



Simva-Denk 40

Film-coated tablet – oral use
HMG-CoA reductase inhibitor
Active substance: simvastatin

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.

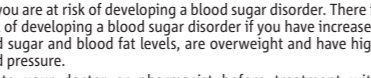
- What is in this leaflet**
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 2. What you need to know before you take Simva-Denk 40
 3. How to take Simva-Denk 40
 4. Possible side effects
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1. What Simva-Denk 40 is and what it is used for
 Simva-Denk 40 is a medicine used to lower high cholesterol levels. Simva-Denk 40 contains the active substance simvastatin. Simvastatin lowers total cholesterol, the levels of "bad" LDL cholesterol and other fats known as triglycerides in the blood. Simvastatin also increases the levels of "good" HDL cholesterol. Simvastatin belongs to the class of medicines known as "statins", which block the body's production of cholesterol in the liver.

Simva-Denk 40 is used in addition to a low cholesterol diet if you

- have increased blood cholesterol levels (*primary hypercholesterolaemia*) or increased fat levels in the blood (*mixed hyperlipidaemia*).
- have a hereditary disease (*homozygous familial hypercholesterolaemia*) that leads to increased cholesterol levels in the blood. You may be given other treatments.
- have a cardiovascular disease (*CHD - coronary heart disease*) or a high risk of cardiovascular disease (because you have diabetes, have already had a stroke or have any other vascular disease). Simva-Denk 40 can prolong life by lowering the risk of cardiovascular complications, regardless of the amount of cholesterol levels in your blood.

In most cases, you will feel no immediate effect of high cholesterol levels. Your doctor can measure cholesterol levels with a simple blood test. Visit your doctor regularly, keep track of your cholesterol levels and discuss treatment goals with your doctor.



or if you are at risk of developing a blood sugar disorder. There is a risk of developing a blood sugar disorder if you have increased blood sugar and blood fat levels, are overweight and have high blood pressure.

Talk to your doctor or pharmacist before treatment with Simva-Denk 40 if you have serious breathing problems.

If you notice any unexplained muscle pain, sensitivity or weakness of the muscles, please contact your doctor immediately. This is necessary because, in rare cases, muscle disorders can be serious, leading to a breakdown in skeletal muscle cells followed by kidney failure; very rarely, such cases have even been fatal.

There is an increased risk of a breakdown in skeletal muscle cells with increasing doses of simvastatin, particularly with the 80 mg dosage. This increased risk is also present in patients:

- who drink large amounts of alcohol
- with kidney dysfunction
- with thyroid disorders
- from 65 years of age
- who are female
- who have already had a muscle disorder during treatment with cholesterol-lowering medicines known as statins, or while taking fibrates
- with a hereditary muscle disorder or a family history of hereditary muscle disorder.

Please talk to your doctor if you one or more of the above disorders or conditions applies to you.

Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

Children and adolescents
 The safety and efficacy of simvastatin have been studied in 10- to 17-year old boys, as well as in girls whose first monthly period (*menstruation*) occurred at least 1 year before (see section 3). Simvastatin has not been studied in children under 10 years of age. For more information, please ask your doctor.

Other medicines and Simva-Denk 40
 Please tell your doctor if you are taking or using, have recently taken or used or might take or use one or more of the following medicines, as taking Simva-Denk 40 with these medicines may increase the risk of muscle disorders (some of these medicines have already been listed above under *Do not take Simva-Denk 40* without any risks. Taking Simva-Denk 40 together with fusidic acid may increase the risk of muscle weakness, sensitivity or pain (possible signs of a breakdown of muscle cells [*rhabdomyolysis*]). See more information regarding *rhabdomyolysis* in section 4.

Warnings and precautions
 Talk to your doctor or pharmacist before taking Simva-Denk 40. Tell your doctor:

- about all your health problems and allergies.
- if you drink large amounts of alcohol.
- if you have a history of liver disease. Simva-Denk 40 may not be suitable for you.
- if you are due to have surgery, as it may be necessary to stop treatment with Simva-Denk 40 for a short while.
- if you are of Asian origin, because another dose might be suitable for you.

Your doctor should examine your blood levels before the start of treatment, as well as while you are taking Simva-Denk 40, in order to check your liver function if you have any signs of liver problems. Your doctor may also measure your blood levels during treatment, in order to continue to monitor your liver function.

During treatment with Simva-Denk 40, your doctor will monitor you closely if you have a blood sugar disorder (*diabetes mellitus*)

• Medicines used to treat AIDS (immune deficiency) belonging to the class of active substances known as HIV protease inhibitors, with active substances such as indinavir, nelfinavir, ritonavir and saquinavir

• Antiviral medicines used to treat viral hepatitis C infections with the active substances boceprevir, telaprevir, elbasvir or grazoprevir

• Medicines used to treat depression with the active substance nefazodone

• Medicines with the active substance cobicistat

• Medicines used to treat heart rhythm disorders with the active substance amiodarone

• Medicines used to treat high blood pressure, chest pain associated with heart disease or other heart conditions with the active substances verapamil, diltiazem or amlodipine

• Medicines for the treatment of a severe and rare hereditary cholesterol metabolism disorder with the active substance lomitapide

• Medicines used to treat complicated skin and skin structure infections and bacteraemia with the active substance dapto-cymycin. It is possible that side effects affecting the muscles may be higher when this medicine is taken during treatment with simvastatin. Your doctor may decide that you stop taking Simva-Denk 40 for a while.

• Medicines used to treat gout with the active substance colchicine.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines not mentioned on the list, including medicines obtained without a prescription.

