Lithium (used to treat some mental problems).
- Cardiac glycosides (for example digoxin), used to treat heart problems.
- Diuretics (water tablets).
- Medicines used to treat heart conditions or high blood pressure, for example beta-blockers or ACE inhibitors.
- Trimethoprim (used to prevent or treat urinary tract infections).
- Anticoagulants (blood thinning tablets like warfarin).
- Any other NSAID or COX-2 (cyclo-oxygenase-2) inhibitor, for example aspirin or ibuprofen.
- Oral steroids (an anti-inflammatory drug).
- Medicines known as SSRIs used to treat depression.
- Medicines to treat diabetes.
- Methotrexate (for some inflammatory diseases and some cancers).
- Cyclosporine and tacrolimus (used to treat some inflammatory diseases and after transplants).
- Quinolone antibiotics (for infections).
- Phenytoin (used to treat seizures).
- Colestipol/cholestyramine (used to lower cholesterol).
- Mifepristone (used to terminate pregnancy).
- Voriconazole (used to treat fungal infections).

How to use Almiral Suppositories

- How much to use

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

Suppositories are designed for insertion into the back passage (rectum). Never take them by mouth.

The doctor may also prescribe another medicine to protect the stomach.

The recommended dose:

Adults

Almiral Suppositories are normally

ALMIRAL SUPPOSITORIES

Diclofenac Sodium (100mg)

inserted one at night. The daily dose should not exceed 150mg. The number of suppositories you need will depend on the strength which the doctor has given you.

Elderly

Your doctor may advise you to take a dose that is lower than the usual adult dose if you are elderly. Your doctor may also want to check closely that the Almira Suppositories are not affecting your stomach, particularly during the first 4 weeks that you are using the suppositories.

Use in children

Almira Suppositories are not suitable for children.

- When to use it

The doctor will tell you how to use Almira Suppositories. Always follow his/her instructions carefully.

- Empty your bowels before inserting a suppository.
- Wash your hands.
- Take out the strip of suppositories and tear off one along the perforation.
- Then take the suppository out of the plastic wrapping by pulling back the loose end.
- Lie on one side with your knees pulled up towards your chest.
- Gently push the suppository pointed end first into your back passage (rectum) with your finger.
- Lower your legs and, if possible, stay still for a few minutes.
- If you feel as if you need to push the suppository out, try to resist this by lying still with your buttocks pressed together. It is important to keep the suppository in the rectum to allow it to melt and the medicine to be absorbed. Pushing the suppository high into the rectum with your finger will help to reduce this feeling.
- Wash your hands.

- How long to use it

Keep using the suppositories for as long as you have been told, unless you have any problems. In that case, check with your doctor.

- If you forget to use it

If you forget to use a suppository, do not worry. Use one as soon as you

remember. If it is nearly time for your next dose though, just take the next dose and forget about the one you missed.

Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

If you accidentally use too many suppositories or use them too often, tell your doctor or go to your nearest casualty department straight away.

While you are using it

- Things you must do

- Whilst you are taking these medicines your doctor may want to give you a check-up from time to time.
- Use your medicine exactly as your doctor has told you.
- Tell all the doctors, dentist and pharmacists treating you that you are using Almira Suppositories.

- Things you must not do

- Do not stop using the medicine unless advised by your doctor.
- Do not use any medicines without consulting your doctor or pharmacist.
- Do not give Almira Suppositories to anyone else, even if they have the same symptoms or condition as you.
- Do not insert 2 suppositories at the same time.

- Things to be careful of

- There is a small increased risk of heart attack or stroke when you are taking any medicine like Almira Suppositories. The risk is higher if you are taking high doses for a long time. Always follow the doctor's instructions on how much to take and how long to take it for.
- Almira Suppositories may reduce the symptoms of infection, for example, headache and high temperature. If you feel unwell and need to see a doctor, remember to mention that you are taking Almira Suppositories.

Driving and using machines

Very occasionally people have reported that diclofenac have made them feel dizzy, tired or sleepy. Problems with eyesight have also been reported. If you are affected in this way, you should not drive or operate machinery.

Side effects

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

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

Some side effects can be serious.

Stop using the suppositories and tell your doctor straight away if you notice:

- 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.
- Allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering.
- Wheezing or shortness of breath (bronchospasm).
- Swollen face, lips, hands or fingers.
- 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.
- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with diclofenac 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).

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

Almira Suppositories may also occasionally cause itching or burning in your back passage or make any haemorrhoids (piles) worse.

The side effects listed below have also been reported.

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

- Stomach pain, heartburn, nausea, vomiting, diarrhoea, indigestion, wind, loss of appetite.
- Headache, dizziness, vertigo.
- Skin rash or spots.
- Raised levels of liver enzymes in the

ALMIRAL SUPPOSITORIES

Diclofenac Sodium (100mg)

- blood.
- Irritation where the suppository is inserted.

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

- Stomach ulcers or bleeding (there have been very rare reported cases resulting in death, particularly in the elderly).
- Vomiting blood.
- Diarrhoea with blood in it or bleeding from the back passage.
- Black, tarry faeces or stools.
- Drowsiness, tiredness.
- low blood pressure
- Skin rash and itching.
- Fluid retention.
- Liver function disorders.

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

Nervous system:

Tingling or numbness in the fingers, tremor, visual disturbances such as blurred or double vision, hearing loss or impairment, ringing in the ears, sleeplessness, nightmares, mood changes, depression, anxiety, mental disorders, disorientation and loss of memory, fits, headaches together with a dislike of bright lights, fever and a stiff neck, disturbances in sensation.

Stomach and digestive system:

Constipation, inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, taste changes, lower gut disorders (including inflammation of the colon, or worsening of ulcerative colitis or Crohn's disease).

Heart, chest or blood:

Palpitations, chest pain, high blood pressure, inflammation of blood vessels, inflammation of the lung, heart disorders, including congestive heart failure or heart attack, blood disorders (including anaemia).

Liver or kidneys:

Kidney or severe liver disorders including liver failure, presence of blood or protein in the urine.

Skin or hair:

- Serious skin rashes including Stevens-Johnson syndrome, Lyell's syndrome and other skin rashes

- which may be made worse by exposure to sunlight.
- Hair loss.

General disorder

- Swelling at application site

Reproductive system

- Impotence

Other side effects that have also been reported include:

Confusion, hallucinations, disturbance of sensation, general feeling of discomfort, stroke, throat disorders, inflammation of the nerves in the eye.

Frequency "not known": Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

Do not be alarmed by this list - most people use Almiral Suppositories without any problems.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) of Vaccines (AEFI)].

Storage and disposal of Almiral Suppositories

- Storage

Keep out of the reach and sight of children.

Store below 30°C in the original package, in order to protect from light and moisture.

- Disposal

Do not use after the expiry date stated on the carton and blister.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Almiral Suppositories are white, smooth, homogenous, torpedo-shaped suppositories.

Almiral Suppositories are placed in

blisters and are available in cartons of 10 suppositories.

- Ingredients

Active ingredients

The active substance is diclofenac sodium. Each suppository contains 100mg diclofenac sodium.

Inactive ingredients

The suppositories also contain hard fat

- MAL No.

Almiral Suppositories 100mg
MAL19900491AZ

Manufacturer

MEDOCHEMIE LTD, 1 – 10,
Constantinoupoleos Street, 3011
Limassol, Cyprus

Product Registration Holder

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Jaya

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