12-05-2021
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RITBAN® Tablets
(Rivaroxaban)

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information

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. Factors that can increase the risk of developing epidural or spinal hematomas in these patients include:
● Use of indwelling epidural catheters. ●Concomitant use of other drugs that affect hemostasis, such as nonsteroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, other anticoagulants. ● A history of traumatic or repeated epidural or spinal punctures, spinal deformity or spinal surgery.
● Optimal timing between the administration of rivaroxaban and neuraxial procedures is not known.
Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary. Consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis.

QUALITATIVE AND QUANTITATIVE COMPOSITION

RITBAN® Tablet 2.5mg	RITBAN® 10mg Tablet	RITBAN® 15mg Tablet	RITBAN® 20mg Tablet
Each film coated tablet contains:	Each film coated tablet contains:	Each film coated tablet contains:	Each film coated tablet contains:
Rivaroxaban MS.....2.5mg	Rivaroxaban MS.....10mg	Rivaroxaban MS.....15mg	Rivaroxaban MS.....20mg

PHARMACEUTICAL FORM
Tablet

CLINICAL PARTICULARS
THERAPEUTIC INDICATIONS: Adults: Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischemic attack. Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. Paediatric population: Treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years and weighing more than 50kg after at least 5 days of initial parenteral anticoagulation treatment.
POSOLOGY AND METHOD OF ADMINISTRATION:
Posology: Acute Coronary Syndrome (ACS): Patient taking **RITBAN®** tablet 2.5mg twice daily should also take a daily dose of 75 - 100mg acetylsalicylic acid (ASA) in addition to either a daily dose of 75mg clopidogrel or a standard daily dose of ticlopidine. Treatment should be regularly evaluated in the individual patient weighing the risk for ischemic events against the bleeding risks. Treatment should be started as soon as possible after stabilization of the ACS event (including revascularization procedures); at the earliest 24 hours after admission to hospital and at the time when parenteral anticoagulation therapy would normally be discontinued. **Reduction of Coronary Artery Disease (CAD) or symptomatic Peripheral Artery Disease (PAD):** Patients taking rivaroxaban 2.5mg twice daily should also take a daily dose of 75 - 100mg acetylsalicylic acid (ASA). duration of treatment should be determined for each individual patient based on regular evaluations and should consider the risk for thrombotic events versus the bleeding risks. **Prevention of stroke and systemic embolism in adults:** The recommended dose is 20mg once daily, which is also the recommended maximum dose. Therapy should be continued long term provided the benefit of prevention of stroke and systemic embolism outweighs the risk of bleeding. If a dose is missed the patient should take immediately The dose should not be doubled within the same day to make up for a missed dose. **Treatment of DVT, treatment of PE and prevention of recurrent DVT and PE in adults:** The recommended dose for the initial treatment of acute DVT or PE is 15mg twice daily for the first three weeks followed by 20mg once daily for the continued treatment and prevention of recurrent DVT and PE. Short duration of therapy (at least 3 months) should be considered in patients with DVT or PE provoked by major transient risk factors (i.e. recent major surgery or trauma). When extended prevention of recurrent DVT and PE is indicated (following completion of at least 6 months' therapy for DVT or PE), the recommended dose is 10mg once daily. In patients in whom the risk of recurrent DVT or PE is considered high, such as those with complicated comorbidities, or who have developed recurrent DVT or PE on extended prevention with 10mg once daily, a dose of 20mg once daily should be considered. The duration of therapy and dose selection should be individualized after careful assessment of the treatment benefit against the risk for bleeding.

	Time period	Dosing schedule	Total daily dose
Treatment and prevention of recurrent DVT and PE	Day 1 - 21	15mg twice daily	30mg
	Day 22 onwards	20mg once daily	20mg
Prevention of recurrent DVT and PE	Following completion of at least 6 months therapy for DVT or PE	10mg once daily or 20mg once daily	10mg or 20mg

