

Package leaflet: information for the user

ARESTON 50mg film-coated tablets

Diclofenac potassium

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Areston is and what it is used for

Diclofenac potassium, the active ingredient in Areston tablets, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

Areston tablets relieve pain, reduce swelling and ease inflammation in:

- Rheumatoid arthritis, osteoarthritis, acute gout, low back pain, ankylosing spondylitis.
- Migraine.
- Conditions affecting the joints and muscles such as sprains and strains, soft tissue sports injuries, frozen shoulder, dislocations, and fractures.
- Conditions affecting the tendons for example, tendonitis, tenosynovitis, bursitis.

They are also used to treat pain and inflammation associated with orthopaedic, dental and other minor surgery.

2. What you need to know before you take Areston

Do not take Areston:

- If you are allergic to diclofenac potassium, aspirin, ibuprofen 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.
- If you have now, or have ever had, a stomach (gastric) or duodenal (peptic) ulcer, or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces).
- If you have had stomach or bowel problems after you have taken other NSAIDs.
- If you have severe heart, kidney or liver failure.
- 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 are more than six months pregnant.

Warnings and precautions

Talk to your doctor or pharmacist before taking Areston if:

- You suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease.
- You have kidney or liver problems, or are you elderly.
- You have a condition called porphyria.
- You suffer from any blood or bleeding disorder. If you do, your doctor may ask you to go for regular check-ups while you are taking these tablets.
- You ever had asthma.
- You are breast-feeding.
- You have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides.
- You have heart problems, or have you had a stroke, or do 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).
- You have diabetes.
- You smoke.
- You have Lupus (SLE) or any similar condition.

Other special warnings

- You should take the lowest dose of Areston for the shortest possible time, particularly if you are underweight or elderly.

- There is a small increased risk of heart attack or stroke when you are taking any medicine like Areston. 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.
- Whilst you are taking these medicines your doctor may want to give you a check-up from time to time.
- If you have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms.
- Because it is an anti-inflammatory medicine, diclofenac may reduce the symptoms of infection, for example, headache and high temperature. If you feel unwell and need to see a doctor, remember to tell him or her that you are taking Areston.

Other medicines and Areston

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

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

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

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.

Although not common, abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. You should not take Areston tablets during the last 3 months of pregnancy as it may affect the baby's circulation.

Taking Areston tablets 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.

Driving or using machines

Very occasionally people have reported that Areston tablets 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.

3. How to take Areston

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

The doctor will tell you how many Areston tablets to take and when to take them. Always follow his/her instructions carefully.

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

Take the tablets preferably before meals.

Swallow the tablets whole with a drink of water. Do not crush or chew them.

The recommended dose is:

Adults

75 mg to 150 mg daily divided into two or three doses. The number of tablets you take will depend on the strength the doctor has given you.

For the relief of migraine in adults:

Take 50 mg at the first signs of an attack. If the migraine has not gone after 2 hours, take another 50 mg. You can take further doses at intervals of 4 to 6 hours if necessary, but you must not take more than 200 mg in a day.

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 Areston tablets are not affecting your stomach.

Use in children and adolescents**Children over 14 years old**

75 mg to 100 mg daily divided into two or three doses.

Children under 14 years old

Areston 50mg tablets are not recommended for children under 14 years old.

The doctor may also prescribe another drug to protect the stomach to be taken at the same time, particularly if you have had stomach problems before, or if you are elderly, or taking certain other drugs as well.

If you take more Areston than you should:

If you, or anyone else, accidentally takes too much, tell your doctor or your nearest hospital casualty department. Take your medicine pack with you so that people can see what you have taken.

If you forgot to take Areston

If you forget to take a dose, take 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.

Do not take more than 150 mg (three 50 mg tablets) in 24 hours.

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

4. Possible 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 taking Areston tablets 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.

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 blood.

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)
- Gastritis (inflammation, irritation or swelling of the stomach lining)
- Vomiting blood
- Diarrhoea with blood in it or bleeding from the back passage
- Black, tarry faeces or stools
- Drowsiness, tiredness
- Hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light headedness)
- Skin rash and itching
- Fluid retention, symptoms of which include swollen ankles
- Liver function disorders, including hepatitis and jaundice.

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

Effects on the nervous system:

Tingling or numbness in the fingers, tremor, visual disturbances such as blurred or double vision, hearing loss or impairment, tinnitus (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.

Effects on the 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).

Effects on the heart, chest or blood:

Palpitations (fast or irregular heart beat), chest pain, hypertension (high blood pressure), inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), heart disorders, including congestive heart failure, or heart attack, blood disorders (including anaemia).

Effects on the liver or kidneys:

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

Effects on skin or hair:

Serious skin rashes including Stevens-Johnson syndrome and Lyell's syndrome and other skin rashes which may be made worse by exposure to sunlight.

Hair loss.

Other side effects that have also been reported include:

Inflammation of the pancreas, impotence, facial swelling, inflammation of the lining of the brain (meningitis), stroke, throat disorders, confusion, hallucinations, malaise (general feeling of discomfort), inflammation of the nerves in the eye.

Medicines such as diclofenac may be associated with a small increased risk of heart attack or stroke.

Do not be alarmed by this list - most people take Areston tablets without any problems.

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:

ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Areston

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 and blister. The expiry date refers to the last day of that month.

Store below 25°C, in the original 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 Areston contains

- The active substance is diclofenac potassium. Each Areston 50 mg tablet contains 50 mg of the active ingredient diclofenac as diclofenac potassium.
- The other ingredients are: colloidal anhydrous silica, starch maize, sodium starch glycolate, povidone, tricalcium phosphate, magnesium stearate. The excipients of film coating: polyethylene glycol 6000, talc and OPADRY WHITE Y-1-7000 (composed of: hydroxypropyl methyl cellulose, polyethylene glycol 400, titanium dioxide (E171)).

What Areston looks like and contents of the pack

Areston 50 mg tablets are white, round shaped, convex and film-coated.

The tablets are supplied in PVC-Al blisters. Boxes of 20 tablets are available.

Marketing Authorisation Holder and Manufacturer

MEDOCHEMIE LTD, 1-10 Constantinoupoleos street, 3011 Limassol, Cyprus

This leaflet was last revised in November 2018.