Rivaroxaban Clonmel 15 mg & 20 mg film-coated tablets (Rivaroxaban) Prescriber Guide

This Prescriber Guide is not a substitute for the Rivaroxaban Clonmel Summary of Product Characteristics (SmPC). Please consult the SmPC for full prescribing information.

A digital version of the Prescriber Guide is available at the following website address: www.hpra.ie

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

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CLONMEL HEALTHCARE
STADA GROUP

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Patient Alert Card

A patient alert card is provided to each patient who is prescribed Rivaroxaban Clonmel with the product package. The implications of anticoagulant treatment should be explained and the importance of compliance, signs of bleeding and when to seek medical attention discussed with the patient or the caregivers.

The patient alert card will inform physicians and dentists about the patient's anticoagulation treatment and will contain emergency contact information. The patient should be instructed to carry the patient alert card at all times and present it to every healthcare provider.

Additional copies of the Patient Alert Card can be obtained by contacting Clonmel Healthcare Ltd. by e-mail at medicalinformation@clonmel-health.ie or by phone 052 6177777.

Prescriber Guide

The Prescriber Guide provides recommendations for the use of Rivaroxaban Clonmel in order to minimise the risk of bleeding during treatment with Rivaroxaban Clonmel.

For further information and additional details on Rivaroxaban Clonmel, please see the Summary of Product Characteristics (SmPC).

The Prescriber Guide does not substitute the Rivaroxaban Clonmel (SmPC). Before prescribing please also read the Rivaroxaban Clonmel SmPC.

Dosing Recommendations

Stroke prevention in adult patients with non-valvular atrial fibrillation

The recommended dose for 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 ischaemic attack (TIA) is 20 mg once daily.

ADULT DOSING SCHEME	
	
Continuous treatment	
Rivaroxaban Clonmel 20 mg once daily*	Take with food

*Recommended dosing scheme for patients with atrial fibrillation and moderate or severe renal impairment see next page.

Patients with renal impairment

In patients with moderate (creatinine clearance [CrCl] 30–49 mL/min) or severe (CrCl 15–29 mL/min) renal impairment the recommended dose is 15 mg once daily. Rivaroxaban Clonmel is to be used with caution in patients with severe renal impairment (CrCl 15–29 mL/min) and is not recommended in patients with CrCl <15 mL/min.

Rivaroxaban Clonmel should be used with caution in patients with renal impairment concomitantly receiving other medicinal products that increase rivaroxaban plasma concentrations.

Duration of therapy

Rivaroxaban Clonmel should be continued long term provided the benefit of stroke prevention therapy outweighs the potential risk of bleeding. Clinical surveillance in line with anticoagulation practice is recommended throughout the treatment period.

Missed dose

If a dose is missed, the patient should take Rivaroxaban Clonmel 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.

Patients with non-valvular atrial fibrillation undergoing PCI with stent placement

There is limited experience of a reduced dose of 15 mg Rivaroxaban Clonmel once daily (or 10 mg Rivaroxaban once daily for patients with moderate renal impairment [creatinine clearance 30–49 mL/min]) in addition to a P2Y12 inhibitor for a maximum of 12 months in patients with non-valvular atrial fibrillation who require oral anticoagulation and undergo PCI with stent placement.

Patients undergoing cardioversion

Rivaroxaban Clonmel 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 Clonmel 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 Rivaroxaban Clonmel as prescribed. Decisions on initiation and duration of treatment should take established guideline recommendations for anticoagulant treatment in patients undergoing cardioversion into account.

Treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), and prevention of recurrent DVT and PE in adult patients and treatment of VTE and prevention of recurrence in children and adolescents

Adults

Adult patients are initially treated with Rivaroxaban Clonmel 15 mg twice daily for the first 3 weeks. This initial treatment is followed by Rivaroxaban Clonmel 20 mg once daily for the continued treatment period. 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 10 mg once daily. In patients in whom the risk of recurrent DVT or PE is considered high, such as those with complicated co-morbidities, or who have developed recurrent DVT or PE on extended prevention with Rivaroxaban 10 mg once daily, a dose of Rivaroxaban Clonmel 20 mg once daily should be considered. Rivaroxaban 10 mg is not recommended for the initial 6 months' treatment of DVT or PE.