If a dose is missed during the 15mg twice daily treatment phase (day 1 - 21), the patient should take immediately to ensure intake of 30mg per day. In this case two 15mg tablets may be taken at once. The patient should continue with the regular 15mg twice daily intake as recommended on the following day. If a dose is missed during the once daily treatment phase, the patient should take immediately, and continue on the following day with the once daily intake as recommended. The dose should not be doubled within the same day to make up for a missed dose.
Treatment of VTE and prevention of VTE recurrence in children and adolescents: Rivaroxaban tablet treatment in children and adolescents aged less than 18 years should be initiated following at least 5 days of initial parenteral anticoagulation treatment .
The dose for children and adolescent is calculated based on body weight.
● **Body weight of 50kg or more:** once daily dose of 20mg rivaroxaban is recommended. This is the maximum daily dose.
● **Body weight from 30 to 50kg:** once daily dose of 15mg rivaroxaban is recommended. This is the maximum daily dose.
The weight of a child should be monitored and the dose reviewed regularly. This is to ensure a therapeutic dose is maintained. Dose adjustments should be made based on changes in body weight only. Treatment should be continued for at least 3 months in children and adolescents. Treatment can be extended up to 12 months when clinically necessary. There is no data available in children to support a dose reduction after 6 months treatment. The benefit-risk of continued therapy after 3 months should be assessed on an individual basis taking into account the risk for recurrent thrombosis versus the potential bleeding risk. If a dose is missed, the missed dose should be taken as soon as possible after it is noticed, but only on the same day. If this is not possible, the patient should skip the dose and continue with the next dose as prescribed. The patient should not take two doses to make up for a missed dose. **Converting from Vitamin K Antagonists (VKA) to Rivaroxaban Tablet:** Prevention of stroke and systemic embolism VKA treatment should be stopped and therapy should be initiated when the International Normalised Ratio (INR) is ≤ 3.0. Treatment of DVT, PE and prevention of recurrence in adults and treatment of VTE and prevention of recurrence in paediatric patients. VKA treatment should be stopped and therapy should be initiated once the INR is ≤ 2.5. When converting patients from VKAs to rivaroxaban, INR values will be falsely elevated after the intake. The INR is not valid to measure the anticoagulant activity, and therefore should not be used. **Converting from rivaroxaban (RITBAN®) to Vitamin K antagonists (VKA):** In patients converting from rivaroxaban 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 should be used followed by VKA dosing, as guided by INR testing. While patients are on both rivaroxaban and VKA the INR should not be tested earlier than 24 hours after the previous dose but prior to the next dose of rivaroxaban. Once discontinued INR testing may be done reliably at least 24 hours after the last dose. **Paediatric patients:** Children who convert from rivaroxaban to VKA need to continue for 48 hours after the first dose of VKA. After 2 days of co-administration an INR should be obtained prior to the next scheduled dose of rivaroxaban. Co-administration of rivaroxaban and VKA is advised to continue until the INR is ≥ 2.0. Once discontinued INR testing may be done reliably 24 hours after the last dose. **Converting from parenteral anticoagulants to rivaroxaban:** For adult and paediatric patients currently receiving a parenteral anticoagulant, discontinue the parenteral anticoagulant and start 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 rivaroxaban to parenteral anticoagulants:** Discontinue and give the first dose of parenteral anticoagulant at the time the next rivaroxaban dose would be taken.
SPECIAL POPULATIONS:
Renal impairment: Adults: Limited clinical data for patients with severe renal impairment (creatinine clearance 15 - 29 ml/min) indicate that rivaroxaban plasma concentrations are significantly increased. Therefore, used with caution in these patients. Use is not recommended in patients with creatinine clearance < 15 ml/min.
In patients with moderate (creatinine clearance 30 - 49 ml/min) or severe (creatinine clearance 15 - 29 ml/min) renal impairment the following dose recommendations apply:
● For the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation, the recommended dose is 15mg once daily.
● For the treatment of DVT, treatment of PE and prevention of recurrent DVT and PE: Patients should be treated with 15mg twice daily for the first 3 weeks. Thereafter, when the recommended dose is 20mg once daily, a reduction of the dose from 20mg once daily to 15mg once daily should be considered if the patient's assessed risk for bleeding outweighs the risk for recurrent DVT and PE.
When the recommended dose is 10mg once daily, no dose adjustment from the recommended dose is necessary. No dose adjustment is necessary in patients with mild renal impairment (creatinine clearance 50 - 80 ml/min).
Paediatric population: ● Children and adolescents with mild renal impairment (glomerular filtration rate 50 - 80 mL/min/1.73m²): no dose adjustment is required, based on data in adults and limited data in paediatric patients. ● Children and adolescents with moderate or severe renal impairment (glomerular filtration rate < 50 mL/min/1.73m²): rivaroxaban is not recommended as no clinical data is available. ● Rivaroxaban 2.5mg tablets are not recommended for use in children below 18 years of age. **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. No clinical data is available in children with hepatic impairment. **Elderly population:** No dose adjustment. **Body weight:** No dose adjustment for adults. For paediatric patients the dose is determined based on body weight. **Gender:** No dose adjustment. **Patients undergoing cardioversion:** Rivaroxaban can be initiated or continued in patients who may require cardioversion. For transesophageal echocardiogram (TEE) guided cardioversion in patients not previously treated with anticoagulants, rivaroxaban treatment should be started at least 4 hours before cardioversion to ensure adequate anticoagulation. For all patients, confirmation should be sought prior to cardioversion that the patient has taken as prescribed. **Patients with non-valvular atrial fibrillation who undergo PCI (percutaneous coronary intervention) with stent placement:** There is limited experience of a reduced dose of 15mg once daily or 10mg once daily for patients with moderate renal impairment (creatinine clearance 30 - 49 ml/min]). **Paediatric population:** The safety and efficacy in children aged 0 to < 18 years have not been established . No data are available.
METHOD OF ADMINISTRATION: Adults: Rivaroxaban is for oral use. The tablets are to be taken with food. **Children and adolescents weighing more than 50kg:** Rivaroxaban is for oral use. The patient should be advised to swallow the tablet with liquid. It should also be taken with food. The tablets should be taken approximately 24 hours apart. In case the patient immediately spits up the dose or vomits within 30 minutes after receiving the dose, a new dose should be given. However, if the patient vomits

