

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

The medicine is dispensed with a doctor’s prescription only

VOLTAREN® 50 mg Suppositories

Composition: Each suppository contains: Diclofenac Sodium 50 mg. Inactive ingredients: See section 6 “Further information”.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

This medicine is not intended for children and adolescents under the age of 14.

1. WHAT IS THIS MEDICINE INTENDED FOR?

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

If you have any questions about how Voltaren works or why this medicine has been prescribed to you, ask your doctor.

Therapeutic group: Non-steroidal anti-inflammatory drugs (NSAIDs).

2. BEFORE USING THE MEDICINE

⚠ Do not use the medicine:

- If you are allergic (hypersensitive) to the active ingredient or to any of the other ingredients of the medicine listed in section 6 “Further information” in this leaflet.
- If you have ever had an allergic reaction after taking medicines to treat inflammation or pain (e.g. acetylsalicylic acid, diclofenac or ibuprofen). Allergic reactions may include: asthma, runny nose, skin rash, face swelling. If you think you may be allergic, ask your doctor for advice.
- If you suffer from a stomach or intestinal ulcer.
- If you suffer or have suffered in the past from gastrointestinal bleeding or perforation, symptoms of which may include blood in your stools or black stools.
- If you suffer from severe kidney or liver disease.
- If you suffer from severe heart failure.
- If you suffer from ischemic heart disease or cerebral vascular disease or peripheral arterial disease (e.g., if you suffered in the past from heart attack, stroke or blocked arteries leading to the heart, brain or legs).
- If you are in the last three months of pregnancy.
- If you suffer from anal pain (sometimes with bleeding and discharge).
- Close to the time of pre-operative preparation for bypass surgery.

If any of these apply to you, **tell your doctor without taking Voltaren Suppositories.**

Voltaren 50 mg suppositories

Special warnings regarding use of the medicine:

⚠ Before using Voltaren Suppositories, inform your doctor if one of the following sections applies to you:

- If you have an established disease of the heart or blood vessels also called cardiovascular disease, including uncontrolled high blood pressure.

- If you have significant risk factors for cardiovascular disease such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes, or if you smoke, and your doctor decides to prescribe Voltaren, you must not increase the dose above 100 mg per day, if you are being treated for more than 4 weeks.

It is generally important to take the lowest dose of Voltaren that relieves your pain and/or swelling and for the shortest time possible. in order to keep your risk for cardiovascular side effects as small as possible.

- If you are taking Voltaren simultaneously with other anti-inflammatory medicines including acetylsalicylic acid, corticosteroids, “blood thinners” or “SSRIs” (see below “Taking other medicines...”).
- If you have asthma or hay fever (seasonal allergic rhinitis).
- If you have ever had gastrointestinal problems such as stomach ulcer, bleeding or black stools, or have experienced stomach discomfort or heartburn after taking anti-inflammatory medicines in the past.
- If you have an inflammation of the colon (ulcerative colitis) or intestinal tract (Crohn’s disease).
- If you have liver or kidney problems.
- If you could be dehydrated (e.g. by sickness, diarrhea, before or after surgery).
- If you have swollen feet.
- If you have a bleeding disorder or other blood disorders, including a rare liver condition called porphyria.

If you experience any of the following symptoms, inform your doctor immediately:

- If, at any time while taking Voltaren, 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 may reduce the symptoms of an infection (e.g. headache and high temperature) and may therefore make the infection more difficult to detect and to treat. If you feel unwell and need to see a doctor, remember to mention that you are taking Voltaren.
- In very rare cases, Voltaren, like other anti-inflammatory medicines, may cause severe allergic skin reactions (e.g. rash).

Like other medicines from the NSAID group, Voltaren, at a dose higher than recommended or during prolonged use may increase the risk of heart attack or stroke. The risk increases when used in patients with heart diseases or at risk for these diseases.

