Axaban-Denk

Apixaban

Prescriber Guide

Version 4.0 | November 2024

This educational material is provided to further minimise the risk of bleeding that is associated with the use of apixaban and to guide healthcare professionals in managing that risk.

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals and patients are asked to report any suspected adverse drug reactions via their national reporting system.

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Patient Alert Card

A Patient Alert Card must be provided to each patient who is prescribed Axaban-Denk 2.5 mg or 5 mg, and the importance and consequences of anticoagulant therapy should be explained. The Patient Alert Card is included inside the 2.5 mg and 5 mg packs.

Specifically, the prescriber should talk to patients about the importance of treatment compliance, the signs or symptoms of bleeding, and when to seek attention from a healthcare professional.

This Patient Alert Card provides information to healthcare professionals on the anticoagulant therapy and contains important contact information in the event of emergencies.

Patients should be advised to carry the Patient Alert Card with them at all times and to show it to every healthcare professional including pharmacists. They should also be reminded about the need to inform healthcare professionals that they are taking Axaban-Denk if they require surgery or invasive procedures.

Therapeutic indication: Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF) with one or more risk factors [1,2]

Risk factors for stroke in adult patients with NVAF include prior stroke or transient ischaemic attack, age ≥ 75 years, hypertension, diabetes mellitus, and symptomatic heart failure (NYHA Class ≥ II).

Dosing recommendations

The recommended dose of Axaban-Denk is 5 mg taken orally twice daily (BD) with water, with or without food. Therapy should be continued long term (Figure 1).

Figure 1

Morning	Night
	
Axaban-Denk 5 mg	Axaban-Denk 5 mg

For patients who are unable to swallow whole tablets, Axaban-Denk tablets may be crushed and suspended in water, or 5 % dextrose in water (D5W), or apple juice or mixed with apple puree and immediately administered orally. Alternatively, Axaban-Denk tablets may be crushed and suspended in 60 ml of water or D5W and immediately delivered through a nasogastric tube. Crushed Axaban-Denk tablets are stable in water, D5W, apple juice, and apple puree for up to 4 hours.

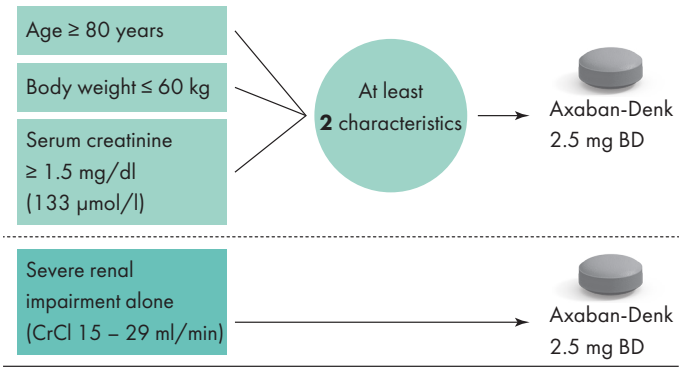
Dose reduction

In patients with at least two of the following characteristics: age ≥ 80 years, body weight ≤ 60 kg, or serum creatinine ≥ 1.5 mg/dl (133 µmol/l), the recommended dose of Axaban-Denk is 2.5 mg taken orally BD (Figure 2).

Patients with exclusive criteria of severe renal impairment (creatinine clearance [CrCl] 15 – 29 ml/min) should also receive Axaban-Denk 2.5 mg BD (Figure 2).

Figure 2

Criteria for Axaban-Denk 2.5 mg BD dose



Missed dose

If a dose is missed, the patient should take Axaban-Denk immediately and then continue with BD intake as before.