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more than 30 minutes after the dose, the dose should not be re-administered and the next dose should be taken as scheduled. **Crushing of tablets:** For patients who are unable to swallow whole tablets, these could be provided by crushing the 15mg or 20mg tablet and mixing it with water or food immediately prior to use and administering orally. The crushed tablet may be given through a nasogastric or gastric feeding tube.

CONTRAINDICATIONS: Hypersensitivity to the active substance or to any of the excipients. ● 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 hemorrhage, known or suspected esophageal varices, arteriovenous malformations, vascular aneurysms or major intraspinal or intracerebral vascular abnormalities. ● Concomitant treatment with any other anticoagulants, e.g. unfractionated heparin (UFH), low molecular weight heparins (enoxaparin, dalteparin, etc.), heparin derivatives (fondaparinux, etc.), oral anticoagulants (warfarin, dabigatran etexilate, apixaban, etc.) 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. ● Hepatic disease associated with coagulopathy and clinically relevant bleeding risk including cirrhotic patients with Child Pugh B and C. ● Pregnancy and breast-feeding.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE: Clinical surveillance in line with anticoagulation practice is recommended throughout the treatment period. **Hemorrhagic risk:** As with other anticoagulants, patients taking are to be carefully observed for signs of bleeding. It is recommended to be used with caution in conditions with increased risk of hemorrhage. Administration should be discontinued if severe haemorrhage occurs. **Paediatric population:** There is limited data in children with cerebral vein and sinus thrombosis who have a CNS infection. The risk of bleeding should be carefully evaluated before and during therapy with rivaroxaban. **Renal impairment:** In adult 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. Used with caution in patients with creatinine clearance 15 - 29 ml/min. Use is not recommended in patients with creatinine clearance < 15 ml/min. Rivaroxaban is not recommended in children and adolescents with moderate or severe renal impairment (glomerular filtration rate < 50 mL/min/1.73 m^2), as no clinical data is available. **Interaction with other medicinal products:** The use is not recommended in patients receiving concomitant systemic treatment with azole-antimycotics (such as ketoconazole, itraconazole, voriconazole and posaconazole) or HIV protease inhibitors (e.g. ritonavir). Care is to be taken if patients are treated concomitantly such as non-steroidal anti-inflammatory medicinal products (NSAIDs), acetylsalicylic acid and platelet aggregation inhibitors or selective serotonin reuptake inhibitors (SSRIs), and serotonin norepinephrine reuptake inhibitors (SNRIs). For patients at risk of ulcerative gastrointestinal disease an appropriate prophylactic treatment may be considered. **Other haemorrhagic risk factors:** As with other antithrombotics, rivaroxaban is not recommended in patients with an increased bleeding risk lead to bleeding complications (e.g. inflammatory bowel disease, oesophagitis, gastritis and gastroesophageal reflux disease), vascular retinopathy/ bronchiectasis or history of pulmonary bleeding. **Patients with prosthetic valves:** Rivaroxaban should not be used for thromboprophylaxis in patients having recently undergone transcatheter aortic valve replacement (TAVR). **Patients with antiphospholipid syndrome:** Not recommended for patients with a history of thrombosis who are diagnosed with antiphospholipid syndrome. **Patients with non-valvular atrial fibrillation who undergo PCI with stent placement:** No data are available for such patients with a history of stroke/transient ischemic attack (TIA). **Haemodynamically unstable PE patients or patients who require thrombolysis or pulmonary embolectomy:** Not recommended, since the safety and efficacy of Rivaroxaban have not been established. **Spinal/epidural anaesthesia or 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. No data is available on the timing of the placement or removal of neuraxial catheter in children while on rivaroxaban. Discontinue rivaroxaban and consider a short acting parenteral anticoagulant. Dosing recommendations before and after invasive procedures and surgical intervention: If an invasive procedure or surgical intervention is required, 20mg should be stopped at least 24 hours before the intervention. Rivaroxaban should be restarted as soon as possible after the invasive procedure or surgical intervention provided the clinical situation allows and adequate hemostasis has been established as determined by the treating physician. **Elderly population:** Increasing age may increase hemorrhagic risk. **Dermatological reactions:** Serious skin reactions, including Stevens-Johnson syndrome/toxic epidermal necrolysis and DRESS syndrome, have been reported during post-marketing surveillance in association with the use of rivaroxaban. **Information about excipients:** Rivaroxaban contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. This medicinal product contains less than 1 mmol sodium (23mg) per dosage unit, that is to say essentially "sodium-free".

