UNILAB

Apixaban
Inhibix™

2.5 mg & 5 mg Film-Coated Tablet

Direct Factor Xa Inhibitor

℞

FORMULATIONS
Each film-coated tablet contains:
Apixaban ..... 2.5 mg
Apixaban ..... 5 mg

PRODUCT DESCRIPTION
Apixaban 2.5 mg: Yellow, round-shaped, biconvex, film-coated tablet debossed with "IU1" on one side and plain on the other side.
Apixaban 5 mg: Pink, oval-shaped, biconvex, film-coated tablet debossed with "IU2" on one side and plain on the other side.

PHARMACODYNAMICS
Pharmacodynamic Properties:
Apixaban is a selective inhibitor of FXa. It does not require antithrombin III for antithrombotic activity. Apixaban inhibits free and clot-bound FXa, and prothrombinase activity.
Apixaban has no direct effect on platelet aggregation, but indirectly inhibits platelet aggregation induced by thrombin. By inhibiting FXa, apixaban decreases thrombin generation and thrombus development.

As a result of FXa inhibition, apixaban prolongs clotting tests such as prothrombin time (PT), INR, and activated partial thromboplastin time (aPTT). Changes observed in these clotting tests at the expected therapeutic dose, however, are small, subject to a high degree of variability, and not useful in monitoring the anticoagulation effect of apixaban.

PHARMACOKINETIC PROPERTIES
Apixaban demonstrates linear pharmacokinetics with dose-proportional increases in exposure for oral doses up to 10 mg.

Absorption
The absolute bioavailability of apixaban is approximately 50% for doses up to 10 mg of apixaban. Food does not affect the bioavailability of apixaban. Maximum concentrations (C_{max}) of apixaban appear 3 to 4 hours after oral administration. At doses ≥25 mg, apixaban displays dissolution-limited absorption with decreased bioavailability.
Following oral administration of 10 mg of apixaban as 2 crushed 5 mg tablets suspended in 30 mL water, exposure was similar to that after oral administration of 2 intact 5 mg tablets. Following oral administration of 10 mg of apixaban as 2 crushed 5 mg tablets mixed with 30 g of applesauce, the C_{max} and AUC were 20% and 16% lower, respectively, when compared to administration of 2 intact 5 mg tablets. Following administration of a crushed apixaban tablet that was suspended in 60 mL D5W and delivered through a nasogastric tube, exposure was similar to that seen in other clinical trials involving healthy volunteers receiving a single oral 5 mg tablet dose.
Distribution
Plasma protein in binding in humans is approximately 87%. The volume of distribution (Vss) is approximately 21 liters.
Metabolism
Approximately 25% of an orally administered apixaban dose is recovered in urine and feces as metabolites. Apixaban is metabolized mainly via CYP3A4 with minor contributions from CYP1A2, 2C8, 2C9, 2C19. O-demethylation and hydroxylation at the 3-oxopiperidynil moiety are the major sites of biotransformation.
Unchanged apixaban is the major or drug-related component in human plasma; there are no active circulating metabolites.
Elimination
Apixaban is eliminated in bot urine and feces. Renal excretion accounts for about 27% of total clearance. Biliary and direct intestinal excretion contributes to elimination of apixaban in the feces. Apixaban has a total clearance of approximately 3.3L/hour and an apparent half-life of approximately 12 hours following oral administration.
Apixaban is a substrate of transport proteins: P-gp and breast cancer resistance protein.
Drug Interaction Studies
In vitro apixaban studies at concentrations significantly greater than therapeutic exposures, no inhibitory effect on the activity of CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C9, CYP2D6, CYP3A4/5, or CYP2C19, nor induction effect on the activity of CYP1A2, CYP2B6, or CYP3A4/5 were observed. Therefore, apixaban is not expected to alter the metabolic clearance of coadministered drugs that are metabolized by these enzymes. Apixaban is not a significant inhibitor of P-gp.

Special Populations
Gender: A study in healthy subjects comparing the pharmacokinetics in males and females showed no meaningful difference.
Race: The results across pharmacokinetic studies in normal subjects showed no differences in apixaban pharmacokinetics among White/Caucasian, Asian, and Black/African American subjects. No dose adjustment is required based on race/ethnicity.
Hemodialysis in ESRD subjects: Systemic exposure to apixaban administered as a single 5 mg dose in ESRD subjects dosed immediately after the completion of a 4-hour hemodialysis session (post-dialysis) is 36% higher when compared to subjects with normal renal function.
The systemic exposure to apixaban administered 2 hours prior to a 4-hour hemodialysis session with a dialysate flow rate of 500 mL/min. The systemic exposure of apixaban is 14% lower on dialysis when compared to not on dialysis.
Protein binding is similar (92% to 94%) between healthy controls and ESRD subjects during the on-dialysis and off-dialysis periods.

