



Losar-Denk 50

Film-coated tablet – oral use
Angiotensin II receptor antagonist
Active substance: losartan

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 Losar-Denk 50 is and what it is used for**
2. **What you need to know before you take Losar-Denk 50**
3. **How to take Losar-Denk 50**
4. **Possible side effects**
5. **How to store Losar-Denk 50**
6. **Contents of the pack and other information**

1. What Losar-Denk 50 is and what it is used for

Losartan belongs to a class of drugs known as angiotensin II receptor antagonists. The substance angiotensin II is formed in your body and helps to regulate your blood pressure. It binds to receptors in the blood vessels making them narrower. This causes your blood pressure to rise. When blood pressure is high, angiotensin II plays a part in maintaining the elevated blood pressure. Losartan prevents angiotensin II from binding to these receptors so that the blood vessels can relax and your blood pressure drops.

Losartan slows down renal impairment in patients with high blood pressure and type-2 diabetes.

Losar-Denk 50 is used

- in the treatment of patients with high blood pressure (hypertension) in adults and in children and adolescents 6- 18 years of age.
- to protect the kidneys of patients with high blood pressure and type-2 diabetes mellitus along with impaired kidney function proven by blood tests, with a urinary protein excretion of ≥ 0.5 g/day (this disease is associated with pathologically high amounts of urinary protein).

- an ACE-inhibitor (e.g., enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
- aliskiren.
Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals. See also section "Do not take Losar-Denk 50".

- if you are taking other medications that may increase serum potassium (see section "Other medicines and Losar-Denk 50").

2. What you need to know before you take Losar-Denk 50

Losartan has been studied in children. Talk to your doctor about whether, and at which dose, your child can be treated with losartan.

Losartan is not recommended for use in children suffering from kidney or liver problems, as limited data are available in these patient groups. Losartan is not recommended for use in children under 6 years old, as it has not been shown to work in this age group.

Other medicines and Losar-Denk 50

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

Tell your doctor if you are taking potassium supplements, potassium-containing salt substitutes, potassium-sparing medicines such as certain diuretics (amiloride, triamterene, spironolactone), or other medicines that may increase serum potassium (e.g., heparin, trimethoprim-containing medicines), as the combination with Losar-Denk 50 is not advisable.

You should be particularly careful when taking any of the following medicines at the same time as Losar-Denk 50:

- Other medicines to treat high blood pressure, as they may cause your blood pressure to drop even further. Your blood pressure may also be reduced by one of the following medicines/classes of drugs: medicines for depression (tricyclic antidepressants), medicines for certain psychiatric conditions (antipsychotic agents), muscle-relaxing medicines (baclofen), cancer treatment medicines (amifostin).
- Anti-inflammatory drugs or painkillers (non-steroidal anti-rheumatic drugs), such as indomethacin, including COX-2 inhibitors, as they may reduce the antihypertensive effect of losartan.
- If you suffer from liver impairment (see section "Do not take Losar-Denk 50" and section 3).
- If you suffer from heart failure with or without renal impairment or concomitant severe life threatening cardiac arrhythmias. Special caution is necessary when you are treated with a beta blocker concomitantly.
- If you suffer from a heart valve or heart muscle disorder.
- If you suffer from coronary artery disease (caused by insufficient blood flow to the blood vessels of the heart) or cerebral artery disease (caused by insufficient blood flow to the brain).
- If you suffer from primary hyperaldosteronism (a disease associated with increased secretion of the hormone aldosterone by the adrenal gland).
- If you are taking any of the following medicines used to treat high blood pressure:

Losar-Denk 50 with food and drink

Losar-Denk 50 can be taken with or without food.

Pregnancy and breast-feeding

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

You must tell your doctor, if you think you are (or might become) pregnant. Usually, your doctor will discontinue treatment with Losar-Denk 50 before you become pregnant or as soon as you discover you are pregnant and will continue treatment with another medicine. Losar-Denk 50 is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or wish to breast-feed. Losar-Denk 50 is not recommended for breast-feeding mothers and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is a new-born, or born prematurely.

Driving and using machines

No studies have been conducted on the effects on the ability to drive and operate machinery.

It is unlikely that Losar-Denk 50 would affect the ability to drive or operate machinery. However, losartan, like other antihypertensive agents, may cause dizziness or fatigue in some persons. Should you suffer from dizziness or fatigue, ask your doctor for advice before pursuing such activities.