Patients with renal impairment

Renal impairment	
Dialysis	Not recommended
Renal failure (CrCl < 15 ml/min)	Not recommended
Severe renal impairment (CrCl 15 – 29 ml/min)	Dose reduction to 2.5 mg BD
Mild (CrCl 51 – 80 ml/min) or moderate (CrCl 30 – 50 ml/min) renal impairment	5 mg BD. No dose adjustment required unless the patient fulfils criteria for dose reduction to 2.5 mg BD based on age, body weight and/or serum creatinine *(refer to dosing section)*

Patients with hepatic impairment

Hepatic impairment	
Hepatic disease associated with coagulopathy and clinically relevant bleeding risk	Contraindicated
Severe hepatic impairment	Not recommended
Mild or moderate hepatic impairment (Child Pugh A or B)	Use with caution No dose adjustment required

Prior to initiating Axaban-Denk, liver function testing should be performed. Patients with elevated liver enzymes, alanine aminotransferase (ALT) / aspartate aminotransferase (AST) > 2 × ULN or total bilirubin ≥ 1.5 × ULN, were excluded in clinical trials. Therefore, Axaban-Denk should be used cautiously in this population.

Patients undergoing catheter ablation

Axaban-Denk can be continued in patients undergoing catheter ablation for atrial fibrillation.

Patients undergoing cardioversion

Axaban-Denk can be initiated or continued in adult patients with NVAF who may require cardioversion.

For patients not previously treated with anticoagulants, exclusion of left atrial thrombus using an image-guided approach (e.g. transesophageal echocardiography [TEE] or computed tomographic scan [CT]) prior to cardioversion should be considered, in accordance with established medical guidelines. For patients in whom a prior intracardiac thrombus has been detected, established medical guidelines should be followed prior to cardioversion.

Patient status	Patient qualifies for dose reduction?	Dosing regimen
Initiating treatment with apixaban	No	5 mg BD for at least 2.5 days (5 single doses) before cardioversion
	Yes	2.5 mg BD for at least 2.5 days (5 single doses) before cardioversion
Insufficient time prior to cardioversion to administer 5 doses of Axaban-Denk	No	10 mg loading dose at least 2 hours before cardioversion, followed by 5 mg BD
	Yes	5 mg loading dose at least 2 hours before cardioversion, followed by 2.5 mg BD

For all patients undergoing cardioversion, confirmation should be sought prior to cardioversion that the patient has taken Axaban-Denk as prescribed. Decisions on initiation and duration of treatment should take established guideline recommendations for anticoagulant treatment in patients undergoing cardioversion into account.

Therapeutic indication: Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults [1,2]

Dosing recommendations

The recommended dose of Axaban-Denk for the treatment of acute DVT and treatment of PE is 10 mg taken orally twice daily (BD) for the first 7 days followed by 5 mg taken orally BD with water, with or without food.

As per available medical guidelines, short duration of treatment (at least 3 months) should be based on major transient /reversible risk factors (e.g. recent surgery, trauma, immobilisation).

The recommended dose of Axaban-Denk for the prevention of recurrent DVT and PE is 2.5 mg taken orally BD with water, with or without food.

When prevention of recurrent DVT and PE is indicated, the 2.5 mg BD dose should be initiated following completion of 6 months of treatment with Axaban-Denk 5 mg BD or with another anticoagulant, as indicated in Figure 3.

The duration of overall therapy should be individualised after careful assessment of the treatment benefit against the risk for bleeding.

For patients who are unable to swallow whole tablets, Axaban-Denk tablets may be crushed and suspended in water, or 5 % dextrose in water (D5W), or apple juice or mixed with apple puree and immediately administered orally. Alternatively, Axaban-Denk tablets may be crushed and suspended in 60 ml of water or D5W and immediately delivered through a nasogastric tube. Crushed Axaban-Denk tablets are stable in water, D5W, apple juice, and apple puree for up to 4 hours.

Figure 3

Dosing schedule	Morning	Night	Daily dose
Treatment of acute DVT or PE (at least 3 months)			
Day 1 – 7: 10 mg BD →	 Axaban-Denk 5 mg  Axaban-Denk 5 mg	 Axaban-Denk 5 mg  Axaban-Denk 5 mg	20 mg
Day 8 onwards: 5 mg BD →	 Axaban-Denk 5 mg	 Axaban-Denk 5 mg	10 mg
Prevention of recurrent DVT and/or PE following completion of 6 months anticoagulation treatment			
2.5 mg BD →	 Axaban-Denk 2.5 mg	 Axaban-Denk 2.5 mg	5 mg

Missed dose

If a dose is missed, the patient should take Axaban-Denk immediately and then continue with BD intake as before.