In addition, like other medicines from the NSAID group, Voltaren may cause gastrointestinal discomfort and rarely, even serious side effects such as the formation of ulcers and bleeding. The risk increases if you are over 60 years of age and during prolonged use. You must consult the doctor if you experience gastrointestinal pain, bloody or black stools, bloody vomit (see also the section: “Side effects”).

⚠ Taking other medicines

If you are taking, or have recently taken, other medicines, including non-prescription medicines and food supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:

- Lithium or selective serotonin-reuptake inhibitors (SSRIs) (medicines used to treat some types of depression)
- Digoxin (a medicine used for heart problems)
- Diuretics (medicines used to increase the amount of urine)
- ACE inhibitors or beta-blockers (classes of medicines used to treat high blood pressure and heart failure)

- Other anti-inflammatory medicines such as acetylsalicylic acid or ibuprofen
- Corticosteroids (medicines used to provide relief for inflamed areas of the body)
- “Blood thinners” (a medicine used to prevent blood clotting)
- Medicines used to treat diabetes, except insulin
- Methotrexate (a medicine used to treat some kinds of cancer or arthritis)
- Ciclosporin, Tacrolimus (medicines primarily used in patients who have received organ transplants)

- Trimethoprim (a medicine used to prevent or treat urinary tract infections)
- Quinolone antibacterials (medicines used to treat infections)
- Voriconazole (a medicine used to treat fungal infections)
- Phenytoin (a medicine used to treat seizures)

⚠ Older people

Elderly patients may be more sensitive to the effects of Voltaren than other adults. Therefore, they should follow the doctor’s instructions particularly carefully and take the minimum number of suppositories needed to provide relief of symptoms. It is especially important for elderly patients to report undesirable effects promptly to their attending doctor.

⚠ Children and adolescents:

This medicine is not intended for children and adolescents under the age of 14.

⚠ Pregnancy and breastfeeding

If you are pregnant, planning to become pregnant or think you may be pregnant, **inform your doctor.** You should not take Voltaren Suppositories while pregnant, unless absolutely necessary.

As with other anti-inflammatory medicines, you must not receive Voltaren Suppositories during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery. You should tell your doctor if you are breastfeeding. You should not breastfeed if you are taking Voltaren Suppositories, as it might be harmful for your infant.

Your doctor will discuss with you the potential risk of taking Voltaren Suppositories during pregnancy or breastfeeding.

⚠ Women of child-bearing potential

Voltaren may make it more difficult to become pregnant. You should not use Voltaren Suppositories unless necessary, if you are planning to become pregnant or if you have problems to become pregnant.

⚠ Driving and using machines

In rare cases, use of the medicine may cause vision disturbances, dizziness or sleepiness. If you experience these effects, you must avoid driving a car, operating machinery and all activities that require alertness. Inform the doctor as soon as possible if you experience these effects.

⚠ Use of the medicine and alcohol consumption

It is not recommended to drink wine or other alcoholic beverages during treatment with the medicine.

⚠ Smoking

Smoking is not recommended during treatment with the medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor’s instructions. Check with the doctor or pharmacist if you are uncertain.

Standard dosage

Do not exceed the recommended dose prescribed by your doctor. It is important that you use the lowest dose that controls your pain and that you do not use Voltaren Suppositories for longer than necessary. Your doctor will tell you exactly how many suppositories of Voltaren to use. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:

Adults -

The total daily dose should usually be divided into 2 to 3 separate doses. Do not exceed 150 mg per day, unless instructed by the doctor.

Children and adolescents -

This medicine is not intended for children and adolescents under the age of 14.

When and how to take the medicine:

It is best to take the suppositories after emptying your bowels.

How to insert the suppository: First, wash your hands thoroughly. Voltaren suppositories are wrapped in foil. Before inserting the suppository, take off all the foil and moisten the suppository with cold water. Lie down on your side and, using your finger, push the suppository well up into the rectum.