Losar-Denk 50 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.

3. How to take Losar-Denk 50

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

Your doctor will decide on the appropriate dose for you depending on your condition and whether you are still taking other medicines. It is important to continue taking Losar-Denk 50 for as long as your doctor prescribes it in order to ensure unimpeded control of your blood pressure.

The usual dose is:

Adult patients with high blood pressure
The usual initial dose is 1 film-coated tablet of Losar-Denk 50 (equivalent to 50 mg losartan potassium) once a day. The maximum antihypertensive effect is achieved 3 to 6 weeks after treatment is initiated.

In some patients this dose may later be increased to 2 film-coated tablets of Losar-Denk 50 (equivalent to 100 mg losartan potassium) once a day.

Please talk to your doctor if you have the impression that the effect of Losar-Denk 50 is too strong or too weak.

Use in children and adolescents

Children below 6 years of age

Losartan is not recommended for use in children under 6 years old, as it has not been shown to work in this age group.

Children and adolescents aged 6- 18 years old

The recommended starting dose in patients who weigh between 20 and 50 kg is 0.7 mg of losartan potassium per kg of body weight administered once a day (up to 25 mg of losartan potassium). The doctor may increase the dose if blood pressure is not controlled.

Other forms of this medicine may be more suitable for children; ask your doctor or pharmacist.

Patients with high blood pressure and type-2 diabetes mellitus

The usual initial dose is 1 film-coated tablet of Losar-Denk 50 (equivalent to 50 mg losartan potassium) once a day. The dose may later be increased to 2 film-coated tablets of Losar-Denk 50 (equivalent to 100 mg losartan potassium) once a day depending on your blood pressure response.

Losartan may be taken with other antihypertensive drugs, such as diuretics, calcium antagonists, alpha or beta blockers as well as central antihypertensive agents and also with insulin and other commonly used antidiabetic agents, such as sulfonylureas, glitazones and glucosidase inhibitors.

Adult patients with heart failure

The usual initial dose is 12.5 mg of losartan potassium once a day. In general, the dose should be increased gradually on a weekly basis (i.e. 12.5 mg daily during the first week, 25 mg daily during the second week, 50 mg daily during the third week, 100 mg daily during the fourth week, 150 mg daily during the fifth week) up to the maintenance dose as determined by your physician.

A maximum dose of 150 mg losartan potassium once daily may be used.
For treatment of heart failure, losartan is usually administered with a diuretic (water pill to increase the amount of urine excreted via the kidneys) and/or digitalis (drug to strengthen the heart) and/or a beta blocker.

Dosage in special patient groups

The doctor may advise a lower dose, particularly at the beginning of treatment, in patients receiving high doses of diuretics, in those with impaired liver function or in patients older than 75 years. The use of losartan is not recommended in patients with severe liver impairment (see section "Do not take Losar-Denk 50").

Method of administration

The film-coated tablets should be swallowed with a glass of water.

Try to take Losar-Denk 50 at the same time every day. It is important to continue taking Losar-Denk 50 until instructed otherwise by your doctor.

If you take more Losar-Denk 50 than you should

If you have accidentally taken too many tablets, inform your doctor immediately. Symptoms of an overdose are low blood pressure and/or a too rapid or possibly too slow heart rate.

If you forget to take Losar-Denk 50

If you have accidentally forgotten to take your daily dose, please take the next dose as prescribed. Do not take a double dose to make up for a forgotten tablet.

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.

If you experience the following symptoms, stop taking Losar-Denk 50 and inform your doctor immediately or go to the accident and emergency department of your nearest hospital:

A severe allergic reaction that may cause rash, itching, swelling of the face, lips, mouth or throat that may be associated with difficulty swallowing or labored breathing.

This is a serious but rare adverse drug reaction that affects more than 1 out of 10,000 but less than 1 out of 1,000 patients. You may require urgent medical attention or hospitalization.

The following adverse drug reactions have been reported in association with losartan:

Common (may affect up to 1 in 10 people):

- dizziness,
- low blood pressure (especially after excessive loss of water from the body, e.g. in patients with severe heart failure or under treatment with high dose diuretics),
- dose-related orthostatic effects such as lowering of blood pressure appearing when rising from a lying or sitting position,
- debility,
- fatigue,
- too little sugar in the blood (hypoglycemia),
- too much potassium in the blood (hyperkalemia),
- changes in kidney function including kidney failure,
- reduced number of red blood cells (anemia),
- increase in blood urea, serum creatinine and serum potassium in patients with heart failure.