Patients with renal impairment

Renal impairment	
Dialysis	Not recommended
Renal failure (CrCl < 15 ml/min)	Not recommended
Severe renal impairment (CrCl 15 – 29 ml/min)	Use with caution
Mild (CrCl 51 – 80 ml/min) or moderate (CrCl 30 – 50 ml/min) renal impairment	No dose adjustment required

Patients with hepatic impairment

Hepatic impairment	
Hepatic disease associated with coagulopathy and clinically relevant bleeding risk	Contraindicated
Severe hepatic impairment	Not recommended
Mild or moderate hepatic impairment (Child Pugh A or B)	Use with caution No dose adjustment required

Prior to initiating Axaban-Denk, liver function testing should be performed. Patients with elevated liver enzymes, ALT/AST > 2 × ULN or total bilirubin ≥ 1.5 × ULN, were excluded in clinical trials. Therefore, Axaban-Denk should be used cautiously in this population.

Haemodynamically unstable PE patients or patients who require thrombolysis or pulmonary embolectomy

Axaban-Denk is not recommended as an alternative to unfractionated heparin (UFH) in patients with PE who are haemodynamically unstable or may receive thrombolysis or pulmonary embolectomy.

Patients with active cancer

Patients with active cancer can be at high risk of both venous thromboembolism and bleeding events. When apixaban is considered for DVT or PE treatment in cancer patients, a careful assessment of the benefits against the risks should be made.

Therapeutic indication: Prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery [1]

Dosing recommendations

The recommended dose of Axaban-Denk is 2.5 mg taken orally twice daily (BD) with water, with or without food. The initial dose should be taken 12 to 24 hours after surgery.

Physicians may consider the potential benefits of earlier anticoagulation for VTE prophylaxis as well as the risks of post-surgical bleeding when deciding on the time of administration within this time window.

In patients undergoing **hip replacement surgery,** the recommended duration of treatment is **32 to 38 days.**

In patients undergoing **knee replacement surgery,** the recommended duration of treatment is **10 to 14 days.**

For patients who are unable to swallow whole tablets, Axaban-Denk tablets may be crushed and suspended in water, or 5 % dextrose in water (D5W), or apple juice or mixed with apple puree and immediately administered orally. Alternatively, Axaban-Denk tablets may be crushed and suspended in 60 ml of water or D5W and immediately delivered through a nasogastric tube. Crushed Axaban-Denk tablets are stable in water, D5W, apple juice, and apple puree for up to 4 hours.

Missed dose

If a dose is missed, the patient should take Axaban-Denk immediately and then continue with BD intake as before.

Patients with renal impairment

Renal impairment	
Dialysis	Not recommended
Renal failure (CrCl < 15 ml/min)	Not recommended
Severe renal impairment (CrCl 15 – 29 ml/min)	Use with caution
Mild (CrCl 51 – 80 ml/min) or moderate (CrCl 30 – 50 ml/min) renal impairment	No dose adjustment required

Patients with hepatic impairment

Hepatic impairment	
Hepatic disease associated with coagulopathy and clinically relevant bleeding risk	Contraindicated
Severe hepatic impairment	Not recommended
Mild or moderate hepatic impairment (Child Pugh A or B)	Use with caution No dose adjustment required

Prior to initiating Axaban-Denk, liver function testing should be performed. Patients with elevated liver enzymes, ALT/AST > 2 × ULN or total bilirubin ≥ 1.5 × ULN, were excluded in clinical trials. Therefore, Axaban-Denk should be used cautiously in this population.

Switching to and from Axaban-Denk [1,2]

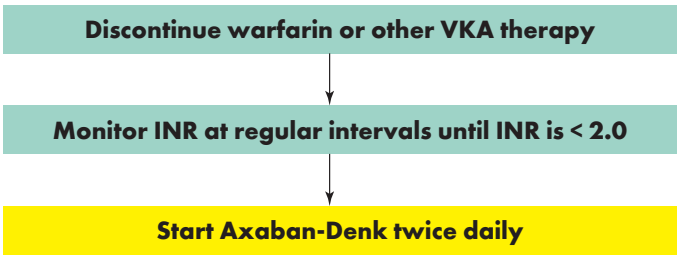
Switching treatment from parenteral anticoagulants to Axaban-Denk (and vice versa) can be done at the next scheduled dose.

