XCEPT®
(Rivaroxaban)

ایکس سیپٹ

2.5mg

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NAME OF THE MEDICINAL PRODUCT
Xcept 2.5 mg film-coated tablets

QUALITATIVE AND QUANTITATIVE COMPOSITION

XCEPT 2.5 mg
1 film-coated tablet contains 2.5 mg Rivaroxaban.
(As per innovator's specs.)

WARNING: (A) PREMATURE DISCONTINUATION OF RIVAROXABAN INCREASES THE RISK OF THROMBOTIC EVENTS, (B) SPINAL/EPIDURAL HEMATOMA

A. PREMATURE DISCONTINUATION OF RIVAROXABAN INCREASES THE RISK OF THROMBOTIC EVENTS
Premature discontinuation of any oral anticoagulant, including Rivaroxaban, increases the risk of thrombotic events. If anticoagulation with rivaroxaban is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.

B. SPINAL/EPIDURAL HEMATOMA
Epidural or spinal hematomas have occurred in patients treated with rivaroxaban who are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures.
Monitor patients frequently for signs and symptoms of neurological impairment and treat, as necessary. Consider the benefits and risks before neuraxial intervention in patient's anticoagulated or to be anticoagulated for thromboprophylaxis. See WARNINGS AND PRECAUTIONS

DESCRIPTION
XCEPT contains Rivaroxaban, a factor Xa inhibitor used as an oral anticoagulant. Rivaroxaban is chemically designated as 5-Chloro-N-({(5S)-2-oxo-3-[4-(3-oxo-4 morpholinyl) phenyl]-1,3-oxazolidin-5¬yl}methyl)-2 thiophenecarboxamide. The molecular formula of Rivaroxaban is C19H18ClN3O5S.

CLINICAL PHARMACOLOGY

Mechanism of Action
Rivaroxaban is a highly selective direct factor Xa inhibitor with oral bioavailability. Inhibition of factor Xa interrupts the intrinsic and extrinsic pathway of the blood coagulation cascade, inhibiting both thrombin formation and development of thrombi. Rivaroxaban does not inhibit thrombin (activated factor II) and no effects on platelets have been demonstrated.

Pharmacodynamics
Dose-dependent inhibition of factor Xa activity may be observed in humans. Neoplastin® prothrombin time (PT), activated partial thromboplastin time (aPTT) and HepTest® are also prolonged dose dependently.
In healthy adult patients, the 3-factor PCC reduces mean Neoplastin PT values by approximately 1.0 second within 30 minutes, compared to reductions of approximately 3.5 seconds observed with the 4-factor PCC. In contrast, the 3-factor PCC has a greater and more rapid overall effect on reversing changes in endogenous thrombin generation than the 4-factor PCC.
The activated partial thomboplastin time (aPTT) and HepTest are also prolonged dose-dependently. There is no need for monitoring of coagulation parameters during treatment with rivaroxaban in clinical routine. However, if clinically indicated, rivaroxaban levels can be measured by calibrated quantitative anti-factor Xa tests.

Pharmacokinetics

Absorption
Rivaroxaban is rapidly absorbed with maximum concentrations (C_{max}) appearing 2 - 4 hours after tablet intake. Oral absorption of Rivaroxaban is almost complete and oral bioavailability is high (80 - 100 %) for the 2.5 mg tablet dose, irrespective of fasting/fed conditions. Intake with food does not affect Rivaroxaban AUC or Cmax at the 2.5 mg dose. Rivaroxaban 2.5 mg tablets can be taken with or without food.
Rivaroxaban pharmacokinetics are approximately linear up to about 15 mg once daily. At higher doses Rivaroxaban displays dissolution limited absorption with decreased bioavailability and decreased absorption rate with increased dose. This is more marked in fasting state than in fed state. Variability in Rivaroxaban pharmacokinetics is moderate with inter-individual variability (CV %) ranging from 30% to 40%.
Absorption of Rivaroxaban is dependent on the site of its release in the gastrointestinal tract. A 29% and 56% decrease in AUC and Cmax compared to tablet is observed when Rivaroxaban granulate is released in the proximal small intestine. Exposure is further reduced when Rivaroxaban is released in the distal small intestine, or ascending colon. Therefore, administration of Rivaroxaban distal to the stomach should be avoided since this can result in reduced absorption and related Rivaroxaban exposure.