In particular, please tell your doctor if you are taking or using one or more of the following medicines:

- medicines used to prevent blood clotting (*anticoagulants*) with active substances such as warfarin, phenprocoumon or acenocoumarol
- another cholesterol-lowering medicine from the fibrate group with the active substance fenofibrate
- another cholesterol-lowering medicine with the active substance niacin
- medicines used to treat tuberculosis with the active substance rifampicin

Also, if you are prescribed a new medicine, tell your treating doctors that you are taking Simva-Denk 40.

Simva-Denk 40 with food and drink
 Grapefruit juice contains one or more components that alter the metabolism of some medicines including Simva-Denk 40. You should avoid drinking grapefruit juice.

Pregnancy and breast-feeding
Pregnancy
 You must not take Simva-Denk 40 if you are pregnant, think you may be pregnant or are planning to have a baby. If you become pregnant during treatment with Simva-Denk 40, stop treatment immediately and tell your doctor.

Breast-feeding
 You must not take Simva-Denk 40 if you are breast-feeding, as it is not known whether this medicine is excreted in human milk. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
 Simva-Denk 40 is not expected to affect the ability to drive or use machines. However, it should be remembered that some people

feel dizzy after taking simvastatin, in which case you should not drive or use machines until you feel better.

Simva-Denk 40 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.

Simva-Denk 40 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 Simva-Denk 40
 Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

During treatment with Simva-Denk 40, you should follow a suitable low cholesterol diet.

Dosage
 The recommended dose is 5 mg simvastatin, 10 mg simvastatin, 20 mg simvastatin, 40 mg simvastatin or 80 mg simvastatin to be taken once daily.

Adults
 The usual dose at the start of treatment is either 10 mg simvastatin per day or 20 mg simvastatin per day or, in some cases, even 40 mg simvastatin per day. After a minimum of 4 weeks, your doctor may increase the dose up to a maximum dose of 80 mg simvastatin per day.

Do not take more than 80 mg simvastatin per day.
 Your doctor may also prescribe lower dosages, especially if you are taking certain medicines from the list above (see section 2) or if you suffer from specific kidney disorders.

The dose of 80 mg simvastatin is recommended only for adult patients with very high cholesterol levels and at high risk of complications associated with heart disease who have not reached their target cholesterol levels at a lower dose.

Children and adolescents
 The usual recommended dose for children (10-17 years) at the start of treatment is 10 mg simvastatin per day as a single dose in the evening. The maximum recommended dose is 40 mg simvastatin per day.

Method of use
 Take the film-coated tablet with a glass of water in the evening (as the body's cholesterol production in the liver takes place mainly at night).

It can be taken with or without food. The film-coated tablet can be divided into equal doses.

Take Simva-Denk 40 for as long as your doctor prescribes it. If your doctor has prescribed you Simva-Denk 40 to be taken with another cholesterol-lowering agent containing the active substance cholestyramine or with other medicines containing anion exchangers, take Simva-Denk 40 at least 2 hours before or at least 4 hours after the anion exchanger.

If you take more Simva-Denk 40 than you should
 Consult a doctor or pharmacist.

If you forget to take Simva-Denk 40
 Do not take a double dose to make up for a forgotten dose, but continue treatment on the next day at the usual time with the prescribed dose.

If you stop taking Simva-Denk 40
 Talk with your doctor or pharmacist about what to do next, as your cholesterol levels may rise again.

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.

The following rare serious side effects were reported:
 If any of the following serious side effects occur, stop taking this medicine and contact a doctor immediately or go to the emergency department of your nearest hospital.

- Muscle disorder with pain, sensitivity, weakness, muscle rupture (very rare) or muscle cramps. Muscle disorders can be serious in rare cases, which can lead to a breakdown in skeletal muscle cells followed by kidney failure; very rarely, such cases have even been fatal.
- Hypersensitivity (*allergic*) reactions with:
 - swelling of the face, tongue and throat, which may cause problems in breathing or swallowing (*angioedema*)
 - severe muscle pain, usually in the shoulders and pelvic region
 - rash with weakness of limbs and neck muscles
 - joint pain or inflammation (*polymyalgia rheumatica*)
 - inflammation of the blood vessels (*vasculitis*)
 - unusual bruises, rashes and swelling of the skin (*dermatomyositis*), skin rash with itchy wheals (hives), skin sensitivity to light, fever, hot flashes
 - shortness of breath (*dyspnoea*) and malaise
 - syndrome with rash, joint disorders and changes in blood count (lupus-like syndrome)

• hepatitis or jaundice with the following symptoms: yellowing of the skin and eyes, itching, dark urine or pale stools, feeling tired or weak, loss of appetite, liver failure (very rare)

• inflammation of the pancreas, often associated with severe abdominal pain

The following very rare serious side effects were reported:

• A serious allergic reaction which causes difficulty in breathing or dizziness (*anaphylaxis*)

• Rash that may occur on the skin or sores in the mouth (lichenoid drug eruptions)

The following side effects have also been reported:
Rare (may affect up to 1 in 1,000 patients treated)

- Low red blood cell count (*anaemia*)
- Numbness or weakness in the arms and legs
- Headache, abnormal skin sensations, dizziness
- Digestive disorders (abdominal pain, constipation, flatulence, indigestion, diarrhoea, nausea, vomiting)
- Rash, itching, hair loss
- Weakness
- Memory loss, confusion
- Blurred vision and impaired vision

Very rare (may affect up to 1 in 10,000 patients treated)

- Gynecomastia (breast enlargement in men)
- Insomnia
- Memory impairment

Not known (cannot be estimated from the available data)

- Erectile dysfunction
- Depression

• Inflammation of the lungs causing breathing problems, including prolonged coughing and/or shortness of breath or fever

• Tendon disorders and even tendon rupture in some cases

Possible side effects that have been reported with some statins (medicines of the same type):

- Sleep disorders, including nightmares
- Sexual difficulties
- Blood sugar disorder (*diabetes mellitus*): The risk of developing a blood sugar disorder is greater if you have increased blood sugar and blood fat levels, are overweight and have high blood pressure. Your doctor will monitor you during treatment with Simva-Denk 40.
- Muscle pain, muscle sensitivity (e.g. tenderness) or persisting muscle weakness, with signs of illness that do not resolve even after discontinuing the product (frequency not known).