ADULT DOSING SCHEME		
Day 1 to 21	Day 22 onwards	Following completion of at least 6 months
Rivaroxaban Clonmel 15 mg twice daily*	Rivaroxaban Clonmel 20 mg once daily*	Rivaroxaban 10 mg once daily* **OR** Rivaroxaban Clonmel 20 mg once daily* In patients in whom the risk of recurrent DVT or PE is considered high (e.g. complicated co-morbidities, recurrent DVT/PE on extended prevention on 10 mg once daily), Rivaroxaban Clonmel 20 mg once daily* should be considered
Rivaroxaban Clonmel 15 mg / 20 mg : MUST BE TAKEN WITH FOOD *For the recommended dosing scheme for patients with DVT/PE and moderate or severe renal impairment see below		

Children

Rivaroxaban Clonmel treatment in children and adolescents aged less than 18 years should be initiated following at least 5 days of initial parenteral anticoagulation treatment.

For children and adolescents weighing ≥30 kg a Rivaroxaban Clonmel tablet (15 mg for children 30 to 50 kg, 20 mg for children ≥50 kg) once daily can be administered.

The dose is determined based on body weight. The weight of a child should be monitored and the dose reviewed regularly. This is to ensure a therapeutic dose is maintained

Patients with renal impairment

Adults

Patients with moderate (CrCl 30–49 mL/min) or severe (CrCl 15–29 mL/min) renal impairment treated for acute DVT, acute PE and prevention of recurrent DVT and PE should be treated with Rivaroxaban Clonmel 15 mg twice daily for the first 3 weeks.

Thereafter, the recommended dose is Rivaroxaban Clonmel 20 mg once daily. A reduction of the dose from 20 mg once daily to 15 mg once daily should be considered if the patient's assessed risk of bleeding outweighs the risk of recurrent DVT and PE. The recommendation for the use of 15 mg is based on pharmacokinetic (PK) modelling and has not been studied in this clinical setting. Rivaroxaban Clonmel is to be used with caution in patients with severe renal impairment (CrCl 15–29 mL/min) and is not recommended in patients with CrCl <15 mL/min. When the recommended dose is 10 mg once daily, (after ≥6 months of therapy) no dose adjustment from the recommended dose is necessary.

Rivaroxaban Clonmel should be used with caution in patients with renal impairment concomitantly receiving other medicinal products that increase Rivaroxaban Clonmel plasma concentrations.

Children

No dose adjustment is required for children and adolescents with mild renal impairment (glomerular filtration rate: 50 mL-80 mL/min/1.73 m^2), based on data in adults and limited data in paediatric patients.

Rivaroxaban Clonmel 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.

Duration of therapy

Adults

Short duration of therapy (≥3 months) should be considered in patients with DVT/PE provoked by major transient risk factors (i.e. recent major surgery or trauma). Longer duration of therapy should be considered in patients with provoked DVT/PE not related to major transient risk factors, unprovoked DVT/PE, or a history of recurrent DVT/PE.

Children

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.

Missed dose

Adults

Twice daily treatment period (15 mg twice daily for the first 3 weeks): If a dose is missed, the patient should take Rivaroxaban Clonmel immediately to ensure intake of 30 mg Rivaroxaban Clonmel per day. In this case, two 15 mg tablets may be taken at once. Continue with the regular 15 mg twice daily intake on the following day.

Once daily treatment period (beyond 3 weeks): If a dose is missed, the patient should take Rivaroxaban Clonmel 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.

Children

Once daily regimen

A 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.

Oral Intake

Rivaroxaban Clonmel 15 mg and 20 mg tablets are to be taken with food. The intake of these doses with food at the same time supports the required absorption of the drug, thus ensuring a high oral bioavailability.

Adults

For patients who are unable to swallow whole tablets, a Rivaroxaban Clonmel tablet may be crushed and mixed with water or apple puree immediately prior to use and then administered orally. After the administration of crushed Rivaroxaban Clonmel 15 mg or 20 mg film-coated tablets, the dose should be immediately followed by food.

The crushed Rivaroxaban Clonmel tablet may also be given through gastric tubes. The crushed tablet should be suspended in 50 ml of water and administered via a nasogastric tube or gastric feeding tube after confirming gastric placement of the tube, after which it should be flushed with water. After the administration of crushed Rivaroxaban Clonmel 15 mg or 20 mg film-coated tablets, the dose should then be immediately followed by enteral feeding.

Children

When doses of Rivaroxaban Clonmel 15 mg or 20 mg are prescribed, these could be provided by crushing the 15 mg or 20 mg tablet and mixing it with water or apple puree immediately prior to use and administered orally.

The crushed Rivaroxaban Clonmel tablet may be given through nasogastric or gastric feeding tube. Gastric placement of the tube should be confirmed before administering Rivaroxaban Clonmel. Avoid administration of Rivaroxaban Clonmel distal to the stomach.

