



Axaban-Denk 5 mg

Film-coated tablet – oral use
Antithrombotic agent
Active substance: apixaban

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.

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- 2. What you need to know before you take Axaban-Denk
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1. What Axaban-Denk is and what it is used for

Axaban-Denk contains the active substance apixaban and belongs to a group of medicines called anticoagulants. This medicine helps to prevent blood clots from forming by blocking Factor Xa, which is an important component of blood clotting.

- Axaban-Denk 5 mg is used in adults:
 - to prevent a blood clot from forming in the heart in patients with an irregular heart beat (atrial fibrillation) and at least one additional risk factor. Blood clots may break off and travel to the brain and lead to a stroke or to other organs and prevent normal blood flow to that organ (also known as a systemic embolism). A stroke can be life-threatening and requires immediate medical attention.
 - to treat blood clots in the veins of your legs (deep vein thrombosis) and in the blood vessels of your lungs (pulmonary embolism), and to prevent blood clots from re-occurring in the blood vessels of your legs and/or lungs.

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

- Do not take Axaban-Denk if**
 - you are allergic to apixaban or any of the other ingredients of this medicine (listed in section 6)
 - you are bleeding excessively
 - you have a disease in an organ of the body that increases the risk of serious bleeding (such as an active or a recent ulcer of your stomach or bowel, recent bleeding in your brain)
 - you have a liver disease which leads to increased risk of bleeding (hepatic coagulopathy)
 - you are taking medicines to prevent blood clotting (e.g. warfarin, rivaroxaban, dabigatran or heparin), except when changing anticoagulant treatment or while having a venous or arterial line and you get heparin through this line to keep it open.

Warnings and precautions
Talk to your doctor or pharmacist before you take this medicine if you have any of the following:
• an increased risk of bleeding, such as:
– bleeding disorders, including conditions resulting in reduced platelet activity
– very high blood pressure, not controlled by medical treatment
– you are older than 75 years
– you weigh 60 kg or less

- a severe kidney disease or if you are on dialysis
- a liver problem or a history of liver problems
Axaban-Denk will be used with caution in patients with signs of altered liver function.
- if you have a prosthetic heart valve
- if your doctor determines that your blood pressure is unstable or another treatment or surgical procedure to remove the blood clot from your lungs is planned
- if you know that you have a disease called antiphospholipid syndrome (a disorder of the immune system that causes an increased risk of blood clots), tell your doctor who will decide if the treatment may need to be changed.

If you need to have surgery or a procedure which may cause bleeding, your doctor might ask you to temporarily stop taking this medicine for a short while. If you are not sure whether a procedure may cause bleeding ask your doctor.

Children and adolescents
Apixaban is not recommended in children and adolescents under 18 years of age.

Other medicines and Axaban-Denk
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Some medicines may increase the effects of apixaban and some may decrease its effects. Your doctor will decide, if you should be treated with apixaban when taking these medicines and how closely you should be monitored.

The following medicines may increase the effects of apixaban and increase the chance for unwanted bleeding:

- some medicines for fungal infections (e.g. ketoconazole, etc.)
- some antiviral medicines for HIV/AIDS (e.g. ritonavir)
- other medicines that are used to reduce blood clotting (e.g. enoxaparin, etc.)
- anti-inflammatory or pain medicines (e.g. acetylsalicylic acid or naproxen). Especially, if you are older than 75 years and are taking acetylsalicylic acid, you may have an increased chance of bleeding.
- medicines for high blood pressure or heart problems (e.g. diltiazem)
- antidepressant medicines called selective serotonin re-uptake inhibitors or serotonin norepinephrine re-uptake inhibitors

The following medicines may reduce the ability of apixaban to help prevent blood clots from forming:
• medicines to prevent epilepsy or seizures (e.g. phenytoin, etc.)- St John's Wort (a herbal supplement used for depression)
- medicines to treat tuberculosis or other infections (e.g. rifampicin)

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.
The effects of apixaban on pregnancy and the unborn child are not known. You should not take apixaban if you are pregnant. **Contact your doctor immediately** if you become pregnant while taking apixaban.
It is not known if apixaban passes into human breast milk. Ask your doctor or pharmacist for advice before taking this medicine while breast-feeding. They will advise you to either stop breast-feeding or to stop/not start taking apixaban.