Laboratory results
 Increases in certain liver enzyme levels and increased levels of a muscle enzyme (*creatine phosphokinase*) have been observed.

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 Simva-Denk 40
 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.

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: HMG-CoA reductase inhibitors, ATC code: C10A A01

After oral ingestion, simvastatin, which is an inactive lactone, is hydrolysed in the liver to the corresponding beta hydroxy acid, which is a potent inhibitor of 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase. This enzyme catalyses the conversion of HMG-CoA to mevalonate, an early and rate-limiting step in the biosynthesis of cholesterol.

Simvastatin reduces LDL cholesterol levels in case of both normal and elevated baseline levels. LDL is formed from VLDL and is catabolised predominantly by specific LDL receptors. The mechanism of the LDL-lowering effect of simvastatin is likely based on both reduction of VLDL cholesterol concentration and induction of LDL receptors, i.e. reduced production as well as increased catabolism of LDL cholesterol. Apolipoprotein B concentration also falls substantially during treatment with simvastatin. In addition, simvastatin moderately increases HDL cholesterol and reduces plasma triglycerides. As a result of these changes, the ratios of total cholesterol to HDL cholesterol and LDL cholesterol to HDL cholesterol are reduced.

General classification for supply
 Medicinal product subject to medical prescription.

What Simva-Denk 40 looks like and contents of the pack
 Simva-Denk 40 are light pink, oval-shaped film-coated tablets with a one-sided break-line, lateral notches and with intact coating. Simva-Denk 40 is available in PVC/PVDC/aluminium blisters.

Pack size: 30 film-coated tablets

Marketing Authorisation Holder and Manufacturer
 DENK PHARMA GmbH & Co. KG
 Prinzregentenstr. 79
 81675 München
 Germany

The pharmacokinetic properties have been evaluated in adults. Pharmacokinetic data in children and adolescents are not available.

Absorption
 In humans, simvastatin is well absorbed and undergoes extensive hepatic first-pass extraction. The extraction in the liver is dependent on the hepatic blood flow. The liver is the primary site of action of the active form. The availability of the beta hydroxy acid to the systemic circulation following an oral dose of simvastatin was found to be less than 5 % of the dose. Maximum plasma concentration of active inhibitors is reached approximately 1-2 hours after ingestion. Concomitant food intake did not affect the absorption. The pharmacokinetics of single and multiple doses of simvastatin showed that no accumulation of medicinal product occurred after multiple dosing.

Distribution
 Plasma protein binding of simvastatin and its active metabolite in humans is > 95 %.

Elimination
 Simvastatin is a substrate of CYP3A4 (see sections 4.3 and 4.5 of the summary of product characteristics). The major metabolites of simvastatin present in human plasma are the beta hydroxy acid and four additional active metabolites. Following an oral dose of radioactively marked simvastatin to volunteers, 13 % of the radioactivity was recovered in the urine and 60 % in the faeces after 96 hours.

The latter amount represents absorbed parts excreted in bile as well as unabsorbed substance. Following intravenous injection of the beta hydroxy acid metabolite, its half-life averaged approx. 1.9 hours. An average of only 0.3 % of the IV dose was excreted in urine as inhibitors. Simvastatin is taken up actively into the hepatocytes by the transporter OATP1B1. Simvastatin is a substrate of the BCRP efflux transporter.

What Simva-Denk 40 contains

• The active substance is simvastatin. Each film-coated tablet contains 40 mg simvastatin.

• The other ingredients are butylhydroxyanisole, lactose monohydrate, pregelatinised maize starch, ascorbic acid, citric acid monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate [vegetable], hydroxypropylcellulose, hypromellose, titanium dioxide, talc, iron oxide yellow, iron oxide red, iron oxide black.

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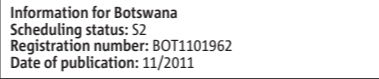
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 Prinzregentenstr. 79
 81675 München
 Germany

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

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Information for Botswana
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Simva-Denk 40

Comprimé pelliculé – voie orale
 Inhibiteur de la HMG-CoA réductase
 Substance active : simvastatine

Notice : information du patient

Veillez 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 Simva-Denk 40 et dans quel cas est-il utilisé
2. Quelles sont les informations à connaître avant de prendre Simva-Denk 40
3. Comment prendre Simva-Denk 40
4. Quels sont les effets indésirables éventuels
5. Comment conserver Simva-Denk 40
6. Contenu de l'emballage et autres informations

1. Qu'est-ce que Simva-Denk 40 et dans quel cas est-il utilisé

Simva-Denk 40 est un médicament destiné à abaisser des taux élevés de cholestérol dans le sang. Simva-Denk 40 contient la substance active simvastatine. La simvastatine réduit le cholestérol total, les taux sanguins de

cholestérol LDL (« mauvais » cholestérol) et d'autres lipides appelés triglycérides. De plus, la simvastatine augmente les taux de cholestérol HDL (« bon » cholestérol). La simvastatine est un médicament qui fait partie de la classe des « statines » qui inhibent la production par l'organisme de cholestérol dans le foie.

Vous devez poursuivre votre régime alimentaire hypocholestérolémiant (destiné à réduire le cholestérol) pendant le traitement.