Uncommon (may affect up to 1 in 100 people):

- somnolence,
- headache,
- sleep disorders,
- palpitations or rapid heartbeat,
- severe chest pain (angina pectoris),
- shortness of breath (dyspnea),
- abdominal pain,
- constipation,
- diarrhea,
- nausea,
- hives (urticaria),
- itching (pruritus),
- rash,
- localized swelling (edema),
- cough.

Rare (may affect up to 1 in 1,000 people):

- hypersensitivity,
- severe allergic reaction characterized by a rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty breathing or swallowing (angioedema),
- inflammation of the vessels (vasculitis, including Henoch-Schoenlein purpura),
- numbness or tingling sensation (paresthesia),
- fainting (syncope),
- very rapid and irregular heartbeat (e.g. atrial fibrillation),
- stroke,
- inflammation of the liver (hepatitis),
- elevated blood alanine aminotransferase levels (ALT; blood test to check liver function), usually resolved upon discontinuation of treatment.

Very rare (may affect up to 1 in 10,000 people):

- severe allergic reaction that may cause rash, itching, swelling of the face, lips, mouth or throat that may be associated with difficulty swallowing or labored breathing.

This is a serious but rare adverse drug reaction that affects more than 1 out of 10,000 but less than 1 out of 1,000 patients. You may require urgent medical attention or hospitalization.

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- stroke,
- inflammation of the liver (hepatitis),
- elevated blood alanine aminotransferase levels (ALT; blood test to check liver function), usually resolved upon discontinuation of treatment.



Not known (frequency cannot be estimated from the available data):

- reduction in the number of platelets (thrombocytopenia),
- migraine,
- liver function abnormalities,
- muscle and joint pain,
- flu-like symptoms,
- back pain and urinary tract infections,
- increased sensitivity to the sun, possibly with reddening after exposure to the sun (photosensitivity),
- unexplained muscle pain with dark (tea-colored) urine (rhabdomyolysis),
- impotence,
- inflammation of the pancreas (pancreatitis),
- low levels of sodium in the blood (hyponatremia),
- depression,
- generally feeling unwell (malaise),
- ringing, buzzing, roaring, or clicking in the ears (tinnitus),
- disturbed taste (dysgeusia).

Side effects in children are similar to those seen in adults.

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 Losar-Denk 50

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: 3 years

Store below 30 °C.

Store in the original package in order to protect from light. 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: Angiotensin II receptor antagonist
ATC Code: C09CA01

Losartan is a synthetically produced oral angiotensin II receptor (AT1 type) antagonist. Angiotensin II, a potent vasoconstrictor, is the primary active hormone of the renin-angiotensin system and an important determinant of the pathophysiology of hypertension. Angiotensin II binds to the AT1 receptor present in many tissues (i.e. smooth vascular muscle, adrenal gland, kidneys and heart) and elicits important biological effects, such as vasoconstriction and the release of aldosterone for example. Angiotensin II also stimulates smooth muscle cell proliferation. Losartan selectively blocks the AT1 receptor. Losartan and its pharmacologically active carboxylic acid metabolite E-3174 block all physiologically relevant effects of angiotensin II *in vitro* and *in vivo*, regardless of its source or route of its synthesis.

Pharmacokinetic properties

Following oral administration, losartan is well absorbed and undergoes first-pass metabolism. One active carboxylic acid metabolite and further inactive metabolites are formed. The systemic bioavailability of losartan film-coated tablets is approx. 33 %. Mean peak plasma concentrations of losartan and its active metabolite are reached in one hour and in 3 – 4 hours, respectively.

Losartan and its active metabolite are ≥ 99 % bound to plasma proteins, primarily albumin. The volume of distribution of losartan is 34 litres.

About 14 % of intravenous or oral losartan is converted to its active metabolite. Following oral and intravenous administration of ¹⁴C-labelled losartan, plasma radioactivity is primarily attributable to losartan and its active metabolite. Minimal conversion of losartan to its active metabolite was seen in about one percent of subjects studied. In addition to the active metabolite, inactive metabolites are formed.

