

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1996

This medicine can be sold without a doctor's prescription

VOLTAREN ACTI-GO®  **NOVARTIS**

Active ingredient and its quantity:

Diclofenac Potassium 12.5mg

For list of excipients and allergens in the medicine, please see section 6.

Read this entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.

This medicine is intended for adults and adolescents over 14 years of age. Swallow in the correct manner. Consult your pharmacist if you need additional information. Refer to your doctor if the fever or pain last longer than 3 days.

1. What is the medicine used for?

The medicine is intended for: short-term treatment (up to 3 days) in adults and adolescents over 14 years of age, for relief of headache, toothache, menstrual pain, joint and muscle pain, back pain and for fever reduction.

Therapeutic group: Voltaren Acti-Go is an analgesic and belongs to the Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) group.

2. Before you take the medicine:

Do not use the medicine if:

- you are hypersensitive (allergic) to the active ingredient or to any of the other ingredients of this medicine.
- you are breastfeeding or in your last trimester of pregnancy.
- you have had in the past an allergic reaction when taking a medicine for pain relief, inflammation or fever, such as: diclofenac, ibuprofen or acetylsalicylic acid (a substance used to prevent blood clots formation). The reactions can include: asthma, wheezing, skin rash, facial swelling, runny nose. If you are not sure, consult your doctor.
- you suffer from a gastric or intestinal ulcer.
- you suffer from bleeding of the digestive system, the symptoms can include: blood in the stools or black stools.
- you suffer from severe liver or kidney disease.
- you suffer from severe heart failure.
- you have recently undergone or are about to undergo heart surgery.
- do not take simultaneously with other medicines of the NSAIDs group.
- you suffer from ischemic heart disease or from cerebrovascular disease or peripheral artery disease (e.g. if you have suffered in the past from a heart attack, stroke or obstruction of arteries leading to the heart, brain or legs).

Special warnings regarding the use of this medicine: Before treatment with Voltaren Acti-Go, tell your doctor if:

- you suffer or have suffered in the past from impaired function of the heart and/or vascular system (including: uncontrolled high blood pressure, congestive heart failure, ischemic heart disease, peripheral arterial disease).
- you have significant risk factors such as: high blood pressure, high levels of cholesterol, of triglycerides, diabetes, if you smoke.
- you have suffered in the past from gastrointestinal problems such as stomach ulcer, bleeding or black stools.
- you have suffered in the past from stomach discomfort or heartburn after taking analgesics or anti-inflammatory medicines.
- you suffer from intestinal problems.
- you are taking analgesics or additional anti-inflammatory medicines.
- you are over 60 years of age.
- you consume more than 3 alcoholic beverages per day.
- you suffer from Systemic Lupus Erythematosus (SLE) or similar medical condition.
- you have asthma or an allergy.
- you have kidney or liver problems.
- you suffer from swelling of the legs.
- you are in danger of dehydration (due to sickness, diarrhea, before or after surgery).
- you suffer from a bleeding disorder or other blood system disorders, including a rare condition of the liver named hepatic porphyria.
- you are pregnant or planning to become pregnant, inform your doctor.
- taking a medicine from this group or any other analgesic has caused you serious side effects in the past.
- you suffer from nasal polyps or from connective tissue disease.

Additional Warnings:

- Medicines such as diclofenac may be associated with a small increase in the risk of heart attack ("myocardial infarction") or stroke. The risk is more likely at high dosages and in prolonged use.
- In general, it is important to take the lowest dosage which relieves the pain for the shortest duration, in order to minimize as much as possible the risk for cardio-vascular side effects.
- Do not exceed the recommended dosage of up to 6 tablets per day or the recommended treatment duration (3 days).
- If during the use of Voltaren Acti-Go you experience signs or symptoms of heart or vascular problems, such as chest pain, shortness of breath, weakness or slurred speech, refer to your doctor immediately.
- This medicine may reduce signs of infection (headache, fever), thus makes infection diagnosis difficult. If you do not feel well

and you refer to your doctor, inform him that you are taking Voltaren Acti-Go.

- If you are about to undergo surgery (including dental surgery) inform your doctor about taking this medicine.
- Elderly patients may be more sensitive to Voltaren Acti-Go compared to other adults. Therefore, be sure to take this medicine according to the doctor's instructions, and to take the minimal amount of tablets required to alleviate the symptoms. It is important to immediately inform the attending doctor about any side effect.
- When taking Voltaren Acti-Go according to the doctor's instructions, at a high dosage or for a prolonged period of time, it is recommended to perform laboratory tests (blood, urine, liver and kidney functions), to make sure the test results are within the normal range. An increase in liver enzymes, which requires discontinuation of treatment after consulting a doctor, may occur.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription drugs and food supplements. Especially inform your doctor or pharmacist if you are taking:

- lithium (lithium levels may increase)
- anti-depressants of the SSRI group (may increase the risk for gastrointestinal bleeding)
- digoxin (used to treat heart problems, digoxin levels may increase)
- diuretics (may reduce blood pressure lowering activity)
- ACE inhibitors and beta blockers (a group of medicines used to treat hypertension and heart failure, concomitant use may reduce blood pressure lowering activity)
- medicines used to treat diabetes (excluding insulin)
- other anti-inflammatory drugs or analgesics such as Acetylsalicylic acid (Aspirin) or ibuprofen (may increase frequency of side effects in the digestive system)
- corticosteroids (may increase the frequency of side effects in the digestive system)
- blood thinners or anti-coagulants such as warfarin (may increase the risk for bleeding)
- methotrexate (used for certain types of cancer or arthritis, may increase methotrexate levels)
- cyclosporine and tacrolimus (mainly used for transplant recipients, concomitant use may increase renal toxicity)
- antibiotics of the quinolone type
- phenytoin (may cause increase in exposure to phenytoin)
- medicines that inhibit the metabolism of Voltaren Acti-Go such as voriconazole
- trimethoprim (for the treatment and prevention of urinary tract infections, may cause an increase of blood potassium levels).

Use of this medicine and food:

Take this medicine before food.

Pregnancy and breastfeeding:

If you are pregnant, think that you are pregnant or plan to become pregnant, do not take Voltaren Acti-Go and refer to your doctor. Especially do not take this medicine if you are in the last three months of pregnancy. If you are breastfeeding, do not take this medicine.

Driving and use of machinery:

In rare cases, the use of this medicine may cause dizziness, tiredness or sleepiness. In addition cases of vision problems were reported. If you experience these effects, you should avoid driving a car, operating dangerous machines and any activity that requires alertness. Inform the doctor as soon as possible if you experience these effects.

Important information about some of the ingredients of this medicine:

This medicine contains lactose. If you have been told by your doctor that you suffer from intolerance to certain sugars, refer to your doctor before use.

3. How to use this medicine

Check with your doctor or pharmacist if you are not sure.

Usual recommended dosage:

Adults and adolescents over 14 years of age: 2 tablets with the appearance of symptoms. If necessary, continue with one or two tablets every 4-6 hours as needed.

Do not take more than 6 tablets in a 24 hour period.

If there is no improvement in your condition within 3 days for fever and 5 days for pain, refer to your doctor.

If the symptoms persist, consult a doctor.

This medicine is not intended for children under 14 years of age.

Do not exceed the recommended dose.

Take the lowest dose which achieves the desired effect.

Swallow the whole medicine with water, take this medicine before food.

If you have accidentally taken a higher dosage, or if you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forget to take a dose, take it as soon as you remember; if the timing is close to the next dose, skip the forgotten dose and take the next dose at the regular time.

Do not take two doses at the same time.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

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

4. Side effects:

Like all medicines, the use of Voltaren Acti-Go can cause side effects, although not everybody gets them. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

Stop use of this medicine and refer to your doctor immediately if you experience one of the following effects:

- Abdominal pain, digestive difficulties, heartburn, flatulence, nausea, vomiting (very common side effects, appear in 1 out of 10).
- Palpitations, sudden and oppressive chest pain (signs of heart attack or myocardial infarction); breathlessness, difficulty of breathing when lying down, swelling of the legs (signs of heart failure). These side effects are uncommon (appear at a frequency of 1-10 out of 1,000).
- Hypertension
- Severe abdominal pain, bloody or black stools, bloody vomit, bloody diarrhea
- An allergic reaction including difficulty in breathing or swallowing, swelling of the face, mouth, tongue or throat, often accompanied by skin rash.
- Fainting
- Sudden difficulty in breathing, feeling of chest tightness accompanied by wheezing or coughing (signs of asthma); sudden and intense headache, stiff neck, difficulty to speak
- Convulsions
- Skin rash accompanied by blisters, peeling skin, purple spots on the skin, blisters in the mouth or eyes, skin inflammation accompanied by peeling or flaking
- Swelling of the arms, hands, legs and feet (edema)
- Change in color or volume of the urine, excess of protein in the urine, blood in the urine
- Yellow skin or eyes (signs of jaundice/hepatic failure), increase of liver enzymes, sensitivity of the upper right side of the abdomen and flu-like symptoms
- bleeding or unusual bruising, high fever or persistent sore throat, frequent infections
- Increased sensitivity of the skin to the sun

Taking medicines such as diclofenac may be associated with increased risk of heart attack (myocardial infarction). The risk is higher with high dosage and prolonged use.

Additional side effects:

Additional side effects that may occur are usually mild. If you feel one of these effects, refer to your doctor or pharmacist.

Appear commonly frequency of up to 1:10: diarrhoea, decrease in appetite; headache, dizziness; skin rash; vertigo.

Rare side effects, frequency up to 1:1,000: drowsiness; unusual