Simva-Denk 40 est utilisé en plus d'une alimentation hypocholestérolémiante si vous avez

- des taux élevés de cholestérol sanguin (*hypercholestérolémie primaire*) ou des taux élevés de graisse dans le sang (*hyperlipidémie mixte*) ;
- une maladie héréditaire (*hypercholestérolémie familiale homozygote*) qui augmente le taux de cholestérol dans le sang. Vous pouvez également recevoir d'autres traitements ;
- une maladie cardiovasculaire (*MC – maladie coronarienne*) ou un risque élevé de maladie cardiovasculaire (parce que vous avez un diabète, un antécédent d'accident vasculaire cérébral ou une autre maladie vasculaire). Simva-Denk 40 peut prolonger votre vie en réduisant le risque de complications cardiovasculaires indépendamment de la quantité de votre cholestérol sanguin.

Chez la plupart des gens, il n'y a pas de symptômes immédiats dus à un taux élevé de cholestérol. Votre médecin peut mesurer votre cholestérol à l'aide d'un simple test sanguin. Consultez votre médecin régulièrement, vérifiez votre cholestérol et discutez avec votre médecin des résultats à atteindre.

2. Quelles sont les informations à connaître avant de prendre Simva-Denk 40

Ne prenez jamais Simva-Denk 40

- si vous êtes allergique à la simvastatine ou à l'un des autres composants contenus dans ce médicament (mentionnés dans la rubrique 6).
- si vous souffrez actuellement d'une maladie du foie.
- si vous êtes enceinte ou allaitez.
- si vous prenez un ou plusieurs des médicaments suivants en même temps que Simva-Denk 40 :
 - médicaments pour le traitement de mycoses contenant les substances actives itraconazole, kétoconazole, posaconazole ou voriconazole
 - antibiotiques pour le traitement des infections contenant les substances actives érythromycine, clarithromycine ou tétrahydrozine

– médicaments pour le traitement du déficit immunitaire associé au SIDA de la classe des inhibiteurs de la protéase du VIH avec des substances actives telles que indinavir, nelfinavir, ritonavir et saquinavir

– médicaments pour le traitement des infections dues au virus de l'hépatite C contenant les substances actives bocéprévir ou télaprevir

– médicaments pour le traitement de la dépression contenant la substance active néfazodone

– médicaments contenant la substance active cobicistat

– médicaments pour réduire le taux de cholestérol contenant la substance active gemfibrozil

– médicaments pour réduire l'activité du système immunitaire (*immunosuppresseurs*) contenant la substance active ciclosporine, qui sont souvent utilisés après des greffes d'organes (transplantations d'organes)

– médicaments pour le traitement du développement de la muqueuse utérine en dehors de l'utérus (*endométriose*) avec la substance active danazol (une hormone de synthèse)

• si vous prenez des médicaments avec la substance active acide fusidique (utilisé pour traiter les infections bactériennes), ou si vous avez pris ou reçu des injections avec ce type de médicament au cours des 7 derniers jours. L'association de médicaments avec la substance active acide fusidique et de la simvastatine peut entraîner des problèmes musculaires sévères (destruction des cellules musculaires [*rhabdomyolyse*]).

Ne dépassez pas la dose de 40 mg de simvastatine si vous prenez le médicament avec la substance active lomitapide (pour le traitement d'un trouble héréditaire rare et sévère lié au métabolisme du cholestérol).

Si vous n'êtes pas sûr que l'un de vos médicaments fasse partie de cette liste, demandez à votre médecin.

Avertissements et précautions
 Adressez-vous à votre médecin ou pharmacien avant de prendre Simva-Denk 40.

Informez votre médecin :

- de tous vos problèmes de santé et des allergies.
- si vous consommez de grandes quantités d'alcool.
- si vous avez des antécédents de maladie hépatique. Il se peut que Simva-Denk 40 ne soit pas indiqué dans votre cas.
- si vous devez être opéré, car il pourrait s'avérer nécessaire d'interrompre brièvement la prise de Simva-Denk 40.
- si vous êtes d'origine asiatique, parce qu'un autre dosage pourrait mieux vous convenir.

Dans la mesure où vous présentez des signes de problèmes hépatiques, votre médecin devra examiner votre sang avant le début du traitement, mais également pendant que vous prenez Simva-Denk 40, et ce afin de contrôler votre fonction hépatique. Votre médecin pourra éventuellement vous prescrire des tests sanguins pendant le traitement pour continuer à surveiller votre fonction hépatique.

Vous devez surveiller étroitement pendant le traitement par Simva-Denk 40 si vous souffrez de diabète ou si vous risquez de développer un diabète. Le risque de développer un diabète existe si vous avez des antécédents de diabète ou si vous êtes en surpoids et si vous souffrez d'hypertension artérielle.

Avant de commencer le traitement par Simva-Denk 40, veuillez parler avec votre médecin ou votre pharmacien si vous souffrez de problèmes respiratoires graves.

Si vous présentez des douleurs, une sensibilité ou une faiblesse musculaires inexplicables, consultez immédiatement votre médecin. Ceci est nécessaire car, dans de rares cas, ces troubles musculaires peuvent être graves, allant jusqu'à la destruction des tissus musculaires qui peut entraîner une

• Médicaments pour le traitement d'un trouble héréditaire rare et sévère lié au métabolisme du cholestérol, et contenant la substance active lomitapide

• Médicaments contenant la substance active daptomycine, utilisés pour le traitement des infections compliquées de la peau et des structures cutanées ainsi que la bactériémie. Il est possible que les effets indésirables affectant les muscles soient plus importants lorsque ce médicament est utilisé pendant un traitement par la simvastatine. Votre médecin pourra décider que vous devez arrêter de prendre Simva-Denk 40 pendant un moment.