Distribution
Plasma protein binding in humans is high at approximately 92 % to 95 %, with serum albumin being the main binding component. The volume of distribution is moderate with V_{ss} being approximately 50 litres.

Metabolism
Rivaroxaban is metabolised via CYP3A4, CYP2J2 and CYP-independent mechanisms. Oxidative degradation of the morpholinone moiety and hydrolysis of the amide bonds are the major sites of biotransformation. Unchanged Rivaroxaban is the most important compound in human plasma, with no major or active circulating metabolites being present.

Elimination
Of the administered Rivaroxaban dose, approximately 2/3 undergoes metabolic degradation, with half then being eliminated renally and the other half eliminated by the faecal route. The final 1/3 of the administered dose undergoes direct renal excretion as unchanged active substance in the urine, mainly via active renal secretion. With a systemic clearance of about 10 l/h, Rivaroxaban can be classified as a low-clearance substance. After oral administration the elimination becomes absorption rate limited. Elimination of Rivaroxaban from plasma occurs with terminal half-lives of 5 to 9 hours in young individuals, and with terminal half-lives of 11 to 13 hours in the elderly.

Pharmacokinetics in special populations

Renal impairment
There is an increase in Rivaroxaban exposure correlated to decrease in renal function, as assessed via creatinine clearance measurements. In individuals with mild (creatinine clearance 50 - 80 ml/min), moderate (creatinine clearance 30 - 49 ml/min) and severe (creatinine clearance 15 - 29 ml/min) renal impairment, Rivaroxaban plasma concentrations (AUC) are increased 1.4, 1.5 and 1.6 fold respectively. Corresponding increases in pharmacodynamic effects are more pronounced. In individuals with mild, moderate and severe renal impairment the overall inhibition of factor Xa activity is increased by a factor of 1.5, 1.9 and 2.0 respectively as compared to healthy patients; prolongation of PT is similarly increased by a factor of 1.3, 2.2 and 2.4 respectively. There are no data in patients with creatinine clearance < 15 ml/min.
Due to the high plasma protein binding Rivaroxaban is not expected to be dialysable.
Use is not recommended in patients with creatinine clearance < 15 ml/min. Rivaroxaban is to be used with caution in patients with creatinine clearance 15 - 29 ml/min.

Hepatic impairment
Cirrhotic patients with mild hepatic impairment (classified as Child Pugh A) exhibit only minor changes in Rivaroxaban pharmacokinetics (1.2 fold increase in Rivaroxaban AUC on average), nearly comparable to their healthy patients. In cirrhotic patients with moderate hepatic impairment (classified as Child Pugh B), Rivaroxaban mean AUC is significantly increased by 2.3 fold compared to healthy patients. Unbound AUC is increased 2.6 fold. These patients also have reduced renal elimination of Rivaroxaban, similar to patients with moderate renal impairment. There are no data in patients with severe hepatic impairment. The inhibition of factor Xa activity is increased by a factor of 2.6 in patients with moderate hepatic impairment as compared to healthy patients; prolongation of PT is similarly increased by a factor of 2.1. Patients with moderate hepatic impairment are more sensitive to Rivaroxaban resulting in a steeper PK/PD relationship between concentration and PT.
Rivaroxaban is contraindicated in patients with hepatic disease associated with coagulopathy and clinically relevant bleeding risk, including cirrhotic patients with Child Pugh B and C.

Elderly
Elderly patients exhibit higher plasma concentrations than younger patients, with mean AUC values being approximately 1.5 fold higher, mainly due to reduced (apparent) total and renal clearance. No dose adjustment is necessary.

Pediatric population
Safety and efficacy have not been established for children and adolescents up to 18 years.

Gender
There are no clinically relevant differences in pharmacokinetics and pharmacodynamics between male and female patients.

INDICATIONS

Xcept is indicated for the:
- Treatment of chronic Coronary Artery Disease (CAD) and/or Peripheral Artery Disease (PAD).
- Co-administered with acetylsalicylic acid (ASA) alone or with ASA plus clopidogrel or ticlopidine, is indicated for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers.

