

Product Information Leaflet

LOFNAC-100

Diclofenac Sodium Suppositories 100 mg

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet :

1. What are LOFNAC-100 and what they are used for
2. What you need to know before you use LOFNAC-100
3. How to use LOFNAC-100
4. Possible side effects
5. How to store LOFNAC-100
6. Contents of the pack and other information

1. WHAT ARE LOFNAC-100 AND WHAT ARE THEY USED FOR

LOFNAC-100 contain diclofenac and belong to a group of medicines called non-steroid anti-inflammatory drugs (NSAIDs). These medicines reduce pain and inflammation, and bring down a high temperature.

LOFNAC-100 are used to treat a number of painful conditions affecting the joints and muscles, fractures, dislocation, back pain, dental and other minor surgeries.

This medicine is a suppository which works when it is placed in your back passage (rectum). It should never be taken by mouth.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE LOFNAC-100

DO NOT use LOFNAC-100 if:

- You know that you are allergic to Diclofenac Sodium, any other NSAIDs or any of the other ingredients of this medicine (listed in section 6)

- You have ever had have ever had, 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 faeces or black, tarry faeces)
- you have had stomach or bowel problems after you have taken other NSAIDs
- you have heart, kidney or liver failure if you have established heart disease and/or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages
- if you have or have had problems with your blood circulation (peripheral arterial disease)
- you are more than six months pregnant
- you suffer from ineffectual straining to empty the bowels, diarrhoea or rectal bleeding

If you are having a medical examination, tell the doctor that you are using LOFNAC-100 as they reduce the signs of fever and inflammation which would otherwise be noticed.

Medicines such as LOFNAC-100 may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

Are you taking other medicines?

Some medicines can interfere with your treatment. Tell your doctor or pharmacist if you are taking any of the following:

- Medicines to treat diabetes
- Anticoagulants (blood thinning tablets like warfarin)
- Diuretics (water tablets)
- Lithium (used to treat some mental problems)
- Methotrexate (for some inflammatory diseases and some cancers)
- Ciclosporin and tacrolimus (used to treat some inflammatory diseases and after transplants)
- Trimethoprim (a medicine used to prevent or treat urinary tract infections)
- Quinolone antibiotics (for infections)
- Any other NSAID or COX-2 (cyclo-oxygenase-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 used to treat depression

- Oral steroids (an anti-inflammatory drug)
- Medicines used to treat heart conditions or high blood pressure, for example betablockers or ACE inhibitors.
- Voriconazole (a medicine used to treat fungal infections).
- Phenytoin (a medicine used to treat seizures)
- Colestipol/cholestyramine (used to lower cholesterol)

Pregnancy, breast-feeding and fertility:

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. Although not common, abnormalities have been reported in babies whose mother have taken NSAIDs during pregnancy. You should not use LOFNAC-100 during the last 3 months of pregnancy as it may affect the baby's circulation.

Are you trying for a baby? Using LOFNAC-100 may make it more difficult to conceive. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.

Driving and using machines:

NSAIDs like this medicine may sometimes cause symptoms such as drowsiness which could make it unsafe to drive or use machines. If you notice any such symptoms, do not drive or operate machinery and ask your doctor or pharmacist for advice.

3. HOW TO USE LOFNAC-100

Suppositories are designed for insertion into the back passage (rectum). Never take them by mouth.

Always use this medicine exactly as your doctor has told you.

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

Adults: 75-150 mg daily in divided doses.

As a general principle, the smallest effective dose should be used, and for the shortest time. Side effects can worsen with increased use.

Elderly: If you are elderly, your doctor may want to reduce the usual adult dosage and to check that the medicine is suiting you, especially during the first four weeks of treatment. Make sure to follow your doctor's instructions carefully and to keep your appointments.

Use in children and adolescents Children: LOFNAC-100 Suppositories are not recommended for use in children.

How to use LOFNAC-100 Suppository:

When practical, clean the area around the rectum with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or soft cloth

Do not open suppository if it seems soft, hold the foil wrapper under cold water or place it in refrigerator for few minutes to harden it before removing the wrapper.

Position the patient to lie on one side with knees bent up to their abdomen or lie on back with feet and legs held up.