• Médicaments pour le traitement de la goutte contenant la substance active colchicine.

Outre les médicaments mentionnés ci-dessus, dites à votre médecin ou à votre pharmacien si vous prenez ou avez récemment pris d'autres médicaments, y compris ceux obtenus sans ordonnance. Veuillez en particulier informer votre médecin si vous prenez ou utilisez un ou plusieurs des médicaments suivants :

• médicaments pour inhiber la coagulation sanguine contenant les substances actives telles que warfarine, phenprocoumone ou acénocoumarol (*anticoagulants*)

• un autre médicament pour réduire le taux de cholestérol du groupe des fibrates contenant la substance active fenofibrate

• un autre médicament pour réduire le taux de cholestérol contenant la substance active niacine

• médicaments pour le traitement de la tuberculose contenant la substance active rifampicine.

Lors de la prescription d'un nouveau médicament, prévenez également vos médecins traitants que vous prenez Simva-Denk 40.

Simva-Denk 40 avec des aliments et boissons

Le jus de pamplemousse contient un ou plusieurs composants qui modifient la métabolisation de certains médicaments, dont Simva-Denk 40. Vous devez par conséquent éviter de consommer du jus de pamplemousse.

Grossesse et allaitement

Grossesse

Vous ne devez pas prendre Simva-Denk 40 si vous êtes enceinte, si vous pensez être enceinte ou planifiez une grossesse. Si vous tombez enceinte pendant le traitement par Simva-Denk 40, arrêtez immédiatement le traitement et informez-en votre médecin. **Allaitement**

Vous ne devez pas prendre Simva-Denk 40 si vous allaitez, car on ne sait pas si le médicament passe dans le lait maternel.

Demandez à votre médecin ou à votre pharmacien avant de prendre tout médicament.

Conduite de véhicules et utilisation de machines

Simva-Denk 40 ne devrait pas influencer l'aptitude à conduire des véhicules ou à utiliser des machines. Il faut cependant tenir compte du fait que certaines personnes ont des vertiges après la prise de simvastatine. Dans ce cas, vous ne devriez reconduire un véhicule ou utiliser une machine que quand vous vous sentez à nouveau mieux.

Simva-Denk 40 contient du lactose

Si votre médecin vous a informé(e) d'une intolérance à certains sucres, contactez-le avant de prendre ce médicament.

Simva-Denk 40 contient du sodium

Ce médicament contient moins de 1 mmol (23 mg) de sodium par comprimé pelliculé, c.-à-d. qu'il est essentiellement « sans sodium ».

3. Comment prendre Simva-Denk 40

Veuillez à toujours prendre ce médicament en suivant exactement les indications de votre médecin. Vérifiez auprès de votre médecin ou pharmacien en cas de doute.

Pendant le traitement par Simva-Denk 40, vous devez suivre un régime hypocholestérolémiant approprié.

Posologie
La dose recommandée est de 5 mg de simvastatine, 10 mg de simvastatine, 20 mg de simvastatine, 40 mg de simvastatine ou 80 mg de simvastatine à prendre une fois par jour.

• Trouble musculaire avec douleurs, sensibilité, faiblesse, rupture musculaire (très rare) ou crampes musculaires. Les troubles musculaires peuvent être graves dans de rares cas, ce qui peut entraîner une dégradation des cellules du muscle squelettique, puis une insuffisance rénale ; très rarement, de tels cas ont même été fatals.

La dose habituelle en début de traitement est soit de 10 mg de simvastatine par jour, soit de 20 mg de simvastatine par jour, voire dans certains cas aussi de 40 mg de simvastatine par jour. Après un intervalle d'au moins 4 semaines, votre médecin peut augmenter la dose jusqu'à la dose maximale de 80 mg de simvastatine par jour.

Ne prenez pas plus de 80 mg de simvastatine par jour.

Votre médecin peut aussi vous prescrire des doses plus faibles, en particulier si vous prenez certains médicaments figurant sur la liste ci-dessus (voir rubrique 2) ou si vous souffrez de troubles rénaux spécifiques.

La dose de 80 mg de simvastatine n'est recommandée que chez les patients adultes présentant des taux de cholestérol très élevés et un risque élevé de complications liées à une maladie cardiaque, et qui n'ont pas atteint leur taux de cholestérol cible à une dose inférieure.

• Inflammation des vaisseaux sanguins (*vasculite*)
• ecchymoses inhabituelles, éruptions cutanées et gonflement de la peau (*dermatomyosite*), éruptions cutanées accompagnées de papules avec des démangeaisons (*urticaire*), sensibilité de la peau à la lumière, fièvre, bouffées de chaleur

• essoufflement (*dyspnée*) et malaise

– syndrome avec éruption cutanée, troubles articulaires et modification de la numération globulaire (syndrome de type lupus).

• Hépatite ou jaunisse avec les symptômes suivants : jaunissement de la peau et des yeux, démangeaisons, urines foncées ou selles pâles, sensation de fatigue ou de faiblesse, perte d'appétit, insuffisance hépatique (très rare).

Il peut être pris indépendamment des repas. Le comprimé pelliculé peut être divisé en doses égales.

Vous devez prendre Simva-Denk 40 pendant la durée prescrite par votre médecin.