PRE-CLINICAL SAFETY DATA
Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, fertility and embryo-foetal development and juvenile toxicity.

The major observed effects in the repeated dose toxicity studies were those related to pharmacodynamic action of apixaban on blood coagulation parameters. In the toxicity studies little to no increase of bleeding tendency was found. However, since this may be due to a lower sensitivity of the non-clinical species compared to humans, this result should be interpreted with caution when extrapolating to humans.

INDICATIONS
Apixaban is a factor Xa inhibitor indicated in the following:
- Prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery.
- Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF), with one or more risk factors, such as prior stroke or transient ischemic attack (TIA); age ≥75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class ≥II).
- Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.

DOSAGE AND ADMINISTRATION
Reduction of risk of stroke and systemic embolism in nonvalvular atrial fibrillation:
- The recommended dose is 5 mg orally twice daily.
- In patients with at least 2 of the following characteristics: age ≥80 years, body weight ≤60 kg, or serum creatinine ≥1.5 mg/dL, the recommended dose is 2.5 mg orally twice daily.

Prophylaxis of DVT following hip or knee replacement surgery:
- The recommended dose is 2.5 mg orally twice daily. The initial dose should be taken 12 to 24 hours after surgery.
  - In patients undergoing hip replacement surgery, the recommended duration of treatment is 35 days.
  - In patients undergoing knee replacement surgery, the recommended duration of treatment is 12 days.

Treatment of DVT and PE:
- The recommended dose is 10 mg taken orally twice daily for 7 days, followed by 5 mg taken orally twice daily.

Reduction in the risk of recurrent DVT and PE following initial therapy:
- The recommended dose of apixaban tablets is 2.5 mg taken orally twice daily after at least 6 months of treatment for DVT or PE.

Missed Dose
If a dose of apixaban tablets is not taken at the scheduled time, the dose should be taken as soon as possible on the same day and twice daily administration should be resumed.
The dose should not be doubled to make up for the missed dose.

Switching
Switching from vitamin K antagonist (VKA) therapy to apixaban
When converting patients from vitamin K antagonist (VKA) therapy to apixaban, warfarin or other VKA therapy should be discontinued and apixaban started when the international normalized ratio (INR) is <2.

Switching from apixaban to VKA therapy
When converting patients from apixaban to VKA therapy, administration of apixaban should be continued for at least 2 days after beginning VKA therapy. After 2 days of co-administration of apixaban with VKA therapy, an INR should be obtained prior to the next scheduled dose of apixaban. Coadministration of apixaban and VKA therapy should be continued until the INR is ≥2.

Renal Impairment
In patients with mild to moderate renal impairment, the following recommendation apply:
- for the prevention of VTE in elective hip and knee replacement surgery (VTEp), for the treatment of DVT, treatment fo PE and prevention of recurrent DVT and PE (VTEt), no dose adjustment is necessary.
- for the prevention of stroke and systemic embolism in patients with NVAF and serum creatinine ≥1.5 mg/dL (133 micromole/L) associated with age ≥80 years or body weight ≤60 kg, a dose reduction is necessary and described above. In the absence of other criteria for dose reduction (age, body weight), no dose adjustment is necessary.

In patients with severe renal impairment (creatinine clearance 15-29 mL/min) the following recommendations apply:
- for the prevention of VTE in elective hip or knee replacement surgery (VTEp), for the treatment of DVT, treatment of PE and prevention of recurrent DVT and PE (VTEt) apixaban is to be used with caution.
- for the prevention of stroke and systemic embolism in patients with NVAF, patients should receive the lower dose of apixaban 2.5 mg twice daily.

In patients with creatinine clearance <15 mL/min, or in patients undergoing dialysis, there is no clinical experience therefore apixaban is not recommended.

Hepatic Impairment
Apixaban is contraindicated in patients with hepatic disease associated with coagulopathy and clinically relevant bleeding risk.
It is not recommended in patients with severe hepatic impairment.
It should be used with caution in patients with mild or moderate hepatic impairment (Child Pugh A or B). No dose adjustment is required in patients with mild or moderate hepatic impairment.
Patients with elevated liver enzymes alanine aminotransferase (ALT)/aspartate aminotransferase (AST) >2 x ULN or total bilirubin ≥ 1.5 x ULN were excluded in clinical trials. Therefore apixaban should be used with caution in this population. Prior to initiating apixaban, liver function testing should be performed.