DOSAGE AND ADMINISTRATION

Reduction of risk of Major Cardiovascular Events (CV death, MI, and Stroke) in Chronic CAD or PAD
2.5 mg twice daily, plus aspirin (75-100 mg) once daily.

Adult dosage

Acute Coronary Syndrome
The recommended dose is 2.5 mg twice daily. Patients should also take a daily dose of 75 - 100 mg ASA or a daily dose of 75 - 100 mg ASA in addition to either a daily dose of 75 mg clopidogrel or a standard daily dose of ticlopidine.
Treatment should be regularly evaluated in the individual patient weighing the risk for ischaemic events against the bleeding risks. Extension of treatment beyond 12 months should be done on an individual patient basis as experience up to 24 months is limited.
Treatment with Xcept should be started as soon as possible after stabilisation of the ACS event (including revascularisation procedures); at the earliest 24 hours after admission to hospital and at the time when parenteral anticoagulation therapy would normally be discontinued.
If a dose is missed the patient should continue with the regular dose as recommended at the next scheduled time. The dose should not be doubled to make up for a missed dose.

Converting from Vitamin K Antagonists (VKA) to Xcept
When converting patients from VKAs to Xcept, International Normalized Ratio (INR) values will be falsely elevated after the intake of Xcept. The INR is not valid to measure the anticoagulant activity of Xcept, and therefore should not be used.

Converting from Xcept to Vitamin K antagonists (VKA)
There is a potential for inadequate anticoagulation during the transition from Xcept to VKA. Continuous adequate anticoagulation should be ensured during any transition to an alternate anticoagulant. It should be noted that Xcept can contribute to an elevated INR.
In patients converting from Xcept to VKA, VKA should be given concurrently until the INR is ≥ 2.0. For the first two days of the conversion period, standard initial dosing of VKA should be used followed by VKA dosing, as guided by INR testing. While patients are on both Xcept and VKA the INR should not be tested earlier than 24 hours after the previous dose but prior to the next dose of Xcept. Once Xcept is discontinued INR testing may be done reliably at least 24 hours after the last dose.

Converting from parenteral anticoagulants to Xcept
For patients currently receiving a parenteral anticoagulant, discontinue the parenteral anticoagulant and start Xcept 0 to 2 hours before the time that the next scheduled administration of the parenteral medicinal product (e.g. low molecular weight heparins) would be due or at the time of discontinuation of a continuously administered parenteral medicinal product (e.g. intravenous unfractionated heparin).

Converting from Xcept to parenteral anticoagulants
Give the first dose of parenteral anticoagulant at the time the next Xcept dose would be taken.

Dosage adjustment

Renal impairment
Limited clinical data for patients with severe renal impairment (creatinine clearance 15 - 29 ml/min) indicate that Rivaroxaban plasma concentrations are significantly increased. Therefore, Xcept is to be used with caution in these patients. Use is not recommended in patients with creatinine clearance < 15 ml/min. No dose adjustment is necessary in patients with mild renal impairment (creatinine clearance 50 - 80 ml/min) or moderate renal impairment (creatinine clearance 30 - 49 ml/min) but patients with moderate renal impairment should be monitored for any signs and symptoms of bleeding

Hepatic impairment
Xcept is contraindicated in patients with hepatic disease associated with coagulopathy and clinically relevant bleeding risk including cirrhotic patients with Child Pugh B and C.

Elderly
No dose adjustment needed but caution and monitoring is advised.

Gender
No dose adjustment is required.

Pediatric population
The safety and efficacy of Xcept in children aged 0 to 18 years have not been established. No data are available. Therefore, Xcept is not recommended for use in children below 18 years of age.

Dosing recommendations before and after invasive procedures and surgical intervention
If an invasive procedure or surgical intervention is required, Xcept 2.5 mg should be stopped at least 24 hours before the intervention, if possible and based on the clinical judgement of the physician. If a patient is to undergo elective surgery and anti-platelet effect is not desired, platelet aggregation inhibitors should be discontinued as directed by the manufacturer's prescribing information. If the procedure cannot be delayed the increased risk of bleeding should be assessed against the urgency of the intervention.
Xcept should be restarted as soon as possible after the invasive procedure or surgical intervention provided the clinical situation allows and adequate haemostasis has been established as determined by the treating physician.