Les effets indésirables graves suivants ont été rapportés dans de très rares cas :

• Réaction allergique grave pouvant entraîner des difficultés respiratoires ou des vertiges (*anaphylaxie*)

• Éruption cutanée ou plaies de la bouche (éruptions lichénoides induites par le médicament)

Les effets indésirables suivants ont également été rapportés :

Rare (peut affecter jusqu'à 1 patient sur 1 000 traités)

• Faible nombre de globules rouges (*anémie*)

• Engourdissement ou faiblesse dans les bras et les jambes

• Maux de tête, sensations cutanées anormales, vertiges

• Troubles digestifs (douleur abdominale, constipation, flatulence, indigestion, diarrhée, nausée, vomissement)

• Éruption cutanée, démangeaisons, perte de cheveux

• Faiblesse

• Perte de mémoire, confusion

• Vision floue et troubles visuels

Très rare (peut affecter jusqu'à 1 patient sur 10 000 traités)

• Gynécomastie (hypertrophie mammaire chez les hommes)

• Insomnie

• Atteinte de la mémoire

Fréquence indéterminée (ne peut être estimée sur la base des données disponibles)

• Dysfonctionnement érectile

• Dépression

• Inflammation des poumons causant des problèmes respiratoires, notamment une toux prolongée et/ou un essoufflement ou de la fièvre

• Troubles des tendons et même rupture des tendons dans certains cas

Effets indésirables éventuels ayant été rapportés avec certaines statines (médicaments du même type) :

• Troubles du sommeil, y compris cauchemars

• Difficultés sexuelles

• Trouble de la glycémie (*diabète sucré*) :

Le risque de développer un trouble de la régulation du taux de sucre dans le sang est plus grand si vous présentez des taux élevés de sucre et de graisse dans le sang, si vous êtes en surpoids et si vous faites de l'hypertension. Votre médecin vous suivra pendant le traitement par Simva-Denk 40.

• Douleur musculaire, sensibilité musculaire (sensibilité au toucher, par exemple) ou faiblesse musculaire persistante, accompagnée de signes de maladie qui ne disparaissent pas, même après l'arrêt du médicament (fréquence indéterminée).

Résultats des analyses de laboratoire

Des augmentations de certains tests de la fonction hépatique et d'une enzyme musculaire (*créatine kinase*) ont été observées.

Déclaration des effets secondaires

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. En signalant les effets indésirables, vous contribuez à fournir davantage d'informations sur la sécurité du médicament.

5. Comment conserver Simva-Denk 40

Tenir ce médicament hors de la vue et de la portée des enfants.

N'utilisez pas ce médicament après la date de péremption indiquée sur la boîte et la plaquette après « Exp. ». La date de péremption fait référence au dernier jour de ce mois.

Durée de conservation : 3 ans.

À conserver à une température inférieure à 30 °C. Conserver dans l'emballage original afin d'en protéger le contenu de la lumière.

Ne jetez aucun médicament au tout-à-l'égout. Demandez à votre pharmacien d'éliminer les médicaments que vous n'utilisez plus. Ces mesures contribueront à protéger l'environnement.

6. Contenu de l'emballage et autres informations Ce que contient Simva-Denk 40

• La substance active est la simvastatine. Chaque comprimé pelliculé contient 40 mg de simvastatine.

• Les autres composants sont : hydroxyanisole butylé, lactose monohydraté, amidon de maïs préaglatinisé, acide ascorbique, acide citrique monohydraté, cellulose microcristalline, croscarmellose sodique, stéarate de magnésium végétal, hydroxypropylcellulose, hypromellose, dioxyde de titane, talc, oxyde de fer jaune, oxyde de fer rouge, oxyde de fer noir.

Conditions de délivrance

Médicament soumis à prescription médicale.

Comment se présente Simva-Denk 40 et contenu de l'emballage extérieur

Simva-Denk 40 se présente sous la forme de comprimés pelliculés rose clair, ovales avec une barre de cassure sur une face, des encoches latérales et un enrobage intact.

Simva-Denk 40 est disponible sous forme de plaquettes thermoformées en PVC/PVDC/aluminium. Présentation : 30 comprimés pelliculés

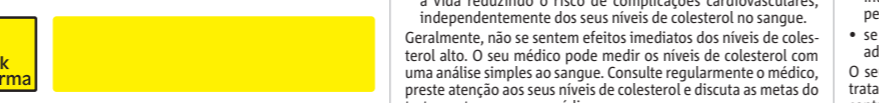
Titulaire de l'Autorisation de Mise sur le Marché et Fabricant

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

Site de production

DENK PHARMA GmbH & Co. KG
Göllstr. 1
84529 Tittmning
Allemagne

La dernière date à laquelle cette notice a été révisée est 02/2020.



Simva-Denk 40

Comprimido revestido por película – para uso oral
Inibidor da reductase da HMG-CoA
Substância ativa: simvastatina

Folheto informativo: Informação para o doente

Leia com atenção todo este folheto antes de começar a tomar este medicamento pois contém informação importante para si.

– Conserve este folheto. Pode ter necessidade de o ler novamente.

– Caso ainda tenha dúvidas, fale com o seu médico ou farmacêutico.

– Este medicamento foi receitado apenas para si. Não deve dá-lo a outros. O medicamento pode ser-lhes prejudicial mesmo que apresentem os mesmos sinais de doença.

– Se tiver quaisquer efeitos indesejáveis, incluindo possíveis efeitos indesejáveis não indicados neste folheto, fale com o seu médico ou farmacêutico. Ver secção 4.

– medicamentos para o tratamento de infeções por fungos com as substâncias ativas itraconazol, cetoconazol, posaconazol ou voriconazol

– antibióticos para tratamento de infeções com as substâncias ativas eritromicina, claritromicina ou telitromicina

– medicamentos para o tratamento da imunodeficiência SIDA da classe de fármacos inibidores da protease do VIH, com substâncias ativas como indinavir, nelfinavir, ritonavir e saquinavir

– medicamentos para o tratamento de infeções pelo vírus da hepatite C com as substâncias ativas boceprevir ou telaprevir

– medicamentos para o tratamento de depressões com a substância ativa nefazodona

– medicamentos com a substância ativa cobicistato

– medicamentos para redução do colesterol com a substância ativa gemfibrozil

– medicamentos para supressão do sistema imunitário (imunossupressores) com a substância ativa ciclosporina, usada frequentemente após transplantes de órgãos

1. O que é Simva-Denk 40 e para que é utilizado

Simva-Denk 40 é um medicamento usado para diminuir os níveis de colesterol alto.

