

Ibuprofen Denk 600

Film-coated tablet – oral use

Non-steroidal anti-inflammatory drug

Active substance: ibuprofen

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 Ibuprofen Denk 600 is and what it is used for

2. What you need to know before you take Ibuprofen Denk 600

3. How to take Ibuprofen Denk 600

4. Possible side effects

5. How to store Ibuprofen Denk 600

6. Contents of the pack and other information

1. What Ibuprofen Denk 600 is and what it is used for

Ibuprofen Denk 600 is an anti-inflammatory and analgesic drug (non-steroidal anti-inflammatory drug/anti-rheumatic drug “NSAID”). It is indicated for symptomatic treatment of pain and inflammation in case of:

- acute arthritis (including gout)
- chronic arthritis, especially rheumatoid arthritis (chronic polyarthritits)
- spondylitis ankylosans (Morbus Bechterew) and other inflammatory ailments of the spine
- irritations in case of degenerative joint and spinal ailments (arthrosis and spondylarthrosis)
- soft tissue rheumatism
- painful swelling and inflammation after injury

2. What you need to know before you take Ibuprofen Denk 600

Do not take Ibuprofen Denk 600

- if you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6);
- if you have a history of bronchospasm, asthma attacks, rhinitis, skin reactions or sudden swelling related to treatment with acetylsalicylic acid or other non-steroidal anti-inflammatory agents;
- in case of unexplained impaired haemopoiesis;
- in case of active or previous history of recurrent gastric or duodenal ulceration (peptic ulcers) or bleeding (2 or more different episodes of proven ulceration or bleeding);
- in case of previous history of gastrointestinal bleeding or perforation related to treatment with non-steroidal anti-rheumatic agents/anti-inflammatory drugs (NSAID);
- in case of brain haemorrhage (cerebrovascular bleeding) or other active haemorrhaging;
- in case of severe liver or renal impairment;

- in case of severe heart failure;
- in case of severe dehydration (e.g. caused by vomiting, diarrhoea or insufficient fluid intake);
- during the third trimester of pregnancy;
- in children and adolescents under 15 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ibuprofen Denk 600. Adverse drug reactions may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

Gastrointestinal safety

Concurrent treatment with Ibuprofen Denk 600 and other non-steroidal anti-inflammatory drugs, including so-called COX-2 inhibitors (cyclooxygenase-2 inhibitors) should be avoided.

Elderly patients:

The elderly have an increased frequency of adverse drug reactions in response to non-steroidal anti-inflammatory drugs, particularly gastrointestinal bleeding and perforation, which may be fatal. Close medical supervision is required in elderly patients.

Gastrointestinal bleeding, ulceration and perforation: Gastrointestinal bleeding, ulceration and perforation, which can be fatal, have been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of serious gastrointestinal events.

The risk of gastrointestinal bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation (see section 2. Do not take Ibuprofen Denk 600) as well as in the elderly. These patients should be consulted about the lowest available dose.

For these patients as well as those requiring concomitant therapy with low-dose acetylsalicylic acid (ASA) or other medications that could increase the risk of gastrointestinal disorders, combination therapy with a drug such as misoprostol or a proton pump inhibitor should be considered to help protect the stomach lining.

If you have a history of gastrointestinal adverse reactions, particularly when elderly, you should report all unusual abdominal symptoms (especially gastrointestinal bleeding) particularly in the initial stages of treatment.

Caution is advised in patients receiving concomitant treatment with medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors that are used in the treatment of depression among other things or antiplatelet agents such as acetylsalicylic acid (ASA) (see section 2. Other medicines and Ibuprofen Denk 600). The treatment should be discontinued if you suffer any gastrointestinal bleeding or ulceration while taking Ibuprofen Denk 600.

Caution should be exercised when giving NSAIDs to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn’s disease) as these conditions may be exacerbated (see section 4).

Cardiovascular effects

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

You should discuss your treatment with your doctor or pharmacist before taking Ibuprofen Denk 600 if you:

- have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including “mini-stroke” or transient ischaemic attack “TIA”).
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Skin reactions:

There have been very rare reports, some of which were fatal, of serious skin reactions while taking Ibuprofen Denk 600, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis/Lyell syndrome related to the use of NSAIDs (see section 4). Patients appear to be at highest risk for these reactions early in the course of therapy, as the reactions occurred during the first month of treatment in the majority of cases. Ibuprofen Denk 600 should be discontinued

at the first appearance of skin rash, mucosal lesions or any other signs of hypersensitivity, and a doctor should be consulted immediately.

The administration of ibuprofen should be avoided during chicken-pox (varicella infection).

Other information

Ibuprofen Denk 600 should only be used in the following cases after careful consideration of the potential benefits and risks:

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

Close medical supervision is required in the following cases:

- impaired renal or liver function;
- dehydration;
- right after major surgery;
- allergies (e.g. skin reactions in response to other medications, asthma, hay fever), chronic rhinitis or chronic respiratory disease associated with airway restriction.

Severe acute hypersensitivity reactions (anaphylactic shock for example) have been observed in very rare cases. Treatment with Ibuprofen Denk 600 must be discontinued immediately at the first signs of a hypersensitivity reaction. A clinician must carry out the required symptomatic medical treatment.

Ibuprofen, the active ingredient of Ibuprofen Denk 600, may reversibly inhibit platelet function (thrombotic aggregation). Patients with coagulation defects should therefore be monitored carefully. Regular monitoring of liver and renal function as well as blood count is required during long-term treatment with Ibuprofen Denk 600.

Your doctor or dentist should be questioned and/or informed if you are taking Ibuprofen Denk 600 prior to undergoing surgery. Prolonged use of painkillers may cause headaches which must not be treated with increased doses of the medication. Consult your doctor for advice if you suffer from frequent headaches despite taking Ibuprofen Denk 600.

More generally, regular use of painkillers, particularly in combination with several analgesics, may lead to permanent kidney damage associated with the risk of renal failure (analgesic nephropathy).

NSAIDs can mask the symptoms of infection or fever.

Children and adolescents

There is a risk of renal impairment in dehydrated children and adolescents. The use of Ibuprofen Denk 600 is not recommended in children and adolescents under the age of 15 years, because of the high concentration of active ingredient. However, there are suitable dosage strengths and/or pharmaceutical forms available for this age group (see section 2. Do not take Ibuprofen Denk 600).

Other medicines and Ibuprofen Denk 600

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Ibuprofen Denk 600 may affect or be affected by some other medicines. For example:

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. acetylsalicylic acid, warfarin, ticlopidine),
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan),
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan),
- if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including “mini-stroke” or transient ischaemic attack “TIA”).
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Some other medicines may also affect or be affected by the treatment of Ibuprofen Denk 600. You should therefore always seek the advice of your doctor or pharmacist before you use Ibuprofen Denk 600 with other medicines.

Concurrent treatment with Ibuprofen Denk 600 and digoxin (drug to increase heart strength), phenytoin (antiepileptic drug) or lithium (drug used to treat mental and psychiatric disorders) can increase plasma levels of these drugs. Increased plasma levels is necessary.

Monitoring of digoxin and phenytoin plasma levels is recommended. Ibuprofen may diminish the effect of diuretics and anti-hypertensive medications. Ibuprofen may diminish the effect of ACE inhibitors (medication used to treat weak heart and high blood pressure). Concomitant use may further increase the risk of renal impairment.

Concurrent treatment with ibuprofen and potassium-sparing diuretics (certain type of diuretic) may increase plasma potassium levels.

Concomitant use of ibuprofen and other anti-inflammatory agents or analgesics from the group of non-steroidal anti-inflammatory drugs or glucocorticoids enhance the risk of gastrointestinal ulceration or bleeding.

Antiplatelet agents and certain antidepressants (selective serotonin-reuptake inhibitors/SSRIs) may increase the risk of gastrointestinal ulceration.

The use of ibuprofen within 24 hours prior to or after the administration of methotrexate may cause increased plasma methotrexate levels as well as an increase in its adverse drug reactions.

There is an increased risk of nephrotoxicity when ciclosporin (agent used to prevent transplant rejection but also used in the treatment of rheumatism) is administered concomitantly with certain non-steroidal anti-inflammatory agents. This effect cannot be ruled out for concurrent treatment with ciclosporin and ibuprofen.

Drugs containing probenecid or sulfinpyrazone (agent used to treat gout) may delay excretion of ibuprofen. This may lead to an accumulation of ibuprofen in the body and an increase in its adverse drug reactions.

Drugs containing probenecid or sulfinpyrazone (agent used to treat gout) may delay excretion of ibuprofen. This may lead to an accumulation of ibuprofen in the body and an increase in its adverse drug reactions.

NSAIDs may enhance the effect of anticoagulants, such as warfarin. Monitoring of coagulation status is recommended during concomitant treatment.

Clinical studies have demonstrated interactions between non-steroidal anti-inflammatory agents and sulfonylureas (hypoglycaemic agent). Blood sugars should be monitored as a precautionary measure during concurrent treatment.

Regular monitoring of liver and renal function as well as blood count is required during long-term treatment with Ibuprofen Denk 600.

Your doctor or dentist should be questioned and/or informed if you are taking Ibuprofen Denk 600 prior to undergoing surgery.

Prolonged use of painkillers may cause headaches which must not be treated with increased doses of the medication. Consult your doctor for advice if you suffer from frequent headaches despite taking Ibuprofen Denk 600.

More generally, regular use of painkillers, particularly in combination with several analgesics, may lead to permanent kidney damage associated with the risk of renal failure (analgesic nephropathy).

NSAIDs can mask the symptoms of infection or fever.

Children and adolescents

There is a risk of renal impairment in dehydrated children and adolescents under the age of 15 years, because of the high concentration of active ingredient. However, there are suitable dosage strengths and/or pharmaceutical forms available for this age group (see section 2. Do not take Ibuprofen Denk 600).

Other medicines and Ibuprofen Denk 600

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Ibuprofen Denk 600 may affect or be affected by some other medicines. For example: medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. acetylsalicylic acid, warfarin, ticlopidine), medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan), medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan), if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including “mini-stroke” or transient ischaemic attack “TIA”).

have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Some other medicines may also affect or be affected by the treatment of Ibuprofen Denk 600. You should therefore always seek the advice of your doctor or pharmacist before you use Ibuprofen Denk 600 with other medicines.

Driving and using machines

When using ibuprofen at higher doses, central nervous system disorders, such as tiredness or dizziness may occur. In individual cases, reactivity and the ability to drive and operate machinery may be affected. This applies in particular in combination with alcohol. You are then unable to react promptly and adequately to unexpected or sudden events. Do not drive in that case. Do not use tools or operate machines. Do not work without a safe support.

3. How to take Ibuprofen Denk 600

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

The recommended dose is:

The dosage of ibuprofen administered depends upon body weight and age.

The recommended dose range for adults and adolescents over the age of 15 is between 1200 mg and 2400 mg of ibuprofen per day. The maximum single dose for adults should not exceed 800 mg of ibuprofen.

Age	Single dose: Number of Ibuprofen Denk 600 film-coated tablets	Total daily dose: Number of Ibuprofen Denk 600 film-coated tablets
Adolescents 15 years and older and adults	½-1 (corresponds to 300 mg–600 mg ibuprofen)	2–4 (corresponds to 1200 mg–2400 mg ibuprofen)

The film-coated tablet can be divided into equal doses.

Long-term treatment with Ibuprofen Denk 600 may be required for patients with rheumatic disease. The attending doctor will decide how long the treatment should take.

Side effects can be minimised if the lowest effective dose required to control symptoms is used for the shortest possible time.

Type of administration

Swallow Ibuprofen Denk 600 whole with ample fluids and make sure not to take them on an empty stomach. If you have a sensitive stomach it is advisable to take Ibuprofen Denk 600 with meals.

If you take more Ibuprofen Denk 600 than you should

Always use Ibuprofen Denk 600 exactly as instructed by your doctor or according to the dosage instructions given in the package leaflet. If you feel that the dose does not relieve your pain adequately, do not increase the dose yourself but talk to your doctor.

If you have taken more Ibuprofen Denk 600 than you should, or if you have taken this medicine after an accident always contact a doctor or nearest hospital to get an opinion of the risk and advise on action to be taken.

The symptoms can include nausea, stomach pain, vomiting (may be blood-streaked), headache, ringing in the ears, confusion and shakiness (may be blood-streaked). Furthermore, bleeding in the gastrointestinal tract may occur.

At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, impaired liver and kidney function, decreased breathing (respiratory depression), fall in blood pressure, purple discoloration of the skin and mucous membranes (cyanosis), cold body feeling, and breathing problems have been reported.

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.

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.

Pregnancy

If you discover you are pregnant when taking Ibuprofen Denk 600 you should inform your doctor. Ibuprofen should only be used during the first and second trimesters of pregnancy with the approval of your doctor. Ibuprofen Denk 600 is contraindicated during the final trimester of pregnancy due to the increased risk of complications for mother and child.

Breast-feeding

The active ingredient ibuprofen and its breakdown products are excreted in very low concentrations in breast milk. As it is not known to affect breast-fed infants adversely, weaning is not generally necessary for short-term use. However, if prescribed for a longer period of time and/or at higher doses, early weaning should be considered.

Fertility

Ibuprofen may make it more difficult for you to become pregnant. You should inform your doctor if you are planning to become pregnant or if you are experiencing difficulties getting pregnant.

Not known: frequency cannot be estimated from the available data

Possible side effects

Please note that the following side effects are mostly dose-dependent and may differ between individuals.

The most common adverse drug reactions affect the digestive tract. Gastric/duodenal ulcers (peptic ulcers), perforation or bleeding, mucosal ulcers or Crohn’s disease.

Common: Gastric/duodenal ulceration (peptic ulcers), sometimes with bleeding and perforation, ulcerative stomatitis, exacerbation of ulcerative colitis or Crohn’s disease.

Uncommon: Gastritis

Very rare: Inflammation of the oesophagus (oesophagitis) and the pancreas (pancreatitis).

If you experience severe upper abdominal pain, vomiting of blood, blood in stool and/or black discolouration of the stool, you must stop taking Ibuprofen Denk 600 immediately and inform your doctor.

Very rare: Formation of membrane-like stenoses in the small and large intestine (intestinal diaphragm-like strictures).

Hepatobiliary disorders

Very rare: Liver impairment, liver damage, particularly during long-term therapy, liver failure, acute inflammation of the liver (hepatitis).

The liver parameters should be monitored regularly during long-term treatment.

Skin and subcutaneous tissue disorders

Very rare: Serious skin reactions, such as rash with redness and blistering (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis/Lyell syndrome), hair loss (alopecia).

Not known: A severe skin reaction known as DRESS syndrome can occur.

Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).

In exceptional cases, severe skin infections and soft tissue complications may occur during chicken-pox (varicella infection).

Renal and urinary disorders

Uncommon: Increased fluid retention in the tissues with development of oedema, particularly in patients suffering from high blood pressure or impaired renal function; nephrotic syndrome (oedema and severe proteinuria); inflammatory renal disease (interstitial nephritis) that may be associated with acute renal impairment.

Very rare: Renal tissue damage (papillary necrosis), hyperuricaemia. Reduced urinary output, fluid retention in the body (oedema) as well as general malaise may signal kidney disease that can lead to kidney failure.