Administration requirements
For oral use. Xcept can be taken with or without food.

CONTRAINDICATIONS
• Hypersensitivity to the active substance
• Active clinically significant bleeding
• Lesion or condition, if considered to be a significant risk for major bleeding. This may include 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
• Hepatic disease associated with coagulopathy and clinically relevant bleeding risk including cirrhotic patients with Child Pugh B and C
• Pregnancy and breast feeding

WARNING AND PRECAUTIONS

Haemorrhagic risk
As with other anticoagulants, patients taking Rivaroxaban are to be carefully observed for signs of bleeding. It is recommended to be used with caution in conditions with increased risk of haemorrhage. Rivaroxaban administration should be discontinued if severe haemorrhage occurs. In addition to adequate clinical surveillance, laboratory testing of haemoglobin/haematocrit could be of value to detect occult bleeding and quantify the clinical relevance of overt bleeding, as judged to be appropriate. The use of Rivaroxaban in combination with dual antiplatelet therapy in patients at known increased risk for bleeding should be balanced against the benefit in terms of prevention of atherothrombotic events. In addition these patients are to be carefully monitored for signs and symptoms of bleeding complications and anaemia after initiation of treatment. Any unexplained fall in haemoglobin or blood pressure should lead to a search for a bleeding site. Although treatment with Rivaroxaban does not require routine monitoring of exposure, Rivaroxaban levels measured with a calibrated quantitative anti-factor Xa assay may be useful in exceptional situations where knowledge of Rivaroxaban exposure may help to inform clinical decisions, e.g., overdose and emergency surgery.

Renal impairment
In patients with severe renal impairment (creatinine clearance < 30 ml/min) Rivaroxaban plasma levels may be significantly increased (1.6 fold on average) which may lead to an increased bleeding risk. Rivaroxaban is to be used with caution in patients with creatinine clearance 15 - 29 ml/min. Use is not recommended in patients with creatinine clearance < 15 ml/min. In patients with moderate renal impairment (creatinine clearance 30 - 49 ml/min) concomitantly receiving other medicinal products which increase Rivaroxaban plasma concentrations Rivaroxaban is to be used with caution.

Other haemorrhagic risk factors
As with other antithrombotics, Rivaroxaban is not recommended in patients with an increased bleeding risk such as:
• congenital or acquired bleeding disorders
• uncontrolled severe arterial hypertension
• other gastrointestinal disease without active ulceration that can potentially lead to bleeding complications (e.g. inflammatory bowel disease, oesophagitis, gastritis and gastroesophageal reflux disease)
• vascular retinopathy
• bronchiectasis or history of pulmonary bleeding
• It should be used with caution in ACS patients:
• > 75 years of age if co-administered with ASA alone or with ASA plus clopidogrel or ticlopidine
• with low body weight (< 60 kg) if co-administered with ASA alone or with ASA plus clopidogrel or ticlopidine

Patients with prosthetic valves
Safety and efficacy of Rivaroxaban have not been studied in patients with prosthetic heart valves; therefore, there are no data to support that Rivaroxaban provides adequate anticoagulation in this patient population. Treatment with Rivaroxaban is not recommended for these patients.

Patients with antiphospholipid syndrome
Direct acting Oral Anticoagulants (DOACs) including rivaroxaban are not recommended for patients with a history of thrombosis who are diagnosed with antiphospholipid syndrome. In particular for patients that are triple positive (for lupus anticoagulant, anticardiolipin antibodies, and anti-beta 2-glycoprotein I antibodies), treatment with DOACs could be associated with increased rates of recurrent thrombotic events compared with vitamin K antagonist therapy.

Patients with prior stroke or Transient Ischemic Attack (TIA)
Rivaroxaban 2.5 mg is contraindicated for the treatment of ACS in patients with a prior stroke or TIA. Few ACS patients with a prior stroke or TIA have been studied but the limited efficacy data available indicate that these patients do not benefit from treatment.