Simva-Denk 40 contém a substância ativa simvastatina. A simvastatina diminui o colesterol total, os valores do "mau" colesterol LDL e de outras gorduras no sangue, os chamados triglicéridos. Além disso, a simvastatina aumenta os valores do "bom" colesterol HDL. A simvastatina pertence à classe dos medicamentos chamados "estatinas", que inibem a produção natural de colesterol do corpo no fígado.

Deverá continuar com uma dieta pobre em colesterol durante o tratamento.

Simva-Denk 40 é usado como complemento a uma dieta pobre em colesterol se

• tiver níveis de colesterol alto no sangue (*hipercolesterolemia primária*) ou níveis elevados de gordura no sangue (*hiperlipidemia mista*).

• tiver uma doença hereditária (*hipercolesterolemia familiar homozigótica*), que se traduz a em níveis de colesterol alto no sangue. Poderá ser submetido a outros tratamentos.

• tiver uma doença cardiovascular (*doença das artérias coronárias - DAC*) ou risco elevado de doença cardiovascular (por sofrer de diabetes, por já ter tido um acidente vascular cerebral ou sofrer de outra doença vascular). Simva-Denk 40 pode prolongar a vida reduzindo o risco de complicações cardiovasculares, independentemente dos seus níveis de colesterol no sangue.

• tiver uma doença cardiovascular (doença das artérias coronárias - DAC) ou risco elevado de doença cardiovascular (por sofrer de diabetes, por já ter tido um acidente vascular cerebral ou sofrer de outra doença vascular). Simva-Denk 40 pode prolongar a vida reduzindo o risco de complicações cardiovasculares, independentemente dos seus níveis de colesterol no sangue.

• sofrer de origem asiática, uma vez que outra dose poderá ser adequada para si.

O seu médico deve fazer análises ao sangue antes de iniciar o tratamento, mas também durante a toma de Simva-Denk 40, para controlar a sua função hepática, se apresentar indícios de problemas no fígado. O seu médico poderá determinar as contagens das suas células do sangue, mesmo durante o tratamento, para continuar a controlar a sua função hepática.

Durante o tratamento com Simva-Denk 40, será cuidadosamente monitorizado pelo seu médico, caso sofra de diabetes (*diabetes mellitus*) ou exista o risco de desenvolver esta doença. O risco de desenvolver diabetes existe se tiver níveis elevados de açúcar e gorduras no sangue, excesso de peso e pressão arterial elevada.

Se sentir dores musculares estranhas, sensibilidade ou fraqueza muscular, dirija-se imediatamente a um médico. É necessário fazê-lo, porque problemas musculares podem ser, em casos raros, graves, o que se pode traduzir na destruição das células musculoesqueléticas com a consequente insuficiência renal;

2. O que precisa de saber antes de tomar Simva-Denk 40

• se tem alergia (hipersensibilidade) à simvastatina ou a qualquer outro componente deste medicamento (indicados na secção 6).

• se sofre atualmente de uma doença hepática.

• se está grávida ou a amamentar.

• se está a tomar um ou mais dos medicamentos seguintes em simultâneo com Simva-Denk 40:

– medicamentos para o tratamento de infeções por fungos com as substâncias ativas itraconazol, cetoconazol, posaconazol ou voriconazol

– antibióticos para tratamento de infeções com as substâncias ativas eritromicina, claritromicina ou telitromicina

– medicamentos para o tratamento da imunodeficiência SIDA da classe de fármacos inibidores da protease do VIH, com substâncias ativas como indinavir, nelfinavir, ritonavir e saquinavir

– medicamentos para o tratamento de infeções pelo vírus da hepatite C com as substâncias ativas boceprevir ou telaprevir

– medicamentos para o tratamento de depressões com a substância ativa nefazodona

– medicamentos com a substância ativa cobicistato

– medicamentos para redução do colesterol com a substância ativa gemfibrozil

– medicamentos para supressão do sistema imunitário (imunossupressores) com a substância ativa ciclosporina, usada frequentemente após transplantes de órgãos

– medicamentos para o tratamento da implantação de fragmentos endometriais fora do útero (*endometriose*) com a substância ativa danazol (uma hormona sintética)

• se está a tomar medicamentos com a substância ativa ácido fusídico usado para tratar infeções bacterianas ou se, nos últimos 7 dias, tomou ou foi injetado com esses medicamentos. A combinação de medicamentos com a substância ativa ácido fusídico e simvastatina pode resultar em graves problemas musculares (destruição das células musculares (*rabdomiólise*)).

Não tome mais de 40 mg de simvastatina se estiver a tomar medicamentos com a substância ativa lomitapida (para o tratamento de uma doença hereditária do metabolismo, grave e rara, relacionada com o colesterol).

Consulte o seu médico se não tiver a certeza se algum dos medicamentos que está a tomar pertence a esta lista.

Advertências e precauções

Fale com o seu médico ou farmacêutico antes de tomar Simva-Denk 40.

Informe o seu médico:

• sobre todos os seus problemas de saúde e alergias.

• se tomar quantidades significativas de álcool.

• se tiver história clínica de doença hepática. Simva-Denk 40 pode não ser indicado para si.