Detach the suppository by holding strip upright and carefully peel the wrapper evenly down both sides. (Moisten the suppository if dry)

Hold the suppository between index finger and thumb, locate the anus and gently insert suppository tip end first with the index finger. The suppository should be fully inserted in to rectum against the wall of rectum.

Hold buttocks together lying down for about 5 minutes to avoid having the suppository comes out. Discard used materials and wash your hands thoroughly

If you use more LOFNAC-100 than you should:

If you (or someone else) uses too many LOFNAC-100, contact your doctor, or nearest hospital, immediately for advice.

Bring the remaining suppositories with you.

If you forget to use LOFNAC-100:

If you miss a dose, leave it out and use the next dose whenever it is due. After that, just carry on as before.

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

4. POSSIBLE SIDE EFFECTS

LOFNAC-100 are suitable for most people, but, like all medicines, this medicine can cause side effects, although not everybody gets them. Some side effects can be serious.

Stop using the suppositories and tell your doctor straight away if you notice:

- Sudden and crushing chest pain (signs of myocardial infarction or heart attack)
- Breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of heart failure)

- Sudden weakness or numbness in the face, arm or leg especially on one side of the body; sudden loss or disturbance 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 symptoms can be an early sign of a stroke
- Stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick)
- Any sign of bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit or black, tarry faeces
- 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 your skin or the whites of your eyes
- Persistent sore throat or high temperature
- An unexpected change in the amount of urine produced and/or its appearance.
- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Lofnac Suppositories and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain.

The side effects listed below have also been reported.

Up to 1 and 10 in every 100 patients have experienced:

Stomach pain, heartburn, nausea, vomiting, diarrhoea, indigestion, wind, loss of appetite

Headache, dizziness, vertigo

Skin rash or spots

Raised levels of liver enzymes in the blood.

Between 1 in every 1000 to 1 in every 10,000 patients have experienced:

Stomach ulcers or bleeding (there have been very rare reported cases resulting in death, particularly in the elderly)

- Gastritis (inflammation, irritation or swelling of the stomach lining)
- Vomiting blood
- Diarrhoea with blood in it or bleeding from the back passage
- Black, tarry faeces or stools
- Drowsiness, tiredness
- Skin rash and itching
- Fluid retention, symptoms of which include swollen ankles
- Liver function disorders, including hepatitis and jaundice
- Asthma (symptoms may include wheezing, breathlessness, coughing and a tightness across the chest).

Very rare These 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 changes, 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, lower gut 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 (low blood pressure, symptoms of which may include faintness, giddiness or light headedness), inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), blood disorders (including anaemia).

Effects on the liver or kidneys:

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

Effects on skin or hair:

Facial swelling, serious skin rashes including Stevens-Johnson syndrome, Lyell's syndrome and other skin rashes which may be made worse by exposure to sunlight. Hair loss.

Effects on the reproductive system:

Impotence.

Medicines such as diclofenac may be associated with a small increased risk of heart attack or stroke.

Do not be alarmed by this list - most people use LOFNAC-100 without any problems. 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 LOFNAC-100

Store in a dry place, below 30°C.

Keep the suppositories in their original pack.

Keep out of the reach and sight of children.

Do not use the suppositories after the expiry date which is printed on the outside of the pack. If your doctor tells you to stop using them, please take any unused suppositories back to your pharmacist to be destroyed. Do not throw them away with your normal household water or waste. This will help to protect the environment

6. FURTHER INFORMATION

What LOFNAC-100 contain:

The active substance is diclofenac sodium. The other ingredient is Polyethylene Glycol BP 1500, Polyethylene Glycol BP 6000, Methyl Paraben BP, Propyl Paraben BP, Butylated Hydroxy Toluene BP, and Titanium Dioxide BP.

What LOFNAC-100 look like and contents of the pack:

LOFNAC-100 are white to off white bullet shaped suppository. One suppository contains 100 mg diclofenac sodium.

2x5 Suppositories packed in PVC/PE foil in carton along with pack insert.

LOFNAC-100 are manufactured by

Bliss GVS Pharma Ltd., Saki Vihar Road, Andheri (East), Mumbai - 400 072, INDIA.