These medicinal products should not be administered simultaneously.

Switching from vitamin K antagonist (VKA) therapy to Axaban-Denk

When converting patients from VKA therapy to Axaban-Denk, discontinue warfarin or other VKA therapy and start Axaban-Denk when the international normalised ratio (INR) is < 2.0 (Figure 4).

Figure 4



Switching from Axaban-Denk to VKA therapy

When converting patients from Axaban-Denk to VKA therapy, continue administration of Axaban-Denk for at least 2 days after beginning VKA therapy. After 2 days of coadministration of Axaban-Denk with VKA therapy, obtain an INR prior to the next scheduled dose of Axaban-Denk. Continue coadministration of Axaban-Denk and VKA therapy until the INR is ≥ 2.0.

Populations potentially at higher risk of bleeding [1,2]

Several subgroups of patients are at increased risk of bleeding and should be **carefully monitored** for signs and symptoms of bleeding complications. Axaban-Denk should be used **with caution** in conditions with an increased haemorrhagic risk. Axaban-Denk administration should be **discontinued** if severe haemorrhage occurs.

Lesion or condition if considered a significant risk factor for major bleeding and where use is contraindicated

This includes:

- Active clinically significant bleeding
- Hepatic disease associated with coagulopathy and clinically relevant bleeding risk
- Current or recent gastrointestinal ulceration
- Presence of malignant neoplasms at high risk of bleeding
- Recent brain or spinal injury
- Recent brain, spinal or ophthalmic surgery
- Recent intracranial haemorrhage
- Known or suspected oesophageal varices, arteriovenous malformations, vascular aneurysms or major intraspinal or intracerebral vascular abnormalities

Interactions with other medicinal products affecting haemostasis	
Anticoagulants • Unfractionated heparins (UFH), low molecular weight heparins (e.g. enoxaparin, dalteparin), heparin derivatives (e.g. fondaparinux) • Oral anticoagulants (e.g. warfarin, rivaroxaban, dabigatran)	Due to an increased bleeding risk, concomitant treatment with Axaban-Denk and any other anticoagulant agent is **contraindicated,** except under specific circumstances of switching anticoagulant therapy, or when UFH is given at doses necessary to maintain an open central venous or arterial catheter, or when UFH is given during catheter ablation for atrial fibrillation.
Platelet aggregation inhibitors, SSRIs/ SNRIs and NSAIDs	The concomitant use of Axaban-Denk with antiplatelet agents increases the risk of bleeding. Apixaban should be used with caution when coadministered with selective serotonin reuptake inhibitors (SSRIs)/ serotonin norepinephrine reuptake inhibitors (SNRIs), non-steroidal anti-inflammatory drugs (NSAIDs), acetylsalicylic acid (ASA) and/or P2Y12 inhibitors (e.g. clopidogrel). There is limited experience of co-administration with other platelet aggregation inhibitors (such as GPIIb/ IIIa receptor antagonists, dipyridamole, dextran or sulfinpyrazone) or thrombolytic agents. As such agents increase the bleeding risk, co-administration of these medicinal products with apixaban is not recommended.

Factors which may increase Axaban-Denk exposure/increase Axaban-Denk plasma levels	
Renal impairment	*See sections on patients with renal impairment under dosing recommendations for each separate indication* • Use is not recommended in patients with CrCl < 15 ml/min or patients undergoing dialysis • No dose adjustment is required in patients with mild or moderate renal impairment **Patients with NVAF** • Patients with severe renal impairment (CrCl 15 – 29 ml/min) should receive the lower dose of Axaban-Denk 2.5 mg BD • Patients with serum creatinine ≥ 1.5 mg/dl (133 µmol/l) associated with age ≥ 80 years or body weight ≤ 60 kg should receive the lower dose of Axaban-Denk 2.5 mg BD
Elderly	• No dose adjustment required **Patients with NVAF** • No dose adjustment required except in combination with other factors
Low body weight ≤ 60 kg	• No dose adjustment required **Patients with NVAF** • No dose adjustment required except in combination with other factors
Concomitant use with strong inhibitors of both CYP3A4 and P-gp	• Axaban-Denk is not recommended in patients receiving concomitant systemic treatment with strong inhibitors of both CYP3A4 and P-gp, such as azole-antimycotics (e.g. ketoconazole, itraconazole, voriconazole and posaconazole) and HIV protease inhibitors (e.g. ritonavir)
Concomitant use with agents not considered strong inhibitors of both CYP3A4 and P-gp	• No dose adjustment for Axaban-Denk is required when co-administered with, for example, diltiazem, naproxen, clarithromycin, amiodarone, verapamil, quinidine and fluconazole