If the suppository is too soft to insert, chill it in the refrigerator for 30 minutes or hold it under cold water **before** taking off the foil. Wash your hands after inserting the suppository.

Do not break the suppositories, as incorrect storage conditions may lead to uneven distribution of the active substance.

Never take suppositories by mouth. Do not swallow!

Duration of treatment:

If you take Voltaren Suppositories for more than a few weeks, you should make sure to visit your doctor for regular check-ups, to ensure that you are not suffering from unnoticed undesirable effects.

Tests and follow-up:

- If you suffer from an established heart disease or significant risks for heart disease, your doctor will periodically re-evaluate whether you should continue treatment with Voltaren, especially if you are treated for more than 4 weeks.
- If you suffer from any liver impairment, kidney impairment or blood impairment, you will have blood tests during treatment. These tests will monitor either your liver function (level of transaminases) or your kidney function (level of creatinine) or your blood count (level of white and red blood cells and platelets). Your doctor will take these blood tests into consideration to decide if treatment needs to be discontinued or if the dose needs to be changed.
- When taking Voltaren according to doctor’s instructions at high doses or for a prolonged period, it is recommended to undergo laboratory tests (blood, urine, liver and kidney function) in order to ascertain that tests results are in the range of normal.
- Elevated liver enzyme levels may occur. If this elevation continues or worsens or if you develop symptoms such as yellowing eyes and skin, nausea, loss of appetite or light urine, if abnormal liver function continues or worsens, if clinical signs or symptoms of liver disease develop, or if other symptoms occur (e.g. eosinophilia, rash), stop taking Voltaren.

If you accidentally take too high a dosage:

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you. Medical treatment may be necessary.

If you forget to take the medicine:

If you forget to take the medicine at the required time, take a dose as soon as you remember. If it is nearly time for your next dose, you should simply take the next dose at the usual time. Never take two doses together in order to make up for the one you missed.

Be sure to adhere to the treatment as recommended by the doctor.

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

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

4. SIDE EFFECTS

As with any medicine, use of Voltaren suppositories may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Some side effects could be serious

Contact the doctor immediately in the following cases:

Uncommon side effects (may affect between 1 and 10 in every 1,000 patients) especially when taking a high daily dose (150 mg) for a long period of time:

- 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)

Rare or very rare side effects (may affect from less than 1 to 10 in every 10,000 patients):

- Spontaneous bleeding or bruising (signs of a drop in the number of platelets (thrombocytopenia))
- High fever, frequent infections, persistent sore throat (signs of a lack of white blood cells (agranulocytosis))
- Difficulty breathing or swallowing, rash, itching, hives, dizziness (signs of allergic, anaphylactic and anaphylactoid reactions)
- Swelling mainly of the face and throat (signs of angioedema)
- Disturbing thoughts or moods (signs of psychotic disorders)
- Impaired memory
- Seizures (signs of convulsions)
- Anxiety
- Stiff neck, fever, nausea, vomiting, headache (signs of aseptic meningitis)

- Sudden and severe headache, nausea, dizziness, numbness, inability or difficulty to speak, weakness or paralysis of limbs or face (signs of stroke)
- Difficulty hearing (signs of hearing impaired)
- Headache, dizziness (signs of high blood pressure, hypertension)
- Rash, purplish-red spots, fever, itching (signs of vasculitis)
- Sudden difficulty breathing and feeling of tightness in chest with wheezing or coughing (signs of asthma or pneumonia if there is fever)
- Vomiting of blood (signs of hematemesis) and/or black or bloody stools (signs of gastrointestinal hemorrhage)
- Bloody diarrhea
- Black stool
- Stomach pain, nausea (signs of gastrointestinal ulcer)
- Diarrhea, abdominal pain, fever, nausea, vomiting (signs of colitis, including ulcerative colitis and exacerbation of ulcerative colitis or Crohn’s disease)
- Severe upper stomach pain (signs of pancreatitis)
- Yellowing of the skin or eyes (signs of jaundice), nausea, loss of appetite, dark urine (signs of hepatitis/liver failure)
- Flu-like symptoms, feeling tired, muscles aches, increased liver enzyme levels in blood test results (signs of liver disorder including fulminant hepatitis, hepatic necrosis, hepatic failure)