Plasma clearance of losartan and its active metabolite is about 600 ml/min and 50 ml/min, respectively, with renal clearance of about 74 ml/min (losartan) and 26 ml/min (active metabolite). When losartan is administered orally, about 4 % of the dose is excreted unchanged in urine and about 6 % is excreted in urine as active metabolite. The pharmacokinetics of losartan and the active metabolite are linear at oral doses of up to 200 mg losartan potassium a day.

Following oral administration, the plasma concentrations of losartan and its active metabolite are polyexponential with a terminal half-life of about 2 hours and 6 – 9 hours, respectively. Neither losartan nor its active metabolite accumulate significantly in plasma when 100 mg doses are administered once a day.

Losartan and its metabolites are excreted in bile and urine. Following oral/intravenous administration of ¹⁴C-labelled losartan to humans, about 35 %/43 % of the radioactivity is eliminated in urine and 58 %/50 % in faeces.

What Losar-Denk 50 contains

The active substance is losartan potassium. Each film-coated tablet contains 50 mg losartan potassium, equivalent to 45.8 mg losartan.

The other ingredients are lactose monohydrate, microcrystalline cellulose, pre-gelatinised starch, magnesium stearate (vegetable), hydroxypropyl cellulose, hypromellose, titan dioxide.

General classification for supply

Medicinal product subject to medical prescription.

What Losar-Denk 50 looks like and contents of the pack

Losar-Denk 50 are white to off-white, round, biconvex film-coated tablets with a break-line on one side, plain on the other side, without facet. The film-coated tablets can be divided into equal parts.

Losar-Denk 50 is available in *Al/PVC/PE/PVdC* opaque white blister packs.

Pack size: 28 film-coated tablets.

Marketing Authorization Holder and Manufacturer

DENK PHARMA GmbH & Co. KG
Prinzregentenstr. 79
81675 München
Germany

Production site

DENK PHARMA GmbH & Co. KG
Göllstr. 1
84529 Tittmoning
Germany

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Information for Botswana

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Losar-Denk 50

Comprimé pelliculé – voie orale
Antagoniste des récepteurs de l'angiotensine II
Substance active : losartan

Notice : information du patient

Veuillez lire attentivement cette notice avant de prendre ce médicament car elle contient des informations importantes pour vous.

- Gardez cette notice. Vous pourriez avoir besoin de la relire.
- Si vous avez d'autres questions, interrogez votre médecin ou votre pharmacien.
- Ce médicament vous a été personnellement prescrit. Ne le donnez pas à d'autres personnes. Il pourrait leur être nocif, même si les signes de leur maladie sont identiques aux vôtres.
- Si vous ressentez un quelconque effet indésirable, parlez-en à votre médecin ou votre pharmacien. Ceci s'applique aussi à tout effet indésirable qui ne serait pas mentionné dans cette notice. Voir rubrique 4.

Que contient cette notice :

1. **Qu'est-ce que Losar-Denk 50 et dans quel cas est-il utilisé**
2. **Quelles sont les informations à connaître avant de prendre Losar-Denk 50**
3. **Comment prendre Losar-Denk 50**
4. **Quels sont les effets indésirables éventuels**
5. **Comment conserver Losar-Denk 50**
6. **Contenu de l'emballage et autres informations**

1. Qu'est-ce que Losar-Denk 50 et dans quel cas est-il utilisé

Le losartan appartient à un groupe de médicaments appelés antagonistes des récepteurs de l'angiotensine II. L'angiotensine II est une substance produite par votre organisme qui contribue à la régulation de la pression artérielle. Elle se lie aux récepteurs de la paroi des vaisseaux sanguins, entraînant leur contraction. Cela induit une augmentation de la pression artérielle. En cas d'hypertension, l'angiotensine II contribue à maintenir une pression artérielle élevée. Le losartan empêche la liaison de l'angiotensine II à ces récepteurs, entraînant la dilatation des vaisseaux sanguins et une diminution de la pression artérielle.

Le losartan ralentit la dégradation de la fonction rénale chez les patients ayant une pression artérielle élevée et un diabète de type 2.

Losar-Denk 50 est utilisé

- pour traiter l'hypertension (pression artérielle élevée) chez les adultes et chez les enfants et adolescents âgés de 6 à 18 ans.
- pour préserver la fonction rénale des patients hypertendus diabétiques ou d'une maladie rénale présentant une excrétion urinaire de protéines $\geq 0,5$ g/jour confirmée par des examens du

sang (cette maladie est associée à des taux pathologiquement élevés de protéines dans les urines).

- pour traiter les patients insuffisants cardiaques lorsque le médecin juge qu'un traitement par les IEC (inhibiteurs de l'enzyme de conversion de l'angiotensine, qui sont des médicaments anti-hypertenseurs) ne convient pas. Si votre insuffisance cardiaque a été stabilisée par un IEC, le traitement ne doit pas être modifié pour passer sous losartan.
- chez les patients présentant une hypertension et un épaississement de la paroi du ventricule gauche. Losar-Denk 50 réduit le risque d'accident vasculaire cérébral.

2. Quelles sont les informations à connaître avant de prendre Losar-Denk 50

Ne prenez jamais Losar-Denk 50

- si vous êtes allergique au losartan ou à l'un des autres composants contenus dans ce médicament (mentionnés dans la rubrique 6),
- si vous êtes enceinte de plus de 3 mois (il est également préférable d'éviter de prendre du losartan en début de grossesse – voir la rubrique « Grossesse et allaitement »),
- si votre fonction hépatique est gravement dégradée,
- si vous avez du diabète ou une insuffisance rénale et que vous êtes traité(e) par un médicament contenant de l'aliskirène pour diminuer votre pression artérielle.

Avertissements et précautions

Adressez-vous à votre médecin ou pharmacien avant de prendre Losar-Denk 50.

Informez votre médecin si vous pensez être enceinte (ou **pourriez débuter une grossesse**). Losar-Denk 50 n'est pas recommandé en début de grossesse, et ne doit pas être utilisé si vous êtes enceinte de plus de 3 mois car il pourrait être très dangereux pour votre bébé (voir la rubrique « Grossesse et allaitement »).
Il est important de prévenir votre médecin avant de prendre Losar-Denk 50

- si vous avez des antécédents d'angio-œdème (réaction d'hypersensibilité se manifestant par un gonflement du visage, des lèvres, de la gorge et/ou de la langue) (voir également rubrique 4),
- si vous avez des vomissements importants ou des diarrhées entraînant une perte très importante de liquides et/ou de sels de votre organisme,
- si vous prenez des diurétiques (médicaments qui augmentent la quantité d'urines éliminées par l'intermédiaire de vos reins) ou si vous faites un régime sans sel pouvant conduire à une perte importante de liquide et de sel de votre organisme (voir rubrique 3),
- si vous présentez un rétrécissement ou un blocage des vaisseaux sanguins qui mènent à vos reins (sténose des artères rénales) ou si vous avez récemment reçu une transplantation rénale,
- si votre fonction hépatique est dégradée (voir la rubrique « Ne prenez jamais Losar-Denk 50 » et la rubrique 3),
- si vous souffrez d'insuffisance cardiaque avec ou sans insuffisance rénale ou d'arythmie cardiaque sévère concomitante engageant le pronostic vital. Une prudence particulière est nécessaire si vous êtes traité(e) simultanément par des bêtabloquants.
- si vous avez un problème au niveau des valves cardiaques ou du muscle cardiaque,
- si vous souffrez d'une maladie des artères coronaires (causée par une réduction de la circulation sanguine dans les vaisseaux cardiaques) ou d'une maladie présentant une excrétion urinaire de protéines $\geq 0,5$ g/jour confirmée par des examens du

- si vous avez un hyperaldostéronisme primaire (un syndrome associé à une augmentation de la sécrétion de l'hormone aldostérone par les glandes surrénales),
- si vous prenez l'un des médicaments suivants pour traiter une hypertension :

- un inhibiteur de l'enzyme de conversion (IEC) (énalapril, lisinopril, ramipril, par exemple), en particulier si vous avez des problèmes rénaux dus à un diabète.
- aliskirène

Votre médecin pourra être amené à surveiller régulièrement le fonctionnement de vos reins, votre pression artérielle et le taux des électrolytes (par ex. du potassium) dans votre sang. Voir aussi la rubrique « Ne prenez jamais Losar-Denk 50 ».

- si vous prenez d'autres médicaments susceptibles d'augmenter le taux de potassium dans votre sang (voir la rubrique « Autres médicaments et Losar-Denk 50 »).

Enfants et adolescents

Le losartan a été étudié chez l'enfant. Adressez-vous à votre médecin pour savoir si votre enfant peut recevoir un traitement par losartan et à quelle dose.</