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTIONS: The extent of interactions in the paediatric population is not known. The below mentioned interaction are as follows. **CYP3A4 and P-gp inhibitors:** 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. Clarithromycin (500mg twice a day), the interaction with clarithromycin is likely not clinically relevant in most patients but can be potentially significant in high-risk patients. (For patients with renal impairment). Erythromycin (500mg three times a day). The interaction with erythromycin is likely not clinically relevant in most patients but can be potentially significant in high-risk patients. Fluconazole (400mg once daily). The interaction with fluconazole is likely not clinically relevant in most patients but can be potentially significant in high-risk patients. (For patients with renal impairment). Given the limited clinical data available with dronedarone, co-administration with rivaroxaban should be avoided. **Anticoagulants:** Due to the increased bleeding risk care is to be taken if patients are treated concomitantly with any other anticoagulants. **NSAIDs/platelet aggregation inhibitors:** Care is to be taken if patients are treated concomitantly with NSAIDs. **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. **Warfarin:** No pharmacokinetic interaction was observed between warfarin and rivaroxaban. **CYP3A4 inducers:** The concomitant use of rivaroxaban with other. phenytoin, carbamazepine, phenobarbital or St. John's Wort (Hypericum perforatum)) may also lead to reduced rivaroxaban plasma concentrations. Therefore, concomitant administration should be avoided. **Other concomitant therapies:** No clinically significant pharmacokinetic or pharmacodynamic interactions were observed when rivaroxaban was co-administered with midazolam, digoxin, atorvastatin or omeprazole. **Laboratory parameters:** Clotting parameters (e.g. PT, aPTT, HepTest) are affected as expected by the mode of action of rivaroxaban.

FERTILITY, PREGNANCY AND LACTATION: Fertility: No specific studies with rivaroxaban in humans have been conducted to evaluate effects on fertility. **Pregnancy:** Safety and efficacy have not been established in pregnant women. Rivaroxaban is contraindicated during pregnancy. Women of child-bearing potential should avoid becoming pregnant during treatment with rivaroxaban. **Breast-feeding:** Safety and efficacy have not been established in breast-feeding women.

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) have been reported. Patients experiencing these adverse reactions should not drive or use machines.

