

## **Package leaflet: Information for the user**

### **Voltaren Akti, 12.5 mg 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 5 days.

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### **1. What Voltaren Akti is and what it is used for**

Diclofenac, the active substance of Voltaren Akti, belongs to the group of medicines called non-steroidal anti-inflammatory drugs. Voltaren Akti is a painkiller that also reduces inflammation (swelling) and fever.

#### **What Voltaren Akti is used for:**

Voltaren Akti tablets are used for short-term treatment of pain (e.g. muscle, joint, back pain, headache, dental pain, menstrual pain).

#### **How Voltaren Akti works**

Voltaren Akti relieves the symptoms of inflammation, such as swelling, pain and fever by blocking the synthesis of the molecules (prostaglandins) responsible for inflammation. It has no effect on the causes of inflammation or fever.

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

You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

### **2. What you need to know before you use Voltaren Akti**

If the medicine was prescribed to you by your doctor, carefully follow the doctor's instructions. They may be different from the general information in this leaflet.

#### **Do not take Voltaren Akti:**

- if you are allergic to diclofenac or any of the other ingredients of this medicine (listed in section 6.1).
- if you have ever had an allergic reaction after taking medicines to treat inflammation, pain or fever (e.g. diclofenac, ibuprofen or acetylsalicylic acid (is also used as a blood thinner)). The symptoms may include: asthma, wheezing, skin rash, face swelling, chest pain, rhinitis. Check with your doctor or pharmacist if you are not sure.

- if you have established heart disease and/or cerebrovascular disease, e.g. if you have had a heart attack, stroke, mini-stroke (transient ischaemic attack, TIA) or blockages to blood vessels to the heart or brain or a surgery to clear or bypass blockages;
- if you have or have had problems with blood circulation (peripheral arterial disease);
- if you have or have had stomach or intestinal ulcers;
- if you have blood in your stools or black stools (a symptom of gastrointestinal bleeding);
- if you suffer from severe kidney or liver damage;
- if you are in the last three months of pregnancy.

**If you have any of the above conditions, tell your doctor without taking Voltaren Akti.**

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Voltaren Akti:

- if you have ever had gastrointestinal problems, such as peptic ulcer, bleeding or black stools;
- if you have experienced stomach discomfort or heartburn after taking non-steroidal anti-inflammatory medicines;
- if you have an intestinal inflammation;
- if you have recently had or are about to undergo stomach or gastrointestinal surgery, as Voltaren Akti can sometimes worsen the healing of a surgical wound in the intestine;
- if you take other painkillers or anti-inflammatory medicines;
- if you have allergic rhinitis, asthma or other lung disease (wheezing, shortness of breath) or nasal polyps;
- if you have liver or kidney problems;
- if you have heart problems;
- if you have swollen feet;
- if you are dehydrated (e.g. are feeling sick, have diarrhoea, before or after surgery);
- If you have a bleeding disorder or other blood disorders, including a rare liver condition called porphyria.

Make sure to inform your doctor before taking diclofenac:

- if you smoke;
- if you have diabetes;
- if you have chest pain, blood clotting disorders, high blood pressure, increased level of cholesterol or triglycerides.

Side effects can be reduced by using the lowest effective dose for the shortest duration possible.

**If you have any of the listed conditions, inform your doctor before taking Voltaren Akti.**

### **Other warnings**

- You should know that medicines such as diclofenac may be associated with an increased risk of heart attack (myocardial infarction) or stroke.

Do not exceed the recommended dose (up to 6 tablets per day) or duration of treatment (5 consecutive days in case of pain).

If, at any time while taking Voltaren Akti 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.

Voltaren Akti may mask symptoms of inflammation (e.g. headache, high fever), making the inflammation more difficult to diagnose and treat. If you feel unwell and need to see a doctor, remember to mention that you are taking Voltaren Akti.

Prolonged use of any painkillers to relieve headache may only increase the problem. Consult your doctor if you are in this situation or suspect that it may be the case.

