



# Atenolol Denk 50

Film-coated tablet – oral use  
Beta-receptor blocker  
Active substance: atenolol

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

**1. What Atenolol Denk is and what it is used for**  
Atenolol is a medicine that reduces the excitability of the heart by blocking its beta receptors.

**Atenolol Denk 50 is used in:**  
Disorders of cardiovascular function, which can be manifested in a tendency to a persistently increased heart rate and temporarily increased blood pressure.  
Chest or heart pain (angina pectoris) that has been present for at least 4 weeks and that either occurs only after physical exercise or that changes, increases or is even present at rest and is associated with a rapid heart rate and high blood pressure.

Heart rhythm disorders if your doctor diagnoses you as having one of the following conditions:

**Heart rhythm disorders stemming from the atria of the heart**  
– as additional treatment if an overactive thyroid causes you to have a rapid heart rate  
– with episodic rapid heart beats stemming from the atria of the heart  
– in atrial fibrillation and atrial flutter if high-dose treatment with cardiac medicines (glycosides) is not effective for you

**Heart rhythm disorders stemming from the ventricles of the heart**  
– if heartbeats are generated in the ventricles of the heart outside the normal heart rhythm as a result of increased activity of certain nerve pathways (on physical exercise, at the beginning of anaesthesia, in conjunction with certain sedatives [halothane anaesthesia] and other medicines [exogenous sympathomimetics])  
– in the event of rapid heart rhythm disorders stemming from the ventricles of the heart and ventricular fibrillation (as a pre-

caution, particularly if the heart rhythm disorders stemming from the ventricles of the heart are caused by increased activity of certain nerve pathways)  
High blood pressure (hypertension).

**2. What you need to know before you take Atenolol Denk**  
Do not take Atenolol Denk

if you are allergic to atenolol, other beta-receptor blockers or to any of the other ingredients of this medicine (listed in section 6),  
if you have heart failure,  
if you have general circulatory failure,  
if you have moderate to major disorders of the stimulus conduction pathway from the atria to the ventricles of the heart,  
if you have a condition of the sinus node (centre for stimulus generation in the atrium of the heart),  
if you have disorders of the stimulus conduction pathway between the sinus node and the atrium,  
if you have a resting pulse rate of less than 50 beats per minute before the beginning of treatment,  
if you have a markedly reduced blood pressure (upper measurement value less than 90 mmHg),  
if you have overacidification of the blood,  
if you have a tendency to bronchial spasm, e.g. in bronchial asthma,  
if you have late stages of circulatory disorders in your arms or legs,  
if you are also taking certain MAO inhibitors (medicines for depression). This excludes MAOB inhibitors (medicines for Parkinson's disease).

Tell your doctor that you are taking Atenolol Denk. If you are taking Atenolol Denk, you should not be given certain intravenous medicines for heart rhythm disorders (such as disopyramide or calcium antagonists of the verapamil or diltiazem type).

**Warnings and precautions**  
Talk to your doctor or pharmacist before taking Atenolol Denk.  
Special care is required when taking Atenolol Denk,  
if you have minor disorders of the stimulus conduction pathway from the atria to the ventricles of the heart,  
if you have diabetes (diabetes mellitus) and your blood sugar values fluctuate widely. If you develop conditions with markedly reduced blood sugar levels, the rapid heart beat is no longer noticed as a warning.  
if you have undergone a strict fast or undertaken heavy physical work for a prolonged period, since you can then develop conditions with severely reduced blood sugar levels,  
if you have a tumour of the adrenal medulla, as this should be treated beforehand with appropriate medicines,  
if you have impaired kidney function (see also section 3. "How to take Atenolol Denk"),  
if you or yourself or members of your family have or have had psoriasis,  
if you have Prinzmetal's angina (chest or heart pain due to reduced circulation in the heart muscle) since the frequency and degree of chest or heart pain may increase,  
if you have already had severe hypersensitivity reaction (allergy) or have been treated for existing hypersensitivity because an increase in hypersensitivity is possible,  
if you have mild circulatory disorders in the arms or legs, as these may be exacerbated.