Factors which may reduce Axaban-Denk exposure/reduce Axaban-Denk plasma levels	
Concomitant use with strong inducers of both CYP3A4 and P-gp	• The concomitant use of Axaban-Denk with strong inducers of both CYP3A4 and P-gp (e.g. rifampicin, phenytoin, carbamazepine, phenobarbital or St. John's Wort) may lead to a ~50 % reduction in Axaban-Denk exposure and should be used with caution **Treatment of DVT or PE** • Axaban-Denk is not recommended

Surgery and invasive procedures [1,2,3]

Axaban-Denk should be discontinued prior to elective surgery or invasive procedures (excluding cardioversion or catheter ablation) with a risk of bleeding (see table below).

If surgery or invasive procedures cannot be delayed, exercise appropriate caution, taking into consideration an increased risk of bleeding. This risk of bleeding should be weighed against the urgency of intervention.

If a patient treated with Axaban-Denk requires an elective procedure, such as surgery or an invasive procedure associated with an increased risk of bleeding, Axaban-Denk should be discontinued for a sufficient period of time prior to the procedure to reduce the risk of anticoagulant-related bleeding. The half-life of Axaban-Denk is approximately 12 hours. Given that Axaban-Denk is a reversible factor Xa (FXa) inhibitor, its anticoagulant activity should abate within 24 to 48 hours from the last administered dose.

Discontinuation of Axaban-Denk prior to elective surgery/ invasive procedure	
Low risk of bleeding (includes interventions for which bleeding, if it occurs, will be minimal, non-critical in its location and/or easily controlled by simple mechanical haemostasis)	At least **24 hours** prior to elective surgery or invasive procedures
Moderate or high risk of bleeding (includes interventions for which the probability of clinically significant bleeding cannot be excluded, or for which the risk of bleeding would be unacceptable)	At least **48 hours** prior to elective surgery or invasive procedures

Temporary discontinuation [1,2]

Discontinuing anticoagulants, including Axaban-Denk, for active bleeding, elective surgery, or invasive procedures places patients at an increased risk of thrombosis. Lapses in therapy should be avoided and if anticoagulation with Axaban-Denk must be temporarily discontinued for any reason, therapy should be restarted as soon as possible, provided the clinical situation allows it and adequate haemostasis has been established.

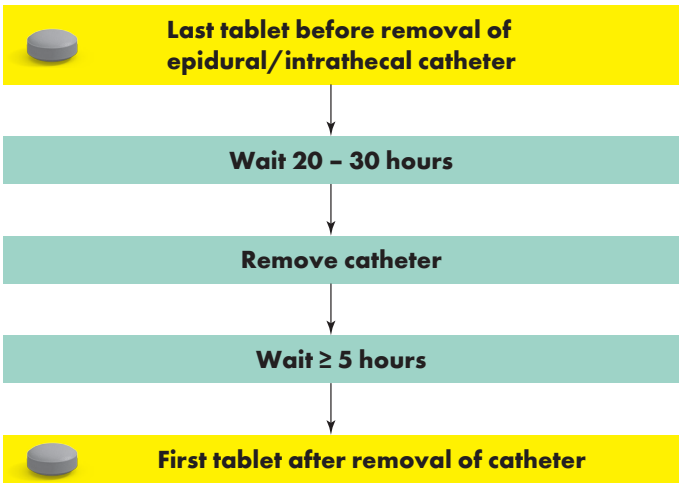
Spinal/epidural anaesthesia or puncture [1]

When neuraxial anaesthesia (spinal/epidural anaesthesia) or spinal/epidural puncture is employed, patients treated with antithrombotic agents for prevention of thromboembolic complications are at risk of developing an epidural or spinal haematoma, which can result in long-term or permanent paralysis. Post-operative indwelling epidural or intrathecal catheters must be removed **at least 5 hours** prior to the first dose of Axaban-Denk.