### **Other medicines and Voltaren Akti**

Inform your doctor or pharmacist if you are taking any of the following medicines:

- lithium, selective serotonin-reuptake inhibitors (SSRIs) (depression medicines);
- digoxin (medicine for treating heart problems);
- ACE inhibitors or beta-blockers (medicines used to treat high blood pressure and heart failure);
- diuretics (medicines used to increase urine excretion);
- medicines used to treat diabetes, except insulin;
- other non-steroidal anti-inflammatory medicines, such as acetylsalicylic acid or ibuprofen;
- glucocorticosteroids (anti-inflammatory medicines);
- medicines used to prevent blood clotting ('blood thinners' or anticoagulants);
- methotrexate (a medicine used to treat some kinds of cancer or rheumatoid arthritis);
- ciclosporin, tacrolimus (medicines used in patients who have received organ transplants);
- trimethoprim (medicine used to prevent or treat urinary tract infection);
- quinolone antibiotics (medicines used to treat infections);
- sulfapyrazone (medicine used to treat gout) or voriconazole (medicine used to treat fungal infections);
- phenytoin (a medicine used to treat seizures);
- colestipol and cholestyramine (medicines used to regulate cholesterol).

**Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines, including over-the-counter medicines.**

### **Voltaren Akti with food and drink**

The tablets should be taken with or after food.

### **Elderly**

Like with other painkillers, Voltaren Akti may cause stronger reaction to active substances in elderly patients compared to other adults. Follow the instructions given to you particularly carefully and take the minimum number of tablets needed to provide relief. It is especially important for elderly patients to report side effects promptly to their doctor.

### **Children and adolescents (under 14 years)**

Do not give Voltaren Akti 12.5 mg tablets to children or adolescents under 14 years of age.

### **Pregnancy, breast-feeding and fertility**

#### **Pregnancy**

If you are pregnant or think you may be pregnant, talk to your doctor before taking the medicine. In particular, you should not take Voltaren Akti during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery.

#### **Breast-feeding**

**Do not take** Voltaren Akti during breast-feeding, as the medicine may harm the child. Tell your doctor if you are breast-feeding.

#### **Fertility**

Like other non-steroidal anti-inflammatory medicines, the active substance of Voltaren Akti diclofenac may make it more difficult to become pregnant. This effect passes after you discontinue using the medicine.

Inform your doctor if you are planning to become or have difficulties with becoming pregnant.

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.

### **Driving and using machines**

Voltaren Akti does not normally affect the ability to drive or use machines. However, as with other anti-inflammatory medicines, it may cause blurred vision, dizziness or drowsiness in rare cases. If you experience these effects, avoid driving a car and using machines. Inform your doctor about this as soon as possible.

### **Important information about some ingredients of Voltaren Akti**

Voltaren Akti tablets contain lactose. If you have been told by your doctor that you have intolerance to some sugars, consult your doctor before taking this medicine.

This medicinal product contains less than 1 mmol (23 mg) sodium per tablet, m.p. that the drug is virtually "sodium-free".

## **3. How to take Voltaren Akti**

### **How much Voltaren Akti to take**

Do not exceed the recommended dose. It is important that you use the lowest effective dose and that you do not take Voltaren Akti for longer than necessary.

### ***Adults and children 14 years and older:***

Take an initial dose of 2 tablets when symptoms appear. If needed, continue with 1 or 2 tablets every 4 to 6 hours. Do not take more than 6 tablets (75 mg) per day.

### **How to take Voltaren Akti**

Swallow the tablets whole with water.

The tablets should be taken with or after food.

### **How long to take Voltaren Akti**

Do not use Voltaren Akti to relieve pain for longer than 5 days. If symptoms persist or worsen, consult your doctor to ensure that they are not due to a serious illness.

### **If you take more Voltaren Akti than you should**

If you accidentally take too many Voltaren Akti tablets, **immediately contact a doctor or call the emergency medical service.** You may require medical attention.

