

Package leaflet: Information for the patient

ARESTON 12.5mg film-coated tablets

Diclofenac potassium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days for relief of fever or for relief of pain.

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

Areston is a painkiller, which also reduce inflammation (swelling) and lower body temperature. Areston is used in the short-term treatment (i.e. maximum 3 days) of pain in the joints and ligaments, muscular pain, headache, dental pain, menstrual pain, acute lower back pain, pain and fever associated with the flu, sore throat and colds.

2. What you need to know before you take Areston

If this medicine has been prescribed by a doctor, follow carefully the instructions of the doctor. These instructions may differ from the general information in this leaflet.

Do not take Areston:

- If you are allergic to diclofenac, soya oil, peanut oil 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, chest pain, runny nose, skin rash or any other allergic type reaction.
- 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; or the pumping power of your heart is reduced giving you exertional tiredness, palpitations and shortness of breath (heart failure).
- If you have or have had a stomach ulcer or ulcer in the gastrointestinal tract.
- If you have ever noticed blood in your stools or black stools (signs of gastrointestinal bleeding).
- If you suffer from severe liver or kidney disease.
- If you have or have had problems with your blood circulation (peripheral arterial disease).
- If you are about 20 weeks of pregnancy or later.
- If you have ever had asthma or wheezing, extensive skin rash (urticaria) or “hay fever”-like runny nose after taking aspirin or other NSAIDs such as ibuprofen.
- If you have a stroke, a bleeding or other bleeding disorders.
- If you have blood disorders.

- If you have certain abnormalities in the bone marrow.

If any of the above applies to you or you are not sure ask your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Areston:

- If you have ever had any stomach problems or heartburn after taking painkillers or anti-inflammatory.
- If you suffer from severe skin reactions.
- If you suffer from asthma, hay fever or have had long-term problems of the respiratory tract, such as nasal polyps or chronic obstructive airways diseases.
- If you have a tendency to develop allergic skin diseases, itchy skin or hives.
- If you have a history of gastrointestinal disease, for example ulcerative colitis or Crohn's disease.
- If you have a bleeding disorder or any other blood disorder, including a rare condition called porphyria.
- If you have an inflammatory disease called systemic lupus erythematosus or another disease of the connective tissue.
- If you have liver or kidney problems.
- If you think you are dehydrated (e.g. due to sickness, diarrhoea, before or after major surgery).
- If you have chickenpox (varicella).
- If you have significant risk factors such as high blood pressure, high cholesterol, high triglycerides, diabetes, or if you smoke; you should discuss your treatment with your doctor or pharmacist.
- If you are currently having medical treatment for a serious illness;
- If you are taking Trimethoprim (a medicine used used to prevent or treat urinary tract infections)
- If you are taking medicines used to treat arthritis or other pain relievers (e.g. acetylsalicylic acid, ibuprofen) or other anti-inflammatory medicines (corticosteroids);

If, at any time while taking Areston you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness, or slurring of speech, contact your doctor immediately.

Medicines such as Areston 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.

Make sure your doctor or pharmacist knows, before you take diclofenac:

- If you smoke.
- If you have diabetes (diabetes mellitus).
- If you have tight, painful feeling in the chest (angina), blood clots, high blood pressure, raised cholesterol or raised levels of cholesterol or triglycerides (certain fats) in your blood.

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

Do not exceed the recommended dose and do not take it longer than the recommended duration (3 days for relief for fever and relief of pain).

Older people may be more sensitive to the effect of diclofenac than other adults. If you are older than 65 years, it is important that you follow the instructions carefully and take the lowest number of tablets that still provides sufficient relief of symptoms. It is especially important for older people to immediately report any side effects to their doctor or pharmacist.

Diclofenac may reduce the symptoms of an infection (e.g. headache, high temperature). This may therefore make it more difficult to detect or treat the infection. If you are not feeling well and need to visit a doctor, remember to mention that you are taking diclofenac.

Prolonged use of any type of painkiller for headaches can make headaches worse. If you think this applies to you, consult your doctor for advice.

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 Areston, as diclofenac can sometimes worsen wound healing in your gut after surgery.

Other medicines and Areston

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

The following medicines may, if they are used concurrently with diclofenac, increase the risk of bleeding or ulcer. If you are taking any of these medicines you must tell your doctor:

- Corticosteroids (for relief of inflammation).
- Anticoagulants or antiplatelet agents (blood thinners).
- Selective serotonin reuptake inhibitors (SSRIs) medicines used to treat some types of depression.
- Other NSAIDs, such as aspirin and ibuprofen (used to relieve inflammation/ pain). Bleeding from the gastrointestinal tract or the formation of ulcers can be side effects of all NSAIDs, including diclofenac. This problem, which in older people can be more severe, may occur at any time during treatment with or without warning symptoms, or a history of severe problems of the gastrointestinal tract.

You should inform your doctor if you used any of the following medicine:

- Lithium (used, among others, for the treatment of manic depression).
- Digoxin (used to treat heart problems).
- Diuretics (used to increase the amount of urine).
- Antihypertensive drugs such as ACE inhibitors or beta-blockers (used to treat high blood pressure or certain other heart conditions).
- Medicines taken orally to treat diabetes (oral anti-diabetic).
- Methotrexate (used to treat certain kinds of cancer or arthritis).
- Cyclosporine (used to prevent immune reactions following organ transplants).
- Quinolones (certain antibiotics), used to treat certain infections.
- Sulfapyrazole (a medicine used to treat gout) or voriconazole (a medicine used to treat fungal infections).
- Phenytoin (a medicine used to treat seizures).
- Colestipol and cholestyramine that can delay or decrease in absorption of diclofenac. Therefore, it is recommended to take diclofenac at least one hour before or 4 to 6 hours after administration of colestipol/ cholestyramine.