Guidance on the use of Axaban-Denk in patients with indwelling intrathecal or epidural catheters

There is no clinical experience with the use of Axaban-Denk with indwelling intrathecal or epidural catheters. In case there is such need and based on the general pharmacokinetic characteristics of apixaban, a time interval of **20 to 30 hours** (i.e., 2 × half-life) between the last dose of Axaban-Denk and catheter withdrawal should elapse, and at least one dose should be omitted before catheter withdrawal. The next dose of Axaban-Denk may be given **at least 5 hours** after catheter removal. As with all anticoagulant drugs, experience with neuraxial blockade is limited and extreme caution is therefore recommended when using Axaban-Denk in the presence of neuraxial blockade (Figure 5).

Figure 5



Patients are to be frequently monitored for signs and symptoms of neurological impairment (e.g. numbness or weakness of the legs, bowel or bladder dysfunction). If neurological compromise is noted, urgent diagnosis and treatment is necessary.

Management of overdose and haemorrhage [1, 2]

Overdose of Axaban-Denk may result in a higher risk of bleeding. In the event of haemorrhagic complications, treatment must be discontinued and the source of bleeding investigated. The initiation of appropriate treatment, e.g. surgical haemostasis or the transfusion of fresh frozen plasma, or the administration of a reversal agent for factor Xa (FXa) inhibitors should be considered.

In controlled clinical trials, orally-administered apixaban in healthy subjects at doses up to 50 mg daily for 3 to 7 days (25 mg twice daily for 7 days or 50 mg once daily for 3 days) had no clinically relevant adverse effects.

In healthy subjects, administration of activated charcoal 2 and 6 hours after ingestion of a 20 mg dose of apixaban reduced mean AUC by 50 % and 27 %, respectively, and had no impact on C_{max}. Mean half-life decreased from 13.4 hours when apixaban was administered alone to 5.3 hours and 4.9 hours, respectively, when activated charcoal was administered 2 and 6 hours after apixaban. Thus, administration of activated charcoal may be useful in the management of overdose or accidental ingestion.

For situations when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding, a reversal agent for FXa inhibitors is existing. However, the reversal agent may not be available in every country. Administration of prothrombin complex concentrates (PCCs) or recombinant factor VIIa may also be considered. Reversal of apixaban pharmacodynamic effects, as demonstrated by changes in the thrombin generation assay, was evident at the end of infusion and reached baseline values within 4 hours after the start of a 4-factor PCC 30-minute infusion in healthy subjects. However, there is no clinical experience with the use of 4-factor PCC products to reverse bleeding in individuals who have received apixaban. Currently there is no experience with the use of recombinant factor VIIa in individuals receiving apixaban. Re-dosing of recombinant factor VIIa could be considered and titrated depending on improvement of bleeding.

Depending on local availability, consultation of a coagulation expert should be considered in case of major bleeding.

Haemodialysis decreased AUC by 14 % in subjects with end-stage renal disease, when a single dose of apixaban 5 mg was administered orally. Therefore, haemodialysis is unlikely to be an effective means of managing overdose.

Use of coagulation tests [1, 2]

Routine clinical monitoring is not required with apixaban treatment. However, a calibrated quantitative anti-factor Xa (FXa) assay may be useful in exceptional situations where knowledge of apixaban exposure may help to inform clinical decisions, e.g. overdose and emergency surgery.

Prothrombin time (PT), INR and activated partial thromboplastin time (aPTT)

Changes observed in these clotting tests at the expected therapeutic dose are small and subject to a high degree of variability. They are not recommended to assess the pharmacodynamic effects of Axaban-Denk.