UNDESIRABLE EFFECTS: The following adverse reactions have been identified during post-approval use of rivaroxaban. ● **Blood and lymphatic system disorders:** agranulocytosis, thrombocytopenia. ● **Hepatobiliary disorders:** jaundice, cholestasis, hepatitis (including hepatocellular injury). ● **Immune system disorders:** hypersensitivity, anaphylactic reaction, anaphylactic shock, angioedema. ● **Nervous system disorders:** hemiparesis. ● **Skin and subcutaneous tissue disorders:** Stevens-Johnson syndrome, drug reaction with eosinophilia and systemic symptoms (DRESS). ● **Gastrointestinal disorders:** Gingival bleeding, gastrointestinal tract hemorrhage (incl. rectal hemorrhage), gastrointestinal and abdominal pains, dyspepsia, nausea, constipation, diarrhoea, vomiting, dry mouth. **Description of selected adverse reactions:** ● Due to the pharmacological mode of action, the use of may be associated with an increased risk of occult or overt bleeding from any tissue or organ which may result in post haemorrhagic anaemia. The signs, symptoms, and severity (including fatal outcome) will vary according to the location and degree or extent of the bleeding and/or anaemia. ● In the clinical studies mucosal bleedings (i.e. epistaxis, gingival, gastrointestinal, genitourinary including abnormal vaginal or increased menstrual bleeding) and anemia were seen more frequently during long term rivaroxaban treatment compared with VKA treatment. ● Menstrual bleeding may be intensified and/or prolonged. Hemorrhagic complications may present as weakness, paleness, dizziness, headache or unexplained swelling, dyspnea and unexplained shock. In some cases, as a consequence of anemia, symptoms of cardiac ischemia like chest pain or angina pectoris have been observed. ● Known complications secondary to severe bleeding such as compartment syndrome and renal failure due to hypoperfusion have been reported. **Paediatric population:** ● In paediatric patients, headache (very common, 16.7%), fever (very common, 11.7%), epistaxis (very common, 11.2%), vomiting (very common, 10.7%), tachycardia (common, 1.5%), increase in bilirubin (common, 1.5%) and bilirubin conjugated increased (uncommon, 0.7%) were reported more frequently as compared to adults. ● Consistent with adult population, menorrhagia was observed in 6.6% (common) of female adolescents after menarche. Thrombocytopenia as observed in the post-marketing experience in adult population was common (4.6%) in paediatric clinical studies. The adverse drug reactions in paediatric patients were primarily mild to moderate in severity.

OVERDOSE: In adults, rare cases of overdose up to 600mg have been reported without bleeding complications or other adverse reactions. There is limited data available in children. The use of activated charcoal to reduce absorption in case of rivaroxaban overdose may be considered. Management should be individualized according to the severity and location of the hemorrhage. Appropriate symptomatic treatment could be used as needed, such as mechanical compression (e.g. for severe epistaxis), surgical hemostasis with bleeding control procedures, fluid replacement and hemodynamic support, blood products (packed red cells or fresh frozen plasma, depending on associated anemia or coagulopathy) or platelets.

PHARMACOLOGICAL PROPERTIES

PHARMACODYNAMIC PROPERTIES: Pharmacotherapeutic group: Antithrombotic agents, direct factor Xa inhibitors. **ATC code:** B01AF01

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. **PHARMACOKINETIC PROPERTIES: Absorption:** The following information is based on the data obtained in adults. Rivaroxaban is rapidly absorbed with maximum concentrations (Cmax) appearing 2 - 4 hours after tablet intake. Oral absorption of rivaroxaban is almost complete and oral bioavailability is high (80 - 100%) for the 2.5mg and 10mg tablet dose, irrespective of fasting/fed conditions. Intake with food does not affect rivaroxaban AUC or Cmax at the 2.5mg and 10mg dose. Rivaroxaban 15mg and 20mg are to be taken with food. **Distribution:** Plasma protein binding in adults is high at approximately 92% to 95%, with serum albumin being the main binding component. The volume of distribution is moderate with Vss being approximately 50 litres. **Biotransformation and elimination:** In adults, 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. 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.

SHELF LIFE

See expiry on the pack.

AVAILABILITY

RITBAN® tablet 2.5mg in a pack of 14's
RITBAN® 10mg tablet in a pack of 10's
RITBAN® 15mg tablet in a pack of 14's
RITBAN® 20mg tablet in a pack of 14's

INSTRUCTIONS

Dosage: As advised by the physician.
To be sold on the prescription of registered medical practitioner.
Keep out of reach of children.
Avoid exposure to heat, light and humidity.
Store between 15 to 30°C.
Improper storage may deteriorate the medicine.

رٹبان® ٹیبلٹ

(ریواروکسیبان)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔
بچوں کی پہنچ سے دور رکھیں۔
دوا کو گرمی، روشنی اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری
سینٹی گریڈ کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی۔

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