



Dologast-Denk 75/20 mg

Modified-release hard capsule – oral use

Non-steroidal anti-phlogistic/antirheumatic

For use in adults

Active substances: diclofenac + omeprazole

Package leaflet:

Information for the patient

Read all of this leaflet carefully before you start taking 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. See section 4.

What is in this leaflet

1. What Dologast-Denk is and what it is used for
2. What you need to know before you take Dologast-Denk
3. How to take Dologast-Denk
4. Possible side effects
5. How to store Dologast-Denk
6. Contents of the pack and other information

1. What Dologast-Denk is and what it is used for

Dologast-Denk contains two active ingredients in a single capsule. These active ingredients are diclofenac sodium (75 mg) and omeprazole (20 mg).

Diclofenac is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) and is used to reduce pain and inflammation of joint disorders.

Omeprazole belongs to a group of medicines called "proton pump inhibitors" which reduce the amount of acid that your stomach produces. Omeprazole reduces the risk of developing peptic

ulcers (ulcers in your stomach or duodenum) caused by non-steroidal anti-inflammatory drugs (NSAIDs).

Dologast-Denk is used in adults for the symptomatic treatment of rheumatoid arthritis, osteoarthritis and ankylosing spondylitis in adult patients at risk of developing NSAID associated gastric and/or duodenal ulcers, who are adequately controlled with diclofenac and omeprazole.

2. What you need to know before you take Dologast-Denk

Do not take Dologast-Denk,

- if you are allergic to diclofenac, omeprazole or to the other ingredients of this medicine (listed in section 6).
- if you have experienced allergic reactions to acetylsalicylic acid, ibuprofen or any other NSAID. Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), asthma, breathing problems, chest pain, runny nose, skin rash or any other allergic type reaction.
- if you are allergic to medicines containing other proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- if you have severe liver failure or severe kidney failure.
- if you are in the last three months of pregnancy.
- if you are taking a medicine containing nelfinavir (used for HIV infection).
- if you have an active gastric or intestinal ulcer, bleeding or perforation.
- if you have an active or history of recurrent stomach/duodenal ulcer (peptic ulcer) or haemorrhage (two or more distinct episodes of proven ulceration or bleeding).
- if you have a history of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.
- 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).
- if you have unexplained blood-formation disorders.
- if you have cerebrovascular bleeding or other active bleeding.

Stomach and intestine

Like other NSAIDs, Dologast-Denk should be used with caution if you have a history of gastrointestinal disease, such as:

- ulcerative colitis or Crohn's disease. Your condition may become worse.
 - gastrointestinal side effects, especially in advanced age.
- Gastrointestinal bleeding, ulcers and perforations, even with a fatal outcome, have been reported with all NSAIDs. They occurred at any time during treatment both with and without warning symptoms or a history of serious gastrointestinal events. They generally have more serious consequences in the elderly.
- The risk of gastrointestinal bleeding, ulcers and perforations is higher with increasing NSAID doses and in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation. The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal.
- You should report any unusual symptoms in the abdominal region (in particular gastrointestinal bleeding).

Warnings and precautions

Talk to your doctor or pharmacist before taking Dologast-Denk.

Dologast-Denk may hide the symptoms of other diseases or make them worse. Therefore, if any of the following happen to you before you start

taking Dologast-Denk or while you are taking it, talk to your doctor straight away:

- You have heart, kidney or liver problems (your doctor may want to carry out some tests while you are taking the capsules).
- You lose a lot of weight for no reason or have problems swallowing.
- You get stomach pain or indigestion.
- You begin to vomit food or blood.
- You pass black stools (blood-stained faeces).
- You experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea.

General

- Always use the lowest effective dose for the shortest period necessary to control symptoms, since any risk of side effects is more likely with high doses and longer-lasting treatment, especially in frail elderly patients or those with a low body weight.
- You should avoid the concomitant use of Dologast-Denk with other NSAIDs, including cyclooxygenase-2 selective inhibitors (COX-2).
- Like other NSAIDs, diclofenac, may mask the signs and symptoms of infection. **Contact your doctor at once if signs of a new infection occur** (e.g. reddening, swelling, pain or fever) or an existing infection becomes worse during the use of Dologast-Denk.
- Prolonged use of pain-killers can result in headaches, which must not be treated by taking higher doses of the medicine.

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If you suffer gastrointestinal bleeding or ulcers on Dologast-Denk, treatment must be stopped. Caution is recommended if you concomitantly use medicines which could increase the risk of ulceration or bleeding, such as systemic corticosteroids, anticoagulants, anti-platelet agents or selective serotonin- reuptake inhibitors.

Patients with a history of ulcers, especially with the complications of bleeding or perforation (see also "Do not take Dologast-Denk") and elderly patients should start and maintain treatment with the lowest effective dose.

Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before taking Dologast-Denk as diclofenac/omeprazole can sometimes worsen wound healing in your gut after surgery.

Cardiovascular and cerebrovascular system

Medicines such as Dologast-Denk are associated with an 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.

- Make sure your doctor knows, before you are given diclofenac,
 - if you smoke.
 - if you have diabetes.
 - if you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides.
- Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

Skin

On NSAID therapy severe skin reactions with redness and blister formation, in some cases with a fatal outcome, have been reported (Stevens-Johnson syndrome and other skin conditions such as exfoliative dermatitis, toxic epidermal necrolysis/Lyell syndrome). The greatest risk for such reactions appears to be at the start (during the first month) of treatment. **Stop taking Dologast-Denk and consult a doctor immediately at the first signs of skin rash, mucosal lesions or other signs of a hypersensitivity reaction.**

Talk to your doctor before taking Dologast-Denk, if you have ever had a skin reaction after treatment with a medicine similar to Dologast-Denk that reduces stomach acid.

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalized exanthematous pustulosis (AGEP) have been reported in association with omeprazole treatment. Stop using Dologast-Denk and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with Dologast-Denk. Remember to also mention any other ill-effects like pain in your joints.

Liver

If you suffer from liver disease Dologast-Denk should be used with caution, as your condition could become worse.

As with other NSAIDs, including diclofenac, values of one or more liver enzymes may increase.

If you take diclofenac for a prolonged period or repeatedly, your liver function should be monitored regularly. If abnormal liver function tests persist or worsen, if clinical signs or symptoms consistent with liver disease develop, or if other manifestations occur (e.g. eosinophilia, rash), diclofenac should be discontinued immediately. Hepatitis may occur without warning symptoms.

If you suffer from hepatic porphyria, using diclofenac may trigger an attack. In that case stop taking Dologast-Denk immediately.

Kidney

As fluid retention and oedema have been reported in association with NSAID therapy, including diclofenac, special care is needed if you suffer from impaired cardiac or kidney function, if you have/had hypertension, if you are elderly, or if you are taking water pills (diuretics) or other medicines that significantly impact the kidney function.

During prolonged treatment with diclofenac

monitoring of kidney function and of the blood picture is recommended.

If you take Dologast-Denk before surgical procedures, you must consult and inform the doctor or dentist.

If you take Dologast-Denk on a long-term basis (longer than one year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Tell your doctor before taking Dologast-Denk if you are due to have a specific blood test (Chromogranin A).

Taking a proton pump inhibitor like Dologast-Denk, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Please inform your doctor, if you have an HIV-1 or hepatitis B infection and therefore you have to take antiviral medicines with the active substance tenofovir. The co-administration of high dose or multiple NSAIDs (e.g. diclofenac sodium) with tenofovir disoproxil fumarate may lead to acute renal failure in patients with risk factors for renal dysfunction.

As a general principle, the habitual use of pain-killers, especially in combination with other pain-relieving active substances, can lead to lasting kidney damage with the risk of kidney failure (analgesic nephropathy).

Other medicines and Dologast-Denk

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Dologast-Denk can affect the way some medicines work and some medicines can have an effect on Dologast-Denk.

Do not take Dologast-Denk if you are taking a medicine containing nelfinavir (used to treat HIV infection).

Respiratory and allergic disorders

Special precaution (readiness for emergency) is needed if you have allergies to other substances (e.g. with skin reactions, itching or hives), asthma, hay fever, swelling of the nasal mucosa (i.e. nasal

polyps), chronic obstructive pulmonary disorders or chronic infections of the respiratory tract (especially if linked to allergic rhinitis-like symptoms) since you are at increased risk for allergic reactions on NSAIDs. The symptoms can be asthmatic attacks (so-called analgesics-asthma), swelling of the skin and mucous membranes (Quincke's oedema) or hives (urticaria).

Other information

Dologast-Denk should only be used after the benefit/risk ratio has been carefully weighed for patients with

- certain congenital blood-forming disorders (e.g. acute intermittent porphyria).
- certain autoimmune diseases (systemic lupus erythematosus and mixed connective tissue disease).

Careful monitoring by the doctor is necessary

- directly after major surgical procedures.
- if you have a coagulation disorder. Diclofenac can temporarily inhibit blood platelet aggregation.
- Blood coagulation should be monitored as a precaution.

During prolonged treatment with diclofenac monitoring of kidney function and of the blood picture is recommended.

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Children and adolescents

Dologast-Denk is not recommended for use in children and adolescents, due to lack of data on safety and efficacy.

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Driving and using machines

These capsules can cause some people to feel dizzy or giddy, drowsy or sleepy, tired or have

problems with their vision. If you are affected, do NOT drive or operate machinery. This effect is increased in conjunction with alcohol.

Dologast-Denk contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially "sodium-free".

3. How to take Dologast-Denk

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one capsule of Dologast-Denk 75/20 mg daily. If your symptoms are not controlled by a once daily dosing, please talk to your doctor. Never take more than one capsule of Dologast-Denk 75/20 mg per day as this could increase the risk of side effects.

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary. Your doctor will decide the duration of treatment. Dologast-Denk is intended for oral use. The capsules must be swallowed whole with a drink of water (about half a glass). Do not chew or break open Dologast-Denk. The capsules are best taken with food.

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