Areston with food, drink and alcohol

For maximum efficacy, the tablets should preferably be taken before meals.

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.

Pregnancy

Do not use diclofenac during pregnancy unless your doctor recommends it.

You must not take diclofenac about 20 weeks of pregnancy or later because it could harm your unborn child or cause problems at delivery.

Breast-feeding

You should not take diclofenac if you are breast-feeding because it might be harmful for your infant.

Fertility

As with other anti-inflammatory medicines, the use of diclofenac may make it more difficult to become pregnant. You should not take this medicine if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

Usually this medicine has no influence on the ability to drive or use machines. However, in rare cases you may experience vision disorders, dizziness or drowsiness (see section 4). If you notice such effects, do not drive or use machines and you must immediately contact your doctor.

Areston contains lactose and soya oil.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

If you are allergic to peanut or soya, do not use this medicinal product.

3. How to take Areston

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

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

As a general recommendation it is important that you use the lowest dose that controls your pain and that you do not take diclofenac for longer than necessary.

Adults and adolescents aged 14 years and over

Take an initial dose of 2 tablets when symptoms appear. If needed, continue with 1 tablet every 4 to 6 hours. Do not take more than 6 tablets in 24 hours, except if prescribed by a doctor. Swallow the whole tablet with a drink of water, preferably before meals. Do not exceed the recommended dose.

Use in children and adolescents

Do not give Areston 12.5mg film-coated tablets to children younger than 14 years.

Elderly

In frail elderly patients use the lowest dose that controls the pain.

Do not take diclofenac for more than 3 days for relief of pain and relief of fever.

If symptoms persist or worsen, tell your doctor to ensure that they are not due to another illness.

If you take more Areston than you should

If you accidentally take too many tablets, immediately contact your doctor or pharmacist. You may need medical attention. Symptoms of an overdose may include vomiting, diarrhoea, dizziness, ringing in the ears (tinnitus), convulsions/ seizures, severe stomach pain or bloody or black stools.

If you forget to take Areston

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

Use diclofenac only when symptoms appear.

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.

Some uncommon (may affect between 1 and 10 in every 1000 people) side effects, especially when taking high daily dose (150mg) for a long period of time. The frequency is expected to be lower for short-term treatment with low dose (up to 75mg daily).

- Palpitations, sudden and oppressive chest pain (signs of myocardial infarction or heart attack).
- Breathlessness, difficulty of breathing when lying down, swelling of the feet or legs (signs of cardiac failure).

Some rare (may affect up to 1 in every 1000 people) or very rare (may affect up to 1 in every 10,000 people) side effects could be serious.

- Severe stomach pain;
- Vomiting blood, bloody diarrhea, blood in the stools or black stools;
- Allergic reaction including difficulty of breathing or swallowing, swelling of the face, mouth, tongue or throat, often associated with skin rash. Collapse;
- Sudden difficulty of breathing and feeling of tightness in chest with wheezing or coughing (signs of asthma).
- High blood pressure
- Sudden and severe headache, difficulty speaking, stiff neck, convulsions
- Skin rash with blisters, peeling of the skin, purple skin lesions, blistering of the eyes and mouth, skin inflammation with flaking or peeling.
- Swelling of the face, feet or legs;
- Any change in the colour or the amount of urine, excess of protein in urine, blood in urine;
- Yellowing of the skin or eyes (signs of hepatitis/liver failure), increased liver enzymes;
- Bleeding or unusual bruising, high fever or persistent sore throat, frequent infections;
- Increased sensitivity of the skin to sun

Diclofenac 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.

Stop taking the product and contact your doctor immediately if you develop signs and symptoms of heart problems or stroke, such as chest pain, shortness of breath, weakness in one part or side of body, or slurring of speech.

Other side effects:

The following side-effects are generally not serious and have been reported only with higher doses of the active substance diclofenac, used for longer duration. If necessary, talk to your doctor or pharmacist.

Common side effects (likely to affect 1 out of 10 people):

- Pain in the gut, stomach pain, diarrhoea, nausea, vomiting, flatulence, indigestion, decreased appetite
- Headache, dizziness.
- Skin rash
- Vertigo

Rare side effects (likely to affect 1 out of 1000 people):

- Unusual tiredness
- Itchy rash
- Drowsiness

Very rare side effects (likely to affect less than 1 out of 10,000 people):

- Low level of white blood cells , low levels of red blood cells
- Constipation, mouth sores,swollen, red and sore tongue, taste disorders, upper abdominal cramp
- Itching and redness of skin, hair loss
- Tingling or numbness of the hands or feet, trembling.
- Visual disorders, blurred vision, ringing in the ears, hearing impaired
- Change in mood, difficulty sleeping, feeling confused

If any of these side-effects gets worse or if you notice any side effects not listed in this leaflet, you should inform your doctor or pharmacist.

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 after EXP. The expiry date refers to the last day of that month.

Store below 30°C in the original package.

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 film-coated tablet contains 12.5mg diclofenac potassium.
- The other excipients are:
 - *Core*: Lactose monohydrate, calcium phosphate, sodium starch glycolate type A, maize starch, povidone K30, cellulose microcrystalline 101, silica colloidal anhydrous, magnesium stearate;
 - *Coating*: Opadry White OY-B-28920 (Polyvinyl alcohol, Titanium dioxide (E171), Talc, Lecithin (soya) (E322), Xanthan gum).

What Areston looks like and contents of the pack:

White, capsule shaped biconvex tablets with dimensions 5x10 mm.

Areston is presented in cold forming aluminium/push through aluminium OPA-Al-PVC/Al blisters containing 10 tablets. Available in packs sizes of 10, 20, 30 and 40 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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