Driving and using machines
Apixaban has not been shown to impair your ability to drive or use machines.

Axaban-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.

Axaban-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 Axaban-Denk

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

Dose
Swallow the tablet with a drink of water. Axaban-Denk can be taken with or without food.

Try to take the tablets at the same times every day to have the best treatment effect.
If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take Axaban-Denk. The tablet may be crushed and mixed with water, or 5% dextrose in water, or apple juice or apple puree, immediately before you take it.

- Instructions for crushing:**
 - Crush the tablets with a pestle and mortar.
 - Transfer all the powder carefully into a suitable container then mix the powder with a little e.g. 30 ml (2 tablespoons), water or one of the other liquids mentioned above to make a mixture.
 - Swallow the mixture.
- Rinse the pestle and mortar you used for crushing the tablet and the container, with a little water or one of the other liquids (e.g. 30 ml), and swallow the rinse.
- If necessary, your doctor may also give you the crushed Axaban-Denk tablet mixed in 60 ml of water or 5% dextrose in water, through a nasogastric tube.

Take Axaban-Denk as recommended for the following:
To prevent a blood clot from forming in the heart in patients with an irregular heart beat and at least one additional risk factor
The recommended dose is one tablet of Axaban-Denk 5 mg twice a day.
The recommended dose is one tablet of Axaban-Denk 2.5 mg twice a day if:
• you have severely reduced kidney function
• two or more of the following apply to you:
– your blood test results suggest poor kidney function (value of serum creatinine is 1.5 mg/dl (133 micromole/l) or greater)
– you are 80 years old or older
– your weight is 60 kg or lower.

The recommended dose is one tablet twice a day, for example, one in the morning and one in the evening. Your doctor will decide how long you must continue treatment for.
To treat blood clots in the veins of your legs and blood clots in the blood vessels of your lungs
The recommended dose is **two tablets** of Axaban-Denk 5 mg twice a day for the first 7 days, for example, two in the morning and two in the evening.
After 7 days the recommended dose is **one tablet** of Axaban-Denk 5 mg twice a day, for example, one in the morning and one in the evening.
For preventing blood clots from re-occurring following completion of 6 months of treatment
The recommended dose is one tablet of Axaban-Denk 2.5 mg twice a day for example, one in the morning and one in the evening.
Your doctor will decide how long you must continue treatment for.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Your doctor might change your anticoagulant treatment as follows:

- **Changing from Axaban-Denk to anticoagulant medicines**
Stop taking Axaban-Denk. Start treatment with the anticoagulant medicines (for example heparin) at the time you would have taken the next tablet.
- **Changing from anticoagulant medicines to Axaban-Denk**
Stop taking the anticoagulant medicines. Start treatment with Axaban-Denk at the time you would have had the next dose of anticoagulant medicine, then continue as normal.
- **Changing from treatment with anticoagulant containing vitamin K antagonist (e.g. warfarin) to Axaban-Denk**
Stop taking the medicine containing a vitamin K antagonist. Your doctor needs to do blood-measurements and instruct you when to start taking Axaban-Denk.
- **Changing from Axaban-Denk to anticoagulant treatment containing vitamin K antagonist (e.g. warfarin)**
If your doctor tells you that you have to start taking the medicine containing a vitamin K antagonist, continue to take Axaban-Denk for at least 2 days after your first dose of the medicine containing a vitamin K antagonist. Your doctor needs to do blood-measurements and instruct you when to stop taking Axaban-Denk.

Patients undergoing cardioversion
If your abnormal heartbeat needs to be restored to normal by a procedure called cardioversion, take Axaban-Denk at the times your doctor tells you, to prevent blood clots in blood vessels in your brain and other blood vessels in your body.

If you take more Axaban-Denk than you should
Tell your doctor immediately if you have taken more than the prescribed dose of Axaban-Denk. Take the medicine pack with you, even if there are no tablets left. If you take more Axaban-Denk than recommended, you may have an increased risk of bleeding. If bleeding occurs, surgery or blood transfusions may be required.

If you forget to take Axaban-Denk
Take the dose as soon as you remember and
• take the next dose of Axaban-Denk at the usual time • then continue as normal.
If you are not sure what to do or have missed more than one dose, ask your doctor or pharmacist.

If you stop taking Axaban-Denk
Do not stop taking Axaban-Denk without talking to your doctor first, because the risk of developing a blood clot could be higher if you stop treatment too early.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

The most common general side effect of apixaban is bleeding which may be potentially life threatening and require immediate medical attention.

The following side effects are known if you take apixaban to prevent a blood clot from forming in the heart in patients with an irregular heart beat and at least one additional risk factor.

- Common side effects (may affect up to 1 in 10 people)**
 - bleeding including:
 - from your nose
 - from your gums
 - blood in the urine
 - bruising and swelling
 - in your stomach, your bowel, from your rectum
 - in your mouth
 - from the vagina
 - anaemia which may cause tiredness or paleness
 - reduced number of platelets in your blood (which can affect clotting)
 - nausea (feeling sick)
 - skin rash
 - blood tests may show:
 - an increase in gamma-glutamyltransferase (GGT) or alanine aminotransferase (ALT)
- Uncommon side effects (may affect up to 1 in 100 people)**
 - low blood pressure which may make you feel faint or have a quickened heartbeat
 - nausea (feeling sick)
 - blood tests may show:
 - an increase in gamma-glutamyltransferase (GGT)
- Uncommon side effects (may affect up to 1 in 100 people)**
 - bleeding:
 - in your eyes
 - in your mouth or blood in your spit when coughing
 - bright/red blood in the stools
 - tests showing blood in the stools or in the urine
 - bleeding occurring after your operation including bruising and swelling, blood or liquid leaking from the surgical wound/incision (wound secretion) or injection site
 - from a haemorrhoid
 - into a muscle
 - itching
 - allergic reactions (hypersensitivity) which may cause: swelling of the face, lips, mouth, tongue and/or throat and difficulty breathing. Contact your doctor immediately if you experience any of these symptoms.
 - blood tests may show:
 - abnormal liver function
 - an increase in some liver enzymes
 - an increase in bilirubin, a breakdown product of red blood cells, which can cause yellowing of the skin and eyes
- Rare side effects (may affect up to 1 in 1,000 people)**
 - skin rash
 - itching
 - allergic reactions (hypersensitivity) which may cause: swelling of the face, lips, mouth, tongue and/or throat and difficulty breathing. Contact your doctor immediately if you experience any of these symptoms.

Rare side effects (may affect up to 1 in 1,000 people)
• bleeding:

- into your lungs or your throat
- into the space behind your abdominal cavity
- into a muscle

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 Axaban-Denk
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 on the bottle after "Exp". The expiry date refers to the last day of that month.
Shelf life: 3 years
Store below 25°C.
Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information
What Axaban-Denk 5 mg contains
• The active substance is apixaban. Each film-coated tablet contains 5 mg apixaban.
• The other ingredients are: lactose, microcrystalline cellulose, croscarmellose sodium, sodium lauryl sulfate, magnesium stearate, hypromellose, titanium dioxide, triacetin, iron oxide red.

General classification for supply
Medicinal product subject to medical prescription
What Axaban-Denk 5 mg looks like and contents of the pack
Axaban-Denk 5 mg are pink, oval-shaped, biconvex film-coated tablets.
Axaban-Denk 5 mg is available in HDPE bottles.
Pack size: 60 film-coated tablets
Marketing Authorisation Holder
DENK PHARMA GmbH & Co. KG
Prinzregentenstr. 79
81675 München
Germany
Manufacturer of bulk, packaging and batch release
Combino Pharm Malta Ltd
HF-60 Hal Far Industrial Estate
Hal Far BBG 3000
Malta
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Other sources of information
Further information on this medicine is available on the Denk Pharma website: www.denkpharma.de/en/educationalmaterial

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SPECIFICATION - DENK PHARMA

- product name: Axaban-Denk 5 mg
- language(s): EN, FR,
- Revision of text: 05.2019
- material number: 7090/001
- dimension: 500 x 160 mm (b x h)
- pharma code: XY (Combino Pharm Malta)
- printing colours:
 - YELLOW
 - BLACK
- artwork creation: 1 / 19.06.2019, WHO
2 / 25.06.2019, WHO