Medicines of the same class of substances of Atenolol Denk may mask the signs of an overactive thyroid.  
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If your heart rate falls too much, your doctor may reduce the dosage.  
If you suffer from reduced circulation in the heart muscle, you should not abruptly discontinue medicines of the group of substances of Atenolol Denk.  
If your breathing becomes difficult because of an increase in airway resistance, you should stop taking Atenolol Denk and have your doctor administer treatment to widen the airways. Observe your skin and mucous membranes for the appearance of pinpoint bleeding and let your doctor know if this happens.

**Paediatric population**  
This medicine is not intended for use in children as there is no experience in the treatment of children with Atenolol Denk.  
**Elderly patients**  
Your doctor may reduce the dosage, particularly if you have disorders of kidney function.  
**Effects following misuse for doping purposes**  
The use of Atenolol Denk may return positive results in antidoping tests.

## Other medicines and Atenolol Denk

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.  
The effect of the substances or groups of products mentioned below may be affected during simultaneous treatment with Atenolol Denk:

- **Blood sugar-lowering medicines to be taken by mouth, insulin:** atenolol may increase their blood sugar-lowering effect. Warning signs of low blood sugar levels, particularly a rapid heart rate and trembling, are masked or attenuated. Have your blood sugar levels checked regularly.
- **Medicines for relaxing the muscles during surgery (e.g., suxamethonium halogenide, tubocurarine):** exacerbation and prolongation of the muscle relaxant effect. If you are due to undergo surgery, tell the anaesthetist that you are taking Atenolol Denk.
- **Medicines for heart failure (e.g., digitalis) and certain medicines for high blood pressure (e.g. reserpine, alpha-methyl dopa, guanfacine, clonidine):** slow heart rate, delayed stimulus conduction in the heart.  
If you are taking clonidine and Atenolol Denk at the same time and stop clonidine abruptly, your blood pressure may suddenly increase very markedly. You must continue taking clonidine for several days after you have stopped taking Atenolol Denk. You may then gradually discontinue clonidine (please ask your doctor). You must not start treatment with Atenolol Denk until several days after discontinuing clonidine.
- **Medicines for heart rhythm disorders (calcium antagonists of the verapamil or diltiazem type):** increase in cardiac depressant effect, reduction in blood pressure, slow heart rate or other heart rhythm disorders and heart failure.
- **Medicines for heart rhythm disorders (e.g., disopyramide, amiodarone):** the effect on the conduction time between the atrium and ventricle of the heart can be increased and the contraction force of the heart can be reduced.
- **Certain medicines which lower blood pressure by widening the blood vessels (calcium antagonists of the nifedipine type):** increase of the blood pressure-lowering effect. If you are suffering from undiagnosed heart failure, this may manifest itself in very rare cases.
- **Sedatives:** the reduction in blood pressure and the cardiac depressant effect may be increased. If you are due to undergo surgery, tell the anaesthetist that you are taking Atenolol Denk.
- **Medicines that increase blood pressure** are administered to you by injection in emergencies (norepinephrine, epinephrine)
- **Anti-inflammatory medicines (indomethacin, ibuprofen)**

Other possible interactions:  
Medicines for heart failure (e.g., digitalis) and certain medicines for high blood pressure (e.g. reserpine, alpha-methyl dopa, guanfacine, clonidine): slow heart rate, delayed stimulus conduction in the heart.  
If you are taking clonidine and Atenolol Denk at the same time and stop clonidine abruptly, your blood pressure may suddenly increase very markedly. You must continue taking clonidine for several days after you have stopped taking Atenolol Denk. You may then gradually discontinue clonidine (please ask your doctor). You must not start treatment with Atenolol Denk until several days after discontinuing clonidine.

**Driving and using machines**  
Treatment with this medicine requires regular medical monitoring. Different reactions in individuals may alter reactivity to such an extent that the ability to drive a vehicle, operate machinery or work without a safe support may be impaired. This applies in particular at the beginning of treatment, following an increase in dosage, following a change in brand and in combination with alcohol.

**Atenolol Denk contains lactose**  
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**Atenolol Denk contains sodium**  
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

## 3. How to take Atenolol Denk

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 Cardiovascular function disorders**  
Half a film-coated tablet once daily (25 mg atenolol per day)  
**Chest or heart pain (angina pectoris)**  
One to two film-coated tablets once daily (50–100 mg atenolol per day)

should monitor the infant's heart function. If you are taking Atenolol Denk at the time of birth or while breast-feeding, there may be an increased risk of low blood sugar levels and a reduced heart rate in your newborn. Take Atenolol Denk at the time of the due date or while breast-feeding only on the express instructions of your doctor.

**Elevated blood pressure**  
Initially: One film-coated tablet once daily (50 mg atenolol per day)  
If necessary, your doctor will increase the dose: Two film-coated tablets once daily (100 mg atenolol per day)  
**Heart rhythm disorders**  
Either one film-coated tablet once or twice daily (50–100 mg atenolol per day) or two film-coated tablets once daily (100 mg atenolol per day)  
**Patients with impaired kidney function**  
As atenolol is excreted via the kidneys, patients with impaired kidney function should reduce the dose of Atenolol Denk. Your doctor will tell you how severely your kidney function is impaired and will prescribe you an appropriate tablet strength. The recommended dose is: **Severely impaired kidney function** (creatinine clearance 10 to 30 ml/min or serum creatinine greater than 1.2 mg/dl and less than 5 mg/dl): reduction to half the dose you usually need. **Very severely impaired kidney function** (creatinine clearance less than 10 ml/min or serum creatinine greater than 5 mg/dl): reduction to one quarter of the dose you usually need.

**Method of administration**  
Please swallow the film-coated tablets whole with sufficient liquid (preferably a glass of water) before meals.  
The film-coated tablet can be divided into equal doses.  
Please talk to your doctor or pharmacist if you feel that Atenolol Denk is too strong or too weak.

**If you take more Atenolol Denk than you should**  
Depending on the degree of the overdose, you may have the following signs:  
slow heart rate even to the extent of a cardiac arrest, marked fall in blood pressure,

heart failure and shock, seizures, disorders of consciousness, breathing difficulties, airway spasm, vomiting.  
If you suspect you have taken an overdose, please consult the nearest doctor immediately.

**If you forget to take Atenolol Denk**  
Do not take a double dose to make up for a forgotten dose.  
**If you stop taking Atenolol Denk**  
Your doctor will decide how long you should be treated with Atenolol Denk. If you wish to interrupt or discontinue the treatment with Atenolol Denk after a prolonged time, do so slowly and by gradually reducing the dose. Sudden discontinuation may result in a heart attack or reduced circulation in the heart muscle with exacerbation of heart or chest pain (angina pectoris) or exacerbation of elevated blood pressure.  
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**  
Like all medicines, this medicine can cause side effects, although not everybody gets them.  
**Common (may affect up to 1 in 10 patients treated):**  
Slow heart rate  
Cold arms and legs  
Dizziness or sweating, central nervous system disorders may occur in particular at the beginning of treatment  
Tiredness  
Temporary gastrointestinal disorders (nausea, vomiting, constipation, diarrhoea)  
**Uncommon (may affect up to 1 in 100 patients treated):**  
Increased dream activity or insomnia  
Elevated liver enzymes (transaminases) in the blood

Conjunctivitis  
Muscle weakness or muscle spasm  
Undiagnosed diabetes may become manifest or existing diabetes may worsen.  
**Rare (may affect up to 1 in 1,000 patients treated):**  
Exacerbation of heart failure, stimulus conduction disorders, low blood pressure, particularly when standing up from a lying position, or fainting episode  
Exacerbation of symptoms in patients with circulatory disorders in the peripheral areas of the body (including patients with intermittent claudication) or with spasms of the finger arteries (Raynaud's syndrome)  
Hallucinations, psychiatric disorders  
Confusion, drowsiness  
Tingling or numbness  
Headache  
Depressive moods  
Nightmares  
Dry mouth  
Liver damage including congestion of bile in the liver  
Pinpoint bleeding in the skin and mucous membranes  
Allergic skin reactions (redness, itching, rash)  
Hair loss  
Induction of psoriasis, worsening symptoms of this condition or psoriasis-like rash (drug class effect)  
Disorders of sex drive and potency  
Breathlessness in patients with a tendency to airway spasms (particularly in conditions that narrow the airways), as airway resistance may be increased  
Disorders of fat metabolism may occur during treatment with Atenolol Denk. While the total blood fat level remains for the most part normal, the distribution of the individual types of blood fat may deteriorate.

Very rare (may affect up to 1 in 10,000 patients treated):  
More severe attacks in patients with heart or chest pain (angina pectoris)  
More severe allergic reactions that do not respond to the usual doses of the antidote epinephrine  
Elevation in certain laboratory tests (ANA), the significance of which has not yet been established

**Not known (cannot be estimated from the available data):**  
Lupus-like syndrome (a condition in which the immune system produces antibodies that predominantly attack the skin and joints)

**Special remarks**  
Since during treatment with other medicines of the same class of substances as Atenolol Denk a deterioration of kidney function has been observed in a very rare number of patients with severe disorders of kidney function, you should have your kidney function monitored regularly while taking Atenolol Denk.  
Since there may be severe liver damage during treatment with other medicines of the same class of substances as Atenolol Denk, you should have your liver function monitored at regular intervals during treatment with Atenolol Denk.  
Following prolonged strict fasting or heavy physical exercise, conditions with reduced blood sugar levels may occur during concomitant treatment with Atenolol Denk. Warning signs of reduced blood sugar levels, particularly a rapid heart rate and trembling, may be masked.  
Disorders of fat metabolism may occur during treatment with Atenolol Denk. While the total blood fat level remains for the most part normal, the distribution of the individual types of blood fat may deteriorate.

pending on the amount of sympathetic tone. Atenolol may increase smooth muscle tone by inhibiting beta-2 receptors.  
**Pharmacokinetic properties**  
Following oral administration about 50% of the atenolol is absorbed by the gastrointestinal tract. As atenolol does not undergo first-pass metabolism, systemic availability is also about 50%. Peak plasma levels are reached after 2–4 hours. Plasma protein binding is about 3%; the relative volume of distribution is 0.7 l/kg. Due to its low lipid solubility atenolol crosses the blood-brain barrier to only a limited extent.  
Atenolol is metabolised to a rather limited extent. No active metabolites of clinical relevance are formed.  
About 90% of systemically available atenolol is eliminated unchanged within 48 hours via the kidneys. The elimination half-life of atenolol in patients with normal renal function is 6–10 hours. In patients with end-stage renal disease the elimination half-life may slow to 140 hours.

**What Atenolol Denk contains**  
The active substance is atenolol. Each film-coated tablet contains 50 mg atenolol.  
The other ingredients are microcrystalline cellulose, lactose monohydrate, polyvidone K29/32, talc, croscarmellose sodium, magnesium stearate (vegetable), maize starch, pregelatinised starch (maize), hydro-mellose, titanium dioxide, macrogol 6000.

**General classification for supply**  
Medicinal product subject to medical prescription

**What Atenolol Denk 50 looks like and contents of the pack**  
Atenolol Denk 50 are white, oblong film-coated tablets with both-sided score, without imprint.

Atenolol Denk 50 is available in aluminium/aluminium blisters.  
Pack size: 100 film-coated tablets

**Marketing Authorisation Holder**  
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Specifications - Denk Pharma

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