• se estiver programada uma cirurgia, pois pode ser necessário interromper o tratamento com Simva-Denk 40 por um breve período.

• se for de origem asiática, uma vez que outra dose poderá ser adequada para si.

O seu médico deve fazer análises ao sangue antes de iniciar o tratamento, mas também durante a toma de Simva-Denk 40, para controlar a sua função hepática, se apresentar indícios de problemas no fígado. O seu médico poderá determinar as contagens das suas células do sangue, mesmo durante o tratamento, para continuar a controlar a sua função hepática.

Durante o tratamento com Simva-Denk 40, será cuidadosamente monitorizado pelo seu médico, caso sofra de diabetes (*diabetes mellitus*) ou exista o risco de desenvolver esta doença. O risco de desenvolver diabetes existe se tiver níveis elevados de açúcar e gorduras no sangue, excesso de peso e pressão arterial elevada.

Se sentir dores musculares estranhas, sensibilidade ou fraqueza muscular, dirija-se imediatamente a um médico. É necessário fazê-lo, porque problemas musculares podem ser, em casos raros, graves, o que se pode traduzir na destruição das células musculoesqueléticas com a consequente insuficiência renal;

2. O que precisa de saber antes de tomar Simva-Denk 40

• se tem alergia (hipersensibilidade) à simvastatina ou a qualquer outro componente deste medicamento (indicados na secção 6).

• se sofre atualmente de uma doença hepática.

• se está grávida ou a amamentar.

• se está a tomar um ou mais dos medicamentos seguintes em simultâneo com Simva-Denk 40:

– medicamentos para o tratamento de infeções por fungos com as substâncias ativas itraconazol, cetoconazol, posaconazol ou voriconazol

– antibióticos para tratamento de infeções com as substâncias ativas eritromicina, claritromicina ou telitromicina

– medicamentos para o tratamento da imunodeficiência SIDA da classe de fármacos inibidores da protease do VIH, com substâncias ativas como indinavir, nelfinavir, ritonavir e saquinavir

– medicamentos para o tratamento de infeções pelo vírus da hepatite C com as substâncias ativas boceprevir ou telaprevir

– medicamentos para o tratamento de depressões com a substância ativa nefazodona

– medicamentos com a substância ativa cobicistato

– medicamentos para tratamento de arritmias cardíacas com a substância ativa amiodarona

• Medicamentos para o tratamento da hipertensão arterial, dores no tórax associadas a doença cardíaca ou de outras cardiopatias com as substâncias ativas verapamil, diltiazem ou amlodipina

• Medicamentos para tratamento de uma doença hereditária do metabolismo, grave e rara, relacionada com o colesterol com a substância ativa lomitapida

• Medicamentos para o tratamento de infeções da pele e das estruturas da pele e de bacteriemia com a substância ativa daptomicina. É possível que os efeitos indesejáveis que afetam os músculos sejam de maior prevalência quando este medicamento é tomado durante o tratamento com simvastatina.

O seu médico poderá decidir que pare de tomar Simva-Denk 40 durante algum tempo.

• Medicamentos para o tratamento da gota com a substância ativa colchicina.

Informe o seu médico ou farmacêutico se estiver a tomar ou tiver tomado recentemente outros medicamentos não referidos, incluindo medicamentos não sujeitos a receita médica.

Informe o seu médico sobretudo se tomar ou usar um ou vários dos seguintes medicamentos:

• medicamentos para evitar a coagulação do sangue (anticoagulantes) com substâncias ativas tais como varfarina, fenprocumona ou acenocumarol

• outro medicamento para baixar o colesterol, do grupo dos fibratos, com a substância ativa fenofibrato

• outro medicamento para baixar o colesterol com a substância ativa niacina

• medicamentos para o tratamento da tuberculose com a substância ativa rifampicina.

Em caso de prescrição de um novo medicamento, informe igualmente os seus médicos assistentes de que está a tomar Simva-Denk 40.

Simva-Denk 40 com alimentos e bebidas

O sumo de toranja contém um ou mais ingredientes que modificam a metabolização de alguns medicamentos, incluindo Simva-Denk 40. Deverá, portanto, evitar o consumo de sumo de toranja.

Gravidez e amamentação

Gravidez

Não pode tomar Simva-Denk 40 se está grávida ou a amamentar, se pensa estar grávida ou planeia engravidar. Se engravidar durante o tratamento com Simva-Denk 40, interrompa-o imediatamente e comunique ao seu médico.

• Medicamentos para o tratamento de infeções por fungos com as substâncias ativas itraconazol, cetoconazol, fluconazol, posaconazol ou voriconazol

• Medicamentos para redução do colesterol com substâncias ativas da classe dos fibratos, como gemfibrozil e bezafibrato

• Medicamentos para tratamento de infeções bacterianas com as substâncias ativas eritromicina, claritromicina ou telitromicina

• Medicamentos para o tratamento da imunodeficiência SIDA da classe de fármacos inibidores da protease do VIH, com substâncias ativas como indinavir, nelfinavir, ritonavir e saquinavir

• Medicamentos antivirais para o tratamento de infeções pelo vírus da hepatite C com as substâncias ativas boceprevir, telaprevir, elbasvir ou grazoprevir

• Medicamentos para o tratamento de depressões com a substância ativa nefazodona

• Medicamentos com a substância ativa cobicistato

• Medicamentos para tratamento de arritmias cardíacas com a substância ativa amiodarona

• Medicamentos para o tratamento da hipertensão arterial, dores no tórax associadas a doença cardíaca ou de outras cardiopatias com as substâncias ativas verapamil, diltiazem ou amlodipina

• Medicamentos para tratamento de uma doença hereditária do metabolismo, grave e rara, relacionada com o colesterol com a substância ativa lomitapida