### **If you forget to take Voltaren Akti**

If you forget to take a dose, take one tablet as soon as you remember. If it is nearly time for your next dose, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

## **4. Possible side effects**

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

### **Some side effects could be serious**

**Uncommon** side effects (*may affect 1 to 10 of 1,000 people*), especially when taking a high dose (150 mg) for a long period of time.

- Rapid heartbeat, sudden and oppressive chest pain (symptoms of myocardial infarction).
- Breathlessness, difficulty breathing when lying down, swelling of the ankles or feet (signs of cardiac failure).

**Some rare** (*may affect up to 1 of 1,000 persons*) **or very rare** (*may affect up to 1 of 10,000 persons*) **symptoms could be serious.**

- Strong stomach pain, bloody or black stools, vomiting of blood, bloody diarrhoea;
- Allergic reaction, including difficulty breathing or swallowing, swelling of the face, lips, mouth, tongue or throat, often accompanied by skin rash. Fainting.
- Sudden difficulty breathing and feeling of tightness in chest with wheezing and coughing (symptoms of asthma).
- Sudden and strong headache, stiff neck, difficulty speaking.
- Seizures.
- Skin rash with blisters, skin peeling, red or purple skin, blistering on the mouth or eyes, skin inflammation with scaling and peeling.
- Swollen hands or feet (oedema).
- Change in urine appearance or reduced urine output, blood in urine.
- Yellowing of the skin or eyes (could be a sign of liver inflammation/liver failure).
- Unusual bleeding or skin bruising (low platelet counts), high temperature or persistent sore throat, frequent infections (lack of certain white blood cells), weakness or paleness (anemia).
- Increased sensitivity of the skin to the sun.

Medicines such as diclofenac may be associated with an increased risk of heart attack (myocardial infarction) or stroke.

Some side effects of unknown frequency (cannot be estimated from the available data) may be serious:

- Mild stomach cramps or pain in the stomach, which starts shortly after starting Voltaren Akti treatment, followed by rectal bleeding or bloody diarrhea usually within 24 hours after the onset of stomach pain.
- Chest pain, which may be a sign of a potentially serious allergic reaction, Kounis syndrome.

**Inform your doctor immediately and stop taking the medicine if you notice any of the listed side effects:**

**Other side effects**

Other potential side effects are mild. Some of these side effects have occurred in case of using high doses of diclofenac over a long period of time. **Talk to your doctor or pharmacist if you are concerned about these side effects.**

**Common side effects** (may affect up to 1 of 10 persons):

- Stomach ache, diarrhoea, nausea, vomiting, gases, indigestion, loss of appetite
- Headache, dizziness
- Skin rash
- Vertigo

**Rare side effects** (may affect up to 1 of 1,000 persons):

- Drowsiness
- Itchy rash

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

- Constipation, mouth ulcers, swollen, red and coarse tongue, taste changes, upper abdomen cramps
- Tingling or numbness of the hands or feet, trembling
- Vision disorders, ringing in the ears, reduced hearing
- Mood changes, sleeplessness, confusion

**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.

## **5. How to store Voltaren Akti**

Keep this medicine out of the sight and reach of children.  
Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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 Voltaren Akti contains:**

- The active substance is diclofenac. One Voltaren Akti tablet contains 12.5 mg of diclofenac potassium.
- The excipients are: anhydrous colloidal silicon dioxide, lactose monohydrate, maize starch, sodium glycolate starch, polyvidone, magnesium stearate, microcrystalline cellulose, methylhydroxypropyl cellulose, titanium dioxide (E171) and stearic acid.

### **What Voltaren Akti looks like and contents of the pack**

White, capsule-shaped tablets with a thin polymer layer; available in packs of 10 tablets.

### **Marketing Authorisation Holder**

GlaxoSmithKline Dungarvan Limited  
Knockbrack  
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### **Manufacturer**

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