Spinal/epidural anaesthesia or puncture
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. The risk of these events may be increased by the post-operative use of indwelling epidural catheters or the concomitant use of medicinal products affecting haemostasis. The risk may also be increased by traumatic or repeated epidural or spinal puncture. 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. 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.
ituations.
To reduce the potential risk of bleeding associated with the concurrent use of Rivaroxaban and neuraxial (epidural/spinal) anaesthesia or spinal puncture, consider the pharmacokinetic profile of Rivaroxaban. Placement or removal of an epidural catheter or lumbar puncture is best performed when the anticoagulant effect of Rivaroxaban is estimated to be low. However, the exact timing to reach a sufficiently low anticoagulant effect in each patient is not known. Platelet aggregation inhibitors should be discontinued.

Dermatological reactions
Serious skin reactions, including Stevens-Johnson syndrome/Toxic Epidermal Necrolysis, may be observed with the use of Rivaroxaban. Patients appear to be at highest risk for these reactions early in the course of therapy: the onset of the reaction occurring in the majority of cases within the first weeks of treatment. Rivaroxaban should be discontinued at the first appearance of a severe skin rash (e.g. spreading, intense and/or blistering), or any other sign of hypersensitivity in conjunction with mucosal lesions.

Effects on ability to drive and use machines
Rivaroxaban has minor influence on the ability to drive and use machines. Adverse reactions like syncope (frequency: uncommon) and dizziness (frequency: common) may occur. Patients experiencing these adverse reactions should not drive or use machines.

ADVERSE REACTIONS

Blood and lymphatic system disorders
Common: Anemia (incl. respective laboratory parameters)
Uncommon: Thrombocythemia (incl. platelet count increased)[A]
Immune system disorders
Uncommon: Allergic reactions, dermatitis allergic.
Nervous system disorders
Common: Dizziness, headache
Uncommon: Cerebral and intracranial hemorrhage, syncope
Eye disorders
Common: Eye hemorrhagic (Incl. conjuctival hemorrhage).
Cardiac disorders
Uncommon: Tachycardia
Vascular disorders
Common: Hypotension, hematoma
Respiratory, thoracic and mediastinal disorders
Common: Epistaxis, hemoptysis
Gastrointestinal disorders
Common: Gingival bleeding, gastrointestinal tract hemorrhage (incl. rectal hemorrhage), gastrointestinal and abdominal pains, dyspepsia, nausea, constipationA, diarrhea, vomiting[A]
Uncommon: dry mouth
Hepatobiliary disorders
Uncommon: Hepatic function abnormal
Rare: Jaundice
Skin and subcutaneous tissue disorders
Common: Pruritus (incl. uncommon cases of generalized pruritus), rash, ecchymosis, cutaneous and subcutaneous hemorrhage
Uncommon: Urticaria
Musculoskeletal and connective tissue disorders
Common: Pain in extremity[A]
Uncommon: Hemarthrosis.
Rare: Muscle hemorrhage
Not known: Compartment syndrome secondary to a bleeding.
Renal and urinary disorders
Common: Urogenital tract hemorrhage (incl. hematuria and menorrhagia[B]), renal impairment (incl. blood creatinine increased, blood urea increased)[A]
Not known: Renal failure/acute renal failure secondary to a bleeding sufficient to cause hypoperfusion
General disorders and administration site conditions
Common: Fever[A], peripheral edema, decreased general strength and energy (incl. fatigue and asthenia)
Uncommon: Feeling unwell (incl. malaise)
Rare: Localized edema[A]
Investigations
Common: Increase in transaminase
Uncommon: Increased bilirubin, increased alkaline phosphataseA, increased LDHA, increased lipaseA, increased amylaseA, increased GGT[A]
Rare: Bilirubin conjugated increased (with or without concomitant increase of ALT).
Injury, poisoning and procedural complications
Common: Postprocedural hemorrhage (incl. postoperative anemia, and wound hemorrhage), contusion, wound secretion[A]
Rare: Vascular pseudoaneurysm[C]
A: observed in prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery
B: observed in treatment of DVT, PE and prevention of recurrence as very common in women < 55 years
C: observed as uncommon in prevention of atherothrombotic events in patients after an ACS (following percutaneous coronary intervention)

DRUG INTERACTIONS

CYP3A4 and P-gp inhibitors
Co-administration of Rivaroxaban with ketoconazole (400 mg once a day) or ritonavir (600 mg twice a day) led to a 2.6 fold / 2.5 fold increase in mean Rivaroxaban AUC and a 1.7 fold / 1.6 fold increase in mean Rivaroxaban Cmax, with significant increases in pharmacodynamic effects which may lead to an increased bleeding risk. Therefore, the use of Rivaroxaban is not recommended in patients receiving concomitant systemic treatment with azole-antimycotics such as ketoconazole, itraconazole, voriconazole and posaconazole or HIV protease inhibitors. These active substances are strong inhibitors of both CYP3A4 and P-gp. Given the limited clinical data available with dronedarone, co-administration with Rivaroxaban should be avoided.