Perioperative Management

If an invasive procedure or surgical intervention is required, if possible and based on the clinical judgement of the physician:

- Rivaroxaban Clonmel 15 mg or 20 mg tablets should be stopped at least 24 hours before the intervention.

If the procedure cannot be delayed the increased risk of bleeding should be assessed against the urgency of the intervention. Rivaroxaban Clonmel should be restarted after the invasive procedure or surgical intervention as soon as possible provided the clinical situation allows, and adequate haemostasis has been established.

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.

Indication-specific recommendations

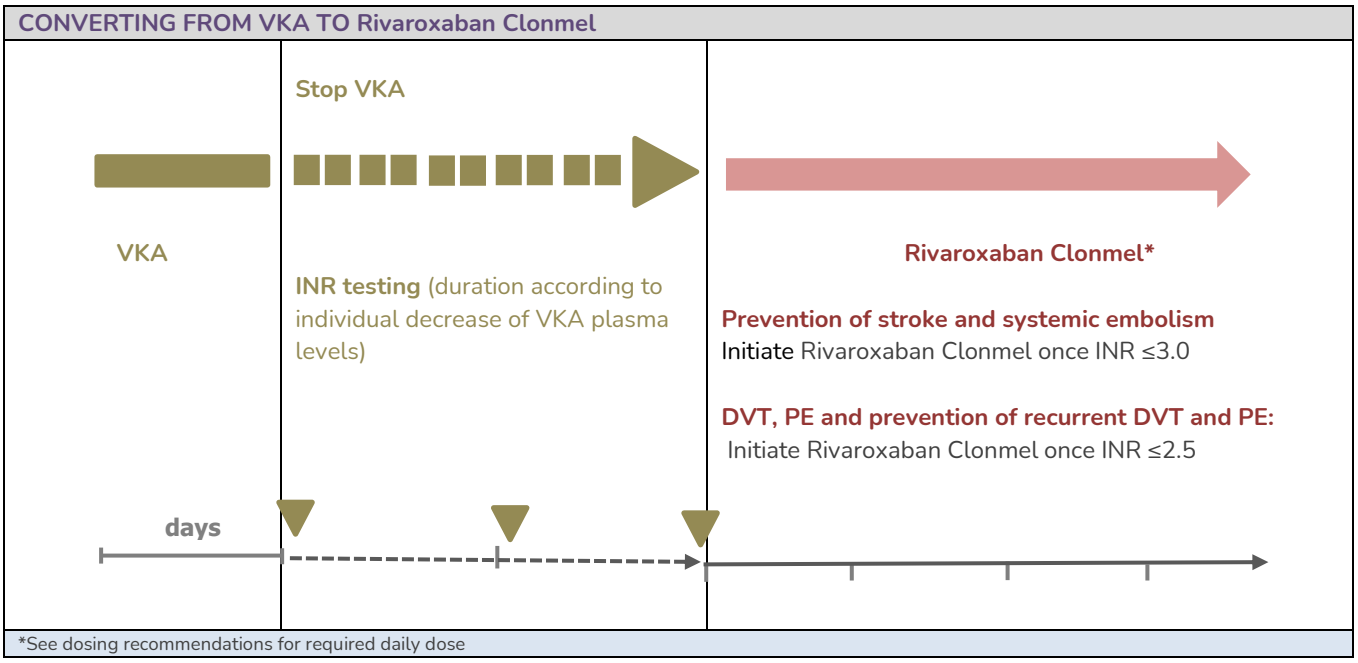
- Prevention of stroke and systemic embolism in adult patients with NVAF
- Treatment of DVT and PE and prevention of recurrent DVT and PE in adult patients
- Treatment of VTE and prevention of VTE recurrence in children

There is no clinical experience with the use of 15 mg and 20 mg Rivaroxaban Clonmel tablets in adults nor with the use of Rivaroxaban Clonmel in children in these situations. To reduce the potential risk of bleeding associated with the concurrent use of Rivaroxaban Clonmel and neuraxial (epidural/spinal) anaesthesia or spinal puncture, consider the pharmacokinetic profile of Rivaroxaban Clonmel. Placement or removal of an epidural catheter or lumbar puncture is best performed when the anticoagulant effect of Rivaroxaban Clonmel is estimated to be low. However, the exact timing to reach a sufficiently low anticoagulant effect in each patient is not known and should be weighed against the urgency of a diagnostic procedure.

