

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medication may be sold without a doctor's prescription

VOLTAREN ACTI-GO® Liquid Gelcaps

Active ingredient and its quantity:

Each capsule contains:
Diclofenac Potassium 12.5mg

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

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

This medicine can be given without a doctor's prescription. 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 indicated for: short-term treatment (up to 3 days) for relief of joint and muscular pain, back pain, headache, toothache, menstrual pain and fever reduction, in adults and adolescents over 14 years of age.

Therapeutic group: Voltaren Acti-Go Liquid Gelcaps 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 in your last trimester of pregnancy or breastfeeding.
- you have previously had 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). Reactions may include: asthma, wheezing, skin rash, facial swelling, runny nose. If you are uncertain, consult your doctor.
- you suffer from a gastric or intestinal ulcer.
- you suffer from bleeding of the digestive system, symptoms may 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 planning to undergo heart surgery.
- do not take simultaneously with other medicines of the NSAIDs group.

Special warnings regarding the use of this medicine:

Before treatment with Voltaren Acti-Go Liquid Gelcaps, 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, in case you smoke.
- you have suffered in the past from gastrointestinal problems such as stomach ulcer, blood in your stools 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 use 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 possible the risk for cardio-vascular side effects.
- Do not exceed the recommended dosage of up to 6 capsules per day or the recommended treatment duration (3 days).
- In case you experience, during treatment with Voltaren Acti-Go Liquid Gelcaps, 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), therefore makes infection diagnosis difficult. In case you do not feel well and you refer to your doctor, inform him that you are taking Voltaren Acti-Go Liquid Gelcaps.
- If you are about to undergo surgery (including dental surgery) tell 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 capsules 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 conduct 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)
- drugs used to treat diabetes (excluding insulin)
- other anti-inflammatory drugs or analgesics such as acetylsalicylic acid (Aspirin) or ibuprofen (may increase frequency of gastrointestinal side effects)
- corticosteroids (may increase the frequency of gastrointestinal side effects)
- 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, 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 Liquid Gelcaps 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:

This medicine should be taken before food.

Pregnancy and breastfeeding:

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

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 sorbitol. 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.

Common recommended dosage:

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

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

If your condition does not improve 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 purpose of use.
- Swallow the whole liquid gelcap with water.
- Take this medicine before food.

If you have accidentally taken a higher dosage, or if you have taken an overdose, or if your 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:

As with all medicines, Voltaren Acti-Go Liquid Gelcaps 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 1000).
- High blood pressure.
- 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 of the 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). 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: diarrhea, decrease in appetite, headache, dizziness, skin rash; vertigo.

Appear rarely frequency up to 1:1000: drowsiness, unusual fatigue, rash accompanied by itching.

Appear very rarely frequency up to 1:10000: decrease in level of white or red blood cells; constipation, mouth ulcers, swollen, red and sore tongue, taste disturbances, upper abdominal cramp; itching and redness of the skin, hair loss; tingling or numbness in hands or legs, trembling; blurred vision, ringing in the ears, hearing deterioration; mood swings, difficulty sleeping, feeling of confusion, disorientation, depression, nightmares, memory disorder, esophageal ulcer.

If any of the side effects worsens, or if you experience side effects not mentioned in this leaflet, consult your doctor.

5. How to store the medicine

- Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package/bottle/carton/label. The expiry date refers to the last day of that month.
- Storage conditions: Store at a temperature below 30°C.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Macrogol 600 (Polyethylene glycol 600), Glycerol 85%, Purified Water, Gelatin, Polysorb 85/70/00 (dry substance), Quinoline yellow 70% E104.

What does the medicine look like and what does the pack contain?

Voltaren Acti-Go Liquid Gelcaps are small yellow capsules.

Registration holder: NCH Ltd., 14 Hamefalsim St., Petach – Tikva.

This leaflet was checked and approved by the Ministry of Health in November 2013.

Drug registration number at the national medicines registry of the Ministry of Health: 150-99-33771-00

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