Anticoagulants
After combined administration of enoxaparin (40 mg single dose) with Rivaroxaban (10 mg single dose) an additive effect on anti-factor Xa activity is observed without any additional effects on clotting tests (PT, aPTT). Enoxaparin does not affect the pharmacokinetics of Rivaroxaban.
Due to the increased bleeding risk care is to be taken if patients are treated concomitantly with any other anticoagulants.

NSAIDs/Platelet aggregation inhibitors
No clinically relevant interactions are observed with NSAIDs/platelet aggregation inhibitors (naproxen, acetylsalicylic acid, Clopidogrel). Care is to be taken if patients are treated concomitantly with NSAIDs (including acetylsalicylic acid) and platelet aggregation inhibitors because these medicinal products typically increase the bleeding risk.

SSRIs/SNRIs
As with other anticoagulants the possibility may exist that patients are at increased risk of bleeding in case of concomitant use with SSRIs or SNRIs due to their reported effect on platelets.

CYP3A4 inducers
Co-administration of Rivaroxaban with the strong CYP3A4 inducer rifampicin leads to an approximate 50% decrease in mean Rivaroxaban AUC, with parallel decreases in its pharmacodynamic effects. The concomitant use of Rivaroxaban with other strong CYP3A4 inducers (e.g. phenytoin, carbamazepine, phenobarbital or St. John's Wort (Hypericum perforatum)) may also lead to reduced Rivaroxaban plasma concentrations. Therefore, concomitant administration of strong CYP3A4 inducers should be avoided unless the patient is closely observed for signs and symptoms of thrombosis.
Concominant use with Defibrotide
Concurrent use of defibrotide and antithrombotics may result in increased risk of bleeding. Concominant use should be avoided.

USE IN SPECIAL POPULATIONS

Pregnancy
Safety and efficacy of Rivaroxaban have not been established in pregnant women. Rivaroxaban is contraindicated during pregnancy.
Nursing mother
Safety and efficacy of Rivaroxaban have not been established in breast feeding women. Use should be avoided.
Pediatrics
The safety and efficacy of Rivaroxaban in children aged 0 to 18 years have not been established.
Elderly
No dose adjustment is recommended.
Renal impairment
No dose adjustment is necessary in patients with mild-moderate renal impairment. In severe renal impairment, caution should be exercised.
Hepatic impairment
Rivaroxaban is contraindicated in patients with hepatic disease associated with coagulopathy and clinically relevant bleeding risk including cirrhotic patients with Child Pugh B and C.

OVER DOSAGE
Rare cases of overdose up to 600 mg have been reported without bleeding complications or other adverse reactions. Due to limited absorption a ceiling effect with no further increase in average plasma exposure is expected at supratherapeutic doses of 50 mg rivaroxaban or above. A specific reversal agent (andexanet alfa) antagonising the pharmacodynamic effect of rivaroxaban is available. The use of activated charcoal to reduce absorption in case of rivaroxaban overdose may be considered.

PRESENTATION
XCEPT® 2.5mg : Pack of 10's tablets.

INSTRUCTIONS
Use as advised by the physician.
Keep all medicines out of the reach of children.
To be sold on the prescription of a registered medical practitioner only.
Protect from light, heat and moisture.
Store below 30°C.
For suspected adverse drug reaction, email us at
reports@pharmevo.biz

For more information on our products
call PharmAssist helpline 0800-82222
Monday to Friday 9:00 am to 6:00 pm
or email us at : pharmassist@pharmevo.biz

Manufactured by:

Our dream, a healthier society

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ہدایات:
ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔
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صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کی جائے۔
روشنی، گرمی اور نمی سے محفوظ، 30°C سے کم درجہ حرارت پر رکھیں۔
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پر مطلع کریں۔

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