- Blister (signs of dermatitis bullous)
- Red or purple skin (possible signs of blood vessel inflammation), skin rash with blisters, blistering of the lips, eyes and mouth, skin inflammation with peeling (signs of erythema multiforme or there is fever, signs of Stevens-Johnson syndrome or toxic epidermal necrolysis)
- Skin rash with peeling (signs of exfoliative dermatitis)
- Increased sensitivity of the skin to sun (signs of photosensitivity reaction)
- Purple skin patches (signs of purpura or Hensch-Schonlein purpura if caused by an allergy)
- Swelling, feeling weak, or abnormal urination (signs of acute renal failure)
- Excess of protein in the urine
- Swollen face or abdomen, high blood pressure (signs of nephrotic syndrome)
- Higher or lower urine output, drowsiness, confusion, nausea (signs of tubulointerstitial nephritis)
- Severely decreased urine output (signs of renal papillary necrosis)

- Generalized swelling (signs of edema)

Additional side effects:

Common side effects (may affect between 1 and 10 in every 100 patients):
Headache, dizziness, vertigo, nausea, vomiting, diarrhea, indigestion (signs of dyspepsia), abdominal pain, flatulence, loss of appetite (signs of decreased appetite), abnormal liver function test results (e.g. level of transaminases increased), skin rash, anal irritation.
Uncommon side effects (may affect between 1 and 10 in every 1,000 patients):
Palpitations, chest pain.

Rare side effects (may affect between 1 and 10 in every 10,000 patients):

Drowsiness (signs of somnolence), stomach pain (signs of gastritis), liver disorder, itchy rash (signs of urticaria), anal pain (sometimes with bleeding and discharge).

Very rare side effects (may affect less than 1 in 10,000 patients):

Low level of red blood cells (anemia), low level of white blood cells (leukopenia), disorientation, depression, difficulty sleeping (signs of insomnia), nightmares, irritability, tingling or numbness of the hands or feet (signs of paresthesia), trembling, taste disorders, vision disorders (signs of visual impairment, vision blurred, diplopia), noises in ears (signs of tinnitus), constipation, mouth sores (signs of stomatitis), swollen, red and sore tongue (signs of glossitis), disorder of the tube that carries food from the throat to the stomach (signs of esophageal disorder), upper abdomen cramp specially after eating (signs of intestinal diaphragm disease), itchy, red and burning rash (signs of eczema), skin reddening (signs of erythema), hair loss (signs of alopecia), stinging and itching, blood in urine, bleeding due to hemorrhoids.

If one or more of these side effects affects you severely, **tell your doctor.**

If any of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, you must consult with the doctor.

If you take Voltaren Suppositories for more than a few weeks, you should make sure to visit your doctor for regular check-ups, to ensure that you are not suffering from unnoticed undesirable effects.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store below 30°C.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains: Hard Fat.
- What the medicine looks like and the contents of the package: Voltaren 50 mg is dispensed in the form of suppositories. Voltaren 50 mg packages contain 10 or 50 suppositories per package (not all package sizes may be marketed). Voltaren 50 mg suppositories are torpedo-shaped with a smooth or slightly rough surface. The color of the suppositories is yellowish-white.

License Holder and address:

Novartis Pharma Services AG, 36 Schacham St., Petach-Tikva.

Manufacturer and address:

Delpharm Hunigue S.A.S., France for Novartis Pharma AG, Basel, Switzerland.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

117-02-23176-00

This leaflet was checked and approved by the Ministry of Health in June 2014.

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