If the symptoms mentioned occur or get worse, stop taking Ibuprofen Denk 600 and contact your doctor immediately.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ibuprofen Denk 600

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister strip after “Exp”. The expiry date refers to the last day of that month.

Shelf life: 36 months.

Store below 30 °C.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

Pharmacodynamic properties

Pharmacotherapeutic group: Non-steroidal anti-inflammatory drug; propionic acid derivative;

ATC Code: M01AE01

Ibuprofen

Ibuprofen is a non-steroidal anti-inflammatory drug/anti-rheumatic agent that has demonstrated its efficacy by inhibition of prostaglandin synthesis in the usual animal studies on inflammation. In humans ibuprofen reduces inflammatory pain, swellings and fever. Furthermore, ibuprofen reversibly inhibits ADP and collagen-induced platelet aggregation.

Very rare: Tinnitus, loss of hearing.

Cardiovascular system

Very rare: Palpitations, oedema, heart failure, heart attack.

Vascular disorders

Very rare: High blood pressure (arterial hypertension).

Pharmacokinetic properties

When taking orally, ibuprofen is absorbed partly in the stomach and then completely in the small intestine. Following hepatic metabolism (hydroxylation, carboxylation), the pharmacologically ineffective metabolites are eliminated completely, primarily via the kidneys (90 %), but also in bile. The elimination half-life is 1.8–3.5 hours in healthy subjects as well as those with liver or renal impairment while plasma protein binding is about 99 %.

Maximum plasma levels are reached 1–2 hours after oral ingestion of normal release ibuprofen tablets.

What Ibuprofen Denk 600 contains

The active substance is ibuprofen.

Each film-coated tablet contains 600 mg ibuprofen. The other ingredients are maize starch, magnesium stearate, sodium starch glycolate (type A), colloidal hydrated silica, macrogol 6000, hypromellose, talc, titanium dioxide.

General classification for supply

Medicinal product subject to medical prescription.

What Ibuprofen Denk 600 looks like and contents of the pack

Oval, white film-coated tablet with breakline on both sides.

The film-coated tablet can be divided into equal doses.

Ibuprofen Denk 600 is available in PVC/PVDC/aluminium blisters.

Pack size: 20 or 100 film-coated tablets.

Marketing Authorisation Holder and Manufacturer

DENK PHARMA GmbH & Co. KG

Prinzregentenstr. 79, 81675 München, Germany

Production site

Göllstr. 1, 84529 Timmington, Germany

This leaflet was last revised in 12/2018.

Information for Botswana

Scheduling status: S2

Registration number: BOT1703022A, BOT1703022

Date of publication: 06/2017

Not known: frequency cannot be estimated from the available data

Possible side effects

Please note that the following side effects are mostly dose-dependent and may differ between individuals.

The most common adverse drug reactions affect the digestive tract. Gastric/duodenal ulcers (peptic ulcers), perforation or bleeding, mucosal ulcers or Crohn’s disease.

Common: Gastric/duodenal ulceration (peptic ulcers), sometimes with bleeding and perforation, ulcerative stomatitis, exacerbation of ulcerative colitis or Crohn’s disease.

Uncommon: Gastritis

Very rare: Inflammation of the oesophagus (oesophagitis) and the pancreas (pancreatitis).

If you experience severe upper abdominal pain, vomiting of blood, blood in stool and/or black discolouration of the stool, you must stop taking Ibuprofen Denk 600 immediately and inform your doctor.

Very rare: Formation of membrane-like stenoses in the small and large intestine (intestinal diaphragm-like strictures).

Hepatobiliary disorders

Very rare: Liver impairment, liver damage, particularly during long-term therapy, liver failure, acute inflammation of the liver (hepatitis).

The liver parameters should be monitored regularly during long-term treatment.

Skin and subcutaneous tissue disorders

Very rare: Serious skin reactions, such as rash with redness and blistering (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis/Lyell syndrome), hair loss (alopecia).

Not known: A severe skin reaction known as DRESS syndrome can occur.

Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).