In the thrombin generation assay, apixaban reduced endogenous thrombin potential, a measure of thrombin generation in human plasma.

Anti-FXa assays

Apixaban also demonstrates anti-FXa activity as evident by reduction in FXa enzyme activity in multiple commercial anti-FXa kits; however, results differ across kits. Data from clinical trials are only available for the Rotachrom® Heparin chromogenic assay. Anti-FXa activity exhibits a close direct linear relationship with apixaban plasma concentration, reaching maximum values at the time of apixaban peak plasma concentrations. The relationship between apixaban plasma concentration and anti-FXa activity is approximately linear over a wide dose range of apixaban.

Table 1 shows the predicted steady-state exposure and anti-FXa activity for each indication. In patients taking apixaban for the prevention of VTE following hip or knee replacement surgery, the results demonstrate a less than 1.6-fold fluctuation in peak-to-trough levels. In patients with NVAF taking apixaban for the prevention of stroke and systemic embolism, the results demonstrate a less than 1.7-fold fluctuation in peak-to-trough levels. In patients taking apixaban for the treatment of DVT and PE or prevention of recurrent DVT and PE, the results demonstrate a less than 2.2-fold fluctuation in peak-to-trough levels.

Table 1

Predicted apixaban steady-state exposure and anti-FXa activity

	Apixaban C_{max} (ng/ml)	Apixaban C_{min} (ng/ml)	Apixaban anti-FXa activity max (IU/ml)	Apixaban anti-FXa activity min (IU/ml)
	Median [5th, 95th percentile]			
Prevention of VTE: elective hip or knee replacement surgery				
2.5 mg BD	77 [41, 146]	51 [23, 109]	1.3 [0.67, 2.4]	0.84 [0.37, 1.8]
Prevention of stroke and systemic embolism: NVAF				
2.5 mg BD*	123 [69, 221]	79 [34, 162]	1.8 [1.0, 3.3]	1.2 [0.51, 2.4]
5 mg BD	171 [91, 321]	103 [41, 230]	2.6 [1.4, 4.8]	1.5 [0.61, 3.4]
Treatment of DVT, treatment of PE and prevention of recurrent DVT and PE				
2.5 mg BD	67 [30, 153]	32 [11, 90]	1.0 [0.46, 2.5]	0.49 [0.17, 1.4]
5 mg BD	132 [59, 302]	63 [22, 177]	2.1 [0.91, 5.2]	1.0 [0.33, 2.9]
10 mg BD	251 [111, 572]	120 [41, 335]	4.2 [1.8, 10.8]	1.9 [0.64, 5.8]

* Dose adjusted based on at least 2 of 3 dose reduction criteria as shown in Figure 2

Abbreviations

ALT	alanine aminotransferase
aPTT	activated partial thromboplastin time
ASA	acetylsalicylic acid
AST	aspartate aminotransferase
BD	twice daily
CT	computed tomographic scan
CrCl	creatinine clearance
D5W	5 % dextrose in water
DVT	deep vein thrombosis
FXa	factor Xa
INR	international normalised ratio
NSAIDs	non-steroidal anti-inflammatory drugs
NVAF	non-valvular atrial fibrillation
NYHA classification	New York Heart Association Functional Classification
PCCs	prothrombin complex concentrates
PE	pulmonary embolism
PT	Prothrombin time
SNRIs	serotonin norepinephrine reuptake inhibitors
SSRIs	selective serotonin reuptake inhibitors
TEE	transesophageal echocardiography
ULN	upper limit of normal
VKA	vitamin K antagonist
VTE	venous thromboembolic events
UFH	unfractionated heparin
HIV	human immunodeficiency virus

References

[1] Axaban-Denk 2.5 mg film coated tablets Summary of Product Characteristics (current version).

[2] Axaban-Denk 5 mg film coated tablets Summary of Product Characteristics (current version).

[3] Surgery and invasive procedures in patients on long-term treatment with direct oral anticoagulants: Thrombin or factor-Xa inhibitors. Recommendations of the Working Group on perioperative haemostasis and the French Study Group on thrombosis and haemostasis. Archives of Cardiovascular Disease 2011; 104: 669 – 676.

Denk Pharma

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