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

The medicine is dispensed with a doctor's prescription only

ABITREN SUPPOSITORIES 50 MG

Suppositories

Composition

Each suppository contains:
Diclofenac Sodium 50 mg

For information on the inactive ingredients, see section 6 - "Further information".

Read the 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 you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

This is an anti-inflammatory and pain relieving medicine, such as those associated with joints, muscles and the skeleton, in dental surgery and other minor surgeries.

Therapeutic group

Non-steroidal anti-inflammatory drugs (NSAIDs).

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you think you are sensitive (allergic) to the active ingredient (diclofenac sodium) or to any of the additional ingredients contained in the medicine (see section 6 – "Further information"), or if you are sensitive (allergic) to aspirin, ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs). Signs of hypersensitivity include swelling of the face and mouth (angioedema), breathing problems, chest pain, runny nose, skin rash or any other allergic reaction.
- you currently have, or have had in the past, a stomach (gastric) or duodenal (peptic) ulcer, or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in stools or black stools).
- you have had stomach or bowel problems after taking other NSAIDs.
- you have heart, kidney or liver failure.
- you have established heart disease and/or cerebrovascular disease e.g., if you have had a heart attack, stroke, transient ischemic attack (TIA), blockage of blood vessels leading to the heart or brain or if you have undergone a procedure to clear or bypass a blockage.
- you have or have had blood circulation problems (peripheral arterial disease).
- you are in the third trimester of pregnancy.
- you are breastfeeding.
- you are suffering from ineffectual straining to empty the bowels, diarrhea or rectal bleeding.

Special warnings regarding use of the medicine

Before treatment with Abitren Suppositories 50 mg, tell the doctor if:

- you are suffering from stomach or bowel disorders, including ulcerative colitis or Crohn's disease.
- you have kidney or liver problems, or you are elderly.
- you have porphyria.
- you are suffering from any blood disorder or from bleeding. If you do, your doctor may refer you for routine checkups while using these suppositories.
- you ever had asthma.
- you have angina, blood clots, high blood pressure, higher than normal blood fat levels (high cholesterol or a high triglyceride level).
- you have heart problems, you had a stroke, or you think you are at risk for these conditions (for example, if you have high blood pressure, diabetes or high cholesterol or you smoke).
- you have diabetes.
- you smoke.
- you have lupus (systemic lupus erythematosus [SLE]) or a similar condition.

Additional special warnings

- Take the lowest dosage of Abitren Suppositories 50 mg for the shortest time possible, especially if you are underweight or elderly.
- Like other medicines similar to Abitren, Abitren Suppositories 50 mg may slightly increase the risk of heart attack or stroke. The risk is higher if you are taking a high dosage for a prolonged period of time. Always follow the doctor's instructions regarding dosage and duration of treatment.
- If at any time during the course of treatment with this medicine you experience any signs or symptoms of heart or vascular problems, such as chest pain, shortness of breath, weakness or speaking difficulty, contact your doctor immediately.
- While you are taking Abitren Suppositories 50 mg, your doctor may refer you to routine checkups from time to time.
- If you have a history of stomach problems after taking NSAIDs, especially if you are elderly, tell the doctor immediately if you notice unusual symptoms.
- Because this is an anti-inflammatory preparation, Abitren Suppositories 50 mg may mask signs of infection, such as headache and high fever. If you do not feel well and must refer to a doctor, remember to mention that you are taking Abitren Suppositories 50 mg.

Before using Abitren Suppositories 50 mg, tell the doctor if you recently underwent or are due to undergo surgery in the stomach or digestive system, since the suppositories can sometimes delay wound healing after intestinal surgery.

Drug interactions

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

- Medicines to treat diabetes
- Anticoagulants (blood thinning tablets like warfarin)
- Diuretics
- Lithium (to treat some mental problems)
- Methotrexate (for some inflammatory diseases and for certain kinds of cancer)
- Ciclosporin and tacrolimus (used to treat some inflammatory diseases and after transplants)
- Trimethoprim (a medicine to treat or prevent urinary tract infections)
- Quinolone antibiotics (for infections)
- Any other NSAIDs or COX-2 (cyclo-oxgenase-2) inhibitor, for example aspirin or ibuprofen
- Mifepristone (a medicine used to terminate pregnancy)
- Cardiac glycosides (for example digoxin), used to treat heart problems
- Medicines known as SSRIs (selective serotonin reuptake inhibitors) used to treat depression
- Oral steroids (an anti-inflammatory drug)
- Medicines used to treat heart problems or high blood pressure, for example beta-blockers or ACE inhibitors
- Voriconazole (a medicine to treat fungal infections)
- Phenytoin (a medicine to treat seizures)
- Colestipol/cholestyramine (used to lower cholesterol)

Pregnancy, breastfeeding and fertility

Pregnancy

This preparation has a possible side effect of kidney damage in the fetus and low amniotic fluid starting from the 20th week of pregnancy. It is recommended to avoid the use of preparations from the NSAID group starting from 20th week of pregnancy and to consult a healthcare professional if necessary.

Although not common, defects have been reported in babies whose mothers took NSAIDs during pregnancy.

Do not use Abitren Suppositories 50 mg during the last 3 months of pregnancy as it may affect the baby's blood circulation.

Are you planning to become pregnant? Using Abitren Suppositories 50 mg may make it difficult to conceive. Consult your doctor if you are planning to become pregnant, or if you having difficulties getting pregnant.

Breastfeeding

As with other NSAIDs, diclofenac passes into breast-milk. Therefore, do not take Abitren Suppositories when breastfeeding.

Driving and operating machinery

Occasionally, patients have reported that diclofenac sodium suppositories made them feel dizzy, tired or drowsy. Problems with eyesight have also been reported. If you are affected in this way after taking the medicine, avoid driving and operating machinery.

Use in children

Abitren Suppositories 50 mg dosage is not suitable for use in children.

Important information about some of the ingredients of the medicine

This medicine contains less than 23 mg sodium per suppository and is therefore considered sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage in adults is generally: 2 suppositories a day.

In severe cases, the doctor may recommend combined treatment with tablets. Do not exceed a total daily dosage of 150 mg diclofenac sodium.

Elderly

Your doctor may advise you to take a dose that is lower than the usual adult dose. Your doctor may also want to check closely that the Abitren suppositories are not adversely affecting your stomach, particularly during the first 4 weeks of using the suppositories.

Use the medicine at set intervals as determined by the attending doctor.

Do not exceed the recommended dosage.

Instructions for use

Do not swallow; the suppositories are intended for insertion into the rectum.

It is recommended to use the suppositories after a bowel movement.

Note: If the suppository is too soft to insert, it can be chilled by keeping in the refrigerator for about 30 minutes, or by holding it under a stream of cold water before removing the wrapping.

How to insert the suppository:

1. First, wash your hands thoroughly.
2. Remove the wrapping from the suppository. The suppository can be moistened with a little water to ease insertion.
3. Lie on your side and gently insert the suppository deep into the rectum with your finger.
4. Wash your hands thoroughly after inserting the suppository.

Tests and follow-up

During prolonged treatment with the medicine, or with treatment requiring high dosages, blood, urine, and liver and kidney function tests should be performed. There may be an elevation in liver enzymes that requires discontinuation of treatment after consulting the doctor (see section 4 - "Side effects").

If you are suffering from an existing heart disease or from significant risk factors for heart disease, your doctor will re-evaluate from time to time whether you should continue the treatment with the medicine, especially if you are being treated for more than four weeks.

If you forget to take the medicine

If you forgot to take this medicine at the required time, take a dose as soon as you remember, but never take two doses together.

Adhere to the treatment regimen as recommended by the doctor.

If you accidentally took a higher dosage

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

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 the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Abitren Suppositories 50 mg may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them. Side effects may be minimized by using the lowest effective dose for the shortest duration necessary.

Some side effects can be serious

Stop treatment and refer to a doctor immediately if the following occur:

- Sudden and crushing chest pain (signs of myocardial infarction or heart attack).
- Shortness of breath, difficulty breathing when lying down, swelling of the legs or feet (signs of heart failure).
- Sudden weakness or numbness in the face, hand or leg, especially on one side of the body, sudden complete or partial loss of vision, sudden difficulty in speaking or ability to understand speech, sudden migraine-like headaches which happen for the first time, with or without disturbed vision. These signs can be an early sign of a stroke.
- Stomach pain, indigestion, heartburn, wind, nausea or vomiting.
- Any sign of bleeding in the stomach or intestine, for example, when emptying the bowels, blood in vomit or black stools.
- Allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering.
- Wheezing or shortness of breath (bronchospasm).
- Swollen face, lips, hands or fingers.
- Yellowing of the skin or the whites of the eyes.
- Persistent sore throat or high fever.
- An unexpected change in the amount of urine and/or its appearance.
- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with diclofenac suppositories and followed by rectal bleeding or bloody diarrhea, usually within 24 hours of the onset of abdominal pain.
- Chest pain, which can be a sign of a serious allergic reaction called Kounis syndrome.
- Symptoms of meningitis, such as: severe headaches, stiff neck, muscle stiffness, severe and persistent nausea and vomiting, and spinal pain (rare).

If you notice that you are bruising more easily than usual or have frequent sore throats or infections, refer to your doctor.

Abitren Suppositories may occasionally cause itching or burning in the rectum or make hemorrhoids worse.

Additional side effects that have been reported:

Common side effects (may affect between 1 and 10 in every 100 patients):

- Stomach pain, heartburn, nausea, vomiting, diarrhea, digestive disorders, wind, loss of appetite
- Headache, dizziness, vertigo
- Skin rash or skin blemishes
- High levels of liver enzymes in the blood
- Irritation at suppository insertion site

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

Fast or irregular heart beat, chest pain, heart problems, including heart attack or shortness of breath, difficulty breathing when lying down, or swelling of the legs or feet (signs of heart failure), especially if you took a high dosage (150 mg per day) for a long period of time.

Rare side effects (may affect between 1 in every 1000 to 1 in every 10,000 patients):

- Stomach ulcers or bleeding (cases resulting in death have been reported rarely, particularly in the elderly)
- Gastritis (inflammation, irritation or swelling of the stomach lining)
- Vomiting blood
- Diarrhea with blood or bleeding from the rectum
- Black stools
- Drowsiness, tiredness
- Skin rash and itching
- Fluid retention (symptoms include swollen ankles)
- Liver function disorders, including hepatitis and jaundice
- Asthma (symptoms may include wheezing, shortness of breath, coughing and a tightness across the chest)

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

Effects on the nervous system:

Inflammation of the lining of the brain (meningitis), tingling or numbness in the fingers, tremor, visual disturbances such as blurred or double vision, taste changes, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood swings, depression, anxiety, irritability, mental disorders, disorientation and loss of memory, fits, headaches together with a dislike of bright lights, fever and a stiff neck.

Effects on the stomach and digestive system:

Constipation, inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, large intestine disorders (including inflammation of the colon, or worsening of ulcerative colitis or Crohn's disease), inflammation of the pancreas.

Effects on the chest or blood:

Hypertension (high blood pressure), hypotension (symptoms may include fainting, or dizziness), inflammation of blood vessels (vasculitis), inflammation of the lungs, blood disorders (including anemia).

Effects on the liver or kidneys:

Kidney or severe liver disorders, including liver failure, appearance of blood or protein in the urine.

Effects on skin or hair:

Facial swelling, severe skin rashes including Stevens-Johnson syndrome, Lyell's syndrome and other skin rashes which may worsen with sunlight exposure.
Hair loss.

Effects on the reproductive system:

Impotence.

Other side effects that have been reported with unknown frequency, including:

Throat disorders, confusion, hallucinations, restlessness (general feeling of discomfort), inflammation of the nerves in the eye, sensation disturbances.

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

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

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 and sight of children and/or infants, 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 (Expiry date) that appears on the package. The expiry date refers to the last day of that month.

Store in a dry place, below 25°C.

Do not throw away medicines into the sewage or household waste. Ask the pharmacist how to dispose of unused medicines. These measures will help protect the environment.

6. FURTHER INFORMATION

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

Witepsol H15, Witepsol E85.

What the medicine looks like and the contents of the package:

White to cream colored suppository.
Each package contains 10 or 100 suppositories.
Not all package sizes may be marketed.

Name of Manufacturer and License Holder and its Address:

Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.

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

015.72.24237

This leaflet was revised in August 2021 according to MOH guidelines.

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