Body Weight
VTEp and VTEt - No dose adjustment required.
NVAF - No dose adjustment required, unless criteria for dose reduction are met.

Gender
No dose adjustment required.

Elderly
VTEp and VTEt - No dose adjustment required.
NVAF - No dose adjustment required, unless criteria for dose reduction are met.

Cardioversion (NVAF)
Patients can stay on apixaban while being cardioverted.

Pediatric Population
The safety and efficacy of apixaban in children and adolescents below age 18 have not been established. No data are available.

METHOD OF ADMINISTRATION
Oral use
Apixaban should be swallowed with water, with or without food.
For patients who are unable to swallow whole tablets, apixaban 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, apixaban tablets may be crushed and suspended in 60 mL of water or D5W and immediately delivered through a nasogastric tube.

Crushed apixaban tablets are stable in water, D5W, apple juice, and apple puree for up to 4 hours.

CONTRAINDICATIONS
- Hypersensitivity to the active substance or to any of the excipients
- Active clinically significant bleeding
- Hepatic disease associated with coagulopathy and clinically relevant bleeding risk.
- Lesion or condition if considered a significant risk factor for major bleeding. This may include current gastrointestinal ulceration, presence of malignant neoplasms at high risk of bleeding, recent brain or spinal injury, recent brain, spinal or ophthalmic surgery, recent intracranial hemorrhage, known or suspected esophageal varices, arteriovenous malformations, vascular aneurysms or major intraspinal or intracerebral vascular abnormalities.
- Concomitant treatment with any other anticoagulant agent e.g., unfractionated heparin (UFH), low molecular weight heparins (enoxaparin, dalteparin, etc.), anticoagulant therapy or when UFH is given at doses necessary to maintain an open central venous or arterial catheter.

WARNINGS AND PRECAUTIONS
Increased Risk of Thrombotic Events after Premature Discontinuation
Premature discontinuation of any oral anticoagulant, including apixaban, in the absence adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from apixaban to warfarin in clinical trials in atrial fibrillation patients. If apixaban is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.

Bleeding
Apixaban increases the risk of bleeding and can cause serious, potentially fatal, bleeding. Cocomitant use of drugs affecting hemostasis increases the risk of bleeding. These include aspirin and other antiplatelet agents, other anticoagulants, heparin, thrombolytic agents, selective serotonin reuptake inhibitors, serotonin norepinephrine reuptake inhibitors and nonsteroidal anti-inflammatory drugs (NSAIDs).

Advise patients of signs and symptoms of blood loss and to report them immediately or go to an emergency room. Discontinue apixaban in patients with active pathological hemorrhage.

Reversal of Anticoagulant Effect
A specific antidote for apixaban is not available, and there is no established way to reverse bleeding in patients taking apixaban. The pharmacodynamic effect of apixaban can be expected to persist for at least 24 hours after the last dose, i.e., for about two drug half-lives. Use of procoagulants reversal agents, such as prothrombin complex concentrate (PCC), activated prothrombin complex concentrate or recombinant factor VIIa, may be considered but has not been evaluated in clinical studies. When PCCs are used, monitoring for the anticoagulation effect of apixabin using a clotting test (PT, INR, or aPTT) or anti-factor Xa (FXa) activity is not useful and is not recommended. Activated oral charcoal reduces absorption of apixaban, thereby lowering apixaban plasma concentration.

Hemodialysis does not appear to have a substantial impact on apixaban exposure. Protamine sulfate and vitamin K are not expected to affect the anticoagulant activity of apixaban. There is no experience with antifibrinolytic agents (tranexamic acid, aminocaproic acid) in individuals receiving apixaban. There is no experience with systemic hemostatics (desmopressin and aprotinin) in individuals receiving apixaban and they are not expected to be effective as a reversal agent.

Spinal/Epidural Anesthesia or Puncture
When neuraxial anesthesia (spinal/epidural anesthesia) or spinal/epidural puncture is employed, patients treated with antithrombotic agents for prevention of thromboembolic complications are at a risk of developing an epidural or spinal hematoma which can result in long-term or permanent paralysis.

The risk of these events may be increased by the postoperative use of indwelling epidural catheters or the concomitant use of medicinal products affecting hemostasis. Indwelling epidural or intrathecal catheters should not be removed earlier than 24 hours after the last administration of apixaban. The next dose of apixaban should not be administered earlier than 5 hours after the removal of the catheter. The risk may also be increased by traumatic or repeated epidural or spinal puncture. If traumatic puncture occurs, delay the administration of apixaban for 48 hours.

Monitor patients frequently 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. Prior to neuraxial intervention the physician should consider the potential benefit versus the risk in anticoagulated patients or in patients to be anticoagulated for thromboprophylaxis.

Patients with Prosthetic Heart Valves
The safety and efficacy of apixaban have not been studied in patients with prosthetic heart valves. Therefore, use of apixaban is not recommended in these patients.

Acute PE in Hemodynamically Unstable Patients or Patients who require Thrombolysis or Pulmonary Embolectomy
Initiation of apixaban is not recommended as an alternative to unfractionated heparin for the initial treatment of patients with PE who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy.

UNDESIRABLE EFFECTS
The safety of apixaban has been investigated in 7 Phase III clinical studies including more than 21,000 patients: more than 5,000 patients in venous thromboembolic event prevention (VTEp) studies, more than 11,000 patients in non-valvular atrial fibrillation (NVAF) studies and more than 4,000 patients in the venous thromboembolic event treatment (VTEt) studies, for an average total exposure of 20 days, 1.7 years and 221 days, respectively.

Common adverse reactions were hemorrhage, contusion, epistaxis, and hematoma (see Table 1 for adverse reaction profile and frequencies by indication).

In the VTEp studies, in total, 11% of the patients treated with apixaban 2.5 mg twice daily experienced adverse reactions. The overall incidence of adverse reactions related to bleeding with apixaban was 10% in the apixaban vs. enoxaparin studies.
In the NVAF studies, the overall incidence of adverse reactions related to bleeding with apixaban was 24.3% in the apixaban vs. warfarin study and 9.6% in the apixaban vs. acetylsalicylic acid study. In the apixaban vs. warfarin study the incidence of ISTH (International Society on Thrombosis and Hemostasis) major gastrointestinal (GI) bleeds (including upper GI, lower GI, and rectal bleeding) with apixaban was 0.76% per year. The incidence of ISTH major intraocular bleeding with apixaban was 0.18% per year.
In the VTEt studies, the overall incidence of adverse reactions related to bleeding with apixaban was 15.6% in the apixaban vs. enoxaparin/warfarin study and 13.3% in the apixaban vs. placebo study.

Tabulated list of adverse reactions

Table 1 shows the adverse reactions ranked under headings of system organ class and frequency using the following convention: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to <1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000); not known (cannot be estimated from the available data) for VTEp, NVAF, , and VTEt, respectively.

Table 1.

System Organ Class	Prevention of VTE in adult patients who have undergone elective hip or knee replacement surgery (VTEp)	Prevention of stroke and systemic embolism in adult patients with NVAF, with one or more risk factors (NVAF)	Treatment of DVT and PE, and prevention of recurrent DVT and PE (VTEt)
Blood and lymphatic system disorders			
Anaemia	Common	-	-
Thrombocytopenia	Uncommon	-	-
Hypersensitivity, allergic oedema and Anaphylaxis	Rare	Uncommon	-
Pruritus	Uncommon	Uncommon	Uncommon
Nervous system disorders			
Brain haemorrhage	-	Uncommon	Rare
Eye disorders			
Eye haemorrhage (including conjunctival haemorrhage)	Rare	Common	Uncommon
Vascular disorders			
Haemorrhage, haematoma	Common	Common	Common
Hypotension (including procedural hypotension)	Uncommon	-	-
Intra-abdominal haemorrhage	-	Uncommon	-
Respiratory, thoracic and mediastinal disorders			
Epistaxis	Uncommon	Common	Common
Haemoptysis	Rare	Uncommon	Uncommon
Respiratory tract haemorrhage	-	Rare	Rare
Gastrointestinal disorders			
Nausea	Common	-	-
Gastrointestinal haemorrhage	Uncommon	Common	Common
Haemorrhoidal haemorrhage, mouth haemorrhage	-	Uncommon	-
Haematochezia	Uncommon	Uncommon	Uncommon
Rectal haemorrhage, gingival bleeding	Rare	Common	Common
Retroperitoneal haemorrhage	-	Rare	-
Hepatobiliary disorders			
Transaminases increased, aspartate aminotransferase increased, gamma-glutamyltransferase increased, liver function test abnormal, blood alkaline phosphatase increased, blood bilirubin increased	Uncommon	-	-
Skin and subcutaneous tissue disorders			
Skin rash	-	Uncommon	-
Musculoskeletal connective tissue			
Muscle haemorrhage	Rare	-	-
Renal and urinary disorders			
Haematuria	Uncommon	Common	Common
Reproductive system and breast disorders			
Abnormal vaginal haemorrhage, urogenital haemorrhage	-	Uncommon	Uncommon
General disorders and administration site conditions			
Application site bleeding	-	Uncommon	-
Investigations			
Occult blood positive	-	Uncommon	Uncommon
Injury, poisoning and procedural complications			
Contusion	Common	Common	Common
Post procedural haemorrhage (including post procedural haematoma, wound haemorrhage, vessel puncture site haematoma and catheter site haemorrhage), wound secretion, incision site haemorrhage (including incision site haematoma), operative haemorrhage	Uncommon	-	-
Traumatic haemorrhage, post procedural haemorrhage, incision site haemorrhage	-	Uncommon	Uncommon

The use of apixaban may be associated with an increased risk of occult or overt bleeding from any tissue or organ, which may result in post-haemorrhagic anemia. The signs, symptoms, and severity will vary according to the location and degree or extent of the bleeding.

INTERACTIONS WITH OTHER MEDICAMENTS
Apixaban is a substrate of both CYP3A4 and P-gp. Inhibitors of CYP3A4 and P-gp increase exposure to apixaban and increase the risk of bleeding. Inducers of CYP3A4 and P-gp decrease exposure to apixaban and increase the risk of stroke and other thromboembolic events.

Strong Dual Inhibitors of CYP3A4 and P-gp
For patients receiving apixaban 5 mg or 10 mg twice daily, the dose of apixaban should be decreased by 50% when coadministered with drugs that are strong dual inhibitors of CYP3A4 and P-gp (e.g., ketoconazole, itraconazole, ritonavir, or clarithromycin).
For patients receiving apixaban at a dose of 2.5 mg twice daily, avoid coadministration with strong dual inhibitors of CYP3A4 and P-gp.

Strong Dual Inducers CYP3A4 and P-gp
Avoid concomitant use of apixaban with strong dual inducers of CYP3A4 and P-gp (e.g., rifampin, carbamazepine, phenytoin, St. John's wort) because such drugs will decrease exposure to apixaban.

Anticoagulants and antiplatelet agents
Coadministration of antiplatelet agents, fibrinolytics, heparin, aspirin, and chronic NSAID use increases the risk of bleeding.

PREGNANCY AND LACTATION
- *Fertility:*
  Studies in animals dosed with apixaban have shown no effect on fertility.
- *Pregnancy: Pregnancy Category B*
  There are no adequate and well-controlled studies of apixaban in pregnant women. Treatment is likely to increase the risk of haemorrhage during pregnancy and delivery. Apixaban should be used during pregnancy only if the potential benefit outweighs the potential risk to the mother and fetus.
- *Nursing Mothers:*
  It is unknown whether apixaban or its metabolites are excreted in human milk. Rats excrete apixaban in milk (12% of the maternal dose).
  Women should be instructed either to discontinue breastfeeding or to discontinue apixaban therapy, taking into account the importance of the drug to the mother.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
Apixaban has no or negligible influence on the ability to drive and use machines.

OVERDOSE AND TREATMENT
There is no antidote to apixaban. Overdose of apixaban may result to 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 hemostasis or the transfusion of fresh frozen plasma 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 (bid) for 7 days or 50 mg once daily (od) 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 apixaban AUC by 50% and 27%, respectively, and had no impact on C_{max}. Mean half-life of apixaban 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 apixaban overdose or accidental ingestion.

If life-threatening bleeding cannot be controlled by the above measures, administration of prothrombin complex concentrates (PCCs) or recombinant VIIa may be considered.

Reversal of apixaban pharmacodynamic effects, as demonstrated by changes in 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.

STORAGE CONDITIONS
Store at temperatures not exceeding 30ºC.

AVAILABILITY
INHIBIX™ (Apixaban) 2.5 mg & 5 mg Film-Coated Tablets, in PVC/PVDC-Alu blister pack of 10's (Box of 3 blister packs x 10 tablets)

CAUTION
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

ADVERSE DRUG REACTION REPORTING STATEMENT
For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph **AND** Unilab at +632-8-**UNILAB**-1 (+632-8-**864522**-1) for Metro Manila or toll-free +1-800-10-UNILAB-1 for provinces, or e-mail productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

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UNILAB
Trusted Quality Healthcare

INHIBIX™ 2.5 mg: DRP-12943
INHIBIX™ 5 mg: DRP-12944

Date of First Authorization: November 2022
Date of Revision: February 2024

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