For the removal of an epidural catheter and based on the general pharmacokinetic characteristics at least 2x half-life, i.e. at least 18 hours in young adult patients and 26 hours in elderly patients should elapse after the last administration of Rivaroxaban Clonmel (see section 5.2 of the SmPC). Following removal of the catheter, at least 6 hours should elapse before the next Rivaroxaban Clonmel dose is administered. If traumatic puncture occurs, the administration of Rivaroxaban Clonmel is to be delayed for 24 hours.

No data is available on the timing of placement or removal of a neuraxial catheter in children while on Rivaroxaban Clonmel. Discontinue Rivaroxaban Clonmel and consider a short acting parenteral anticoagulant.

Converting from VKA to Rivaroxaban Clonmel

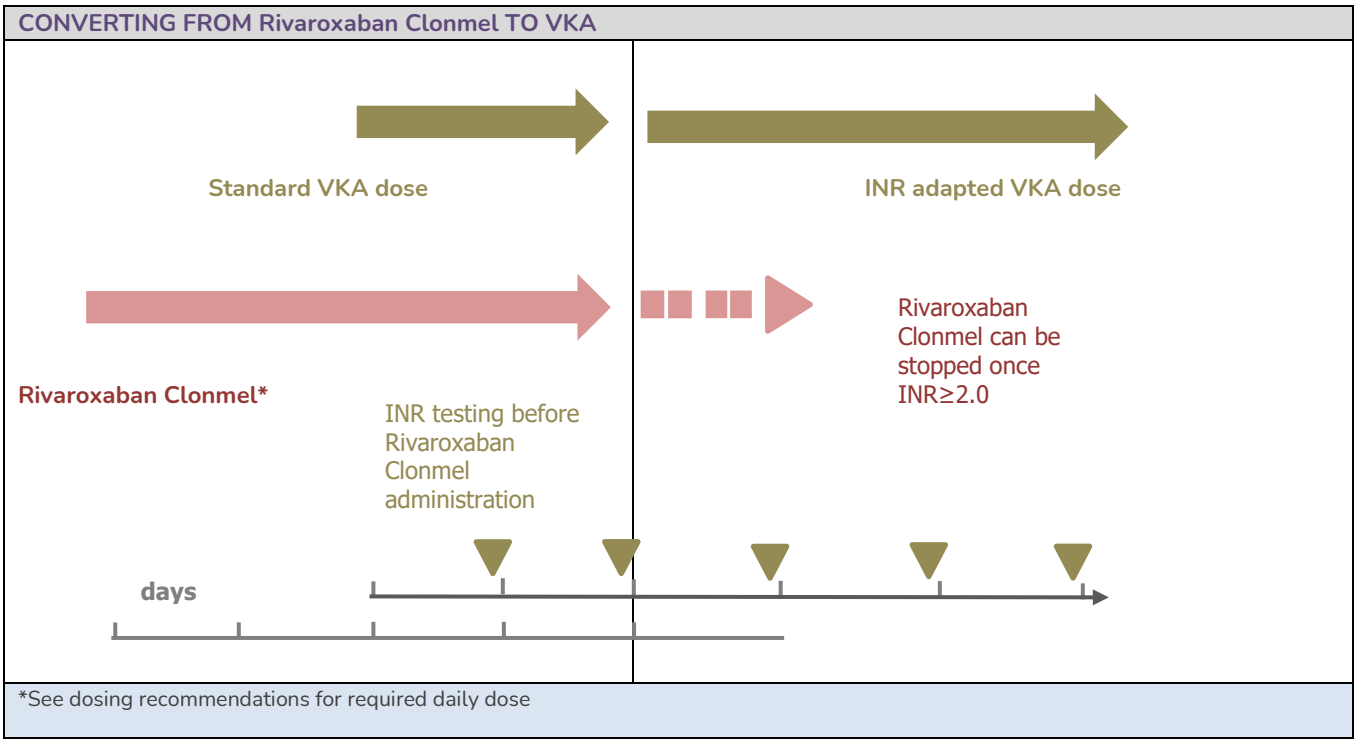


For patients treated for **prevention of stroke and systemic embolism**, treatment with VKA should be stopped and Rivaroxaban Clonmel therapy should be initiated when the **INR ≤3.0**.

For adult patients treated for **DVT, PE and prevention of recurrent DVT** and **PE** and **treatment of VTE and prevention of recurrence in paediatric patients**, treatment with VKA should be stopped and Rivaroxaban Clonmel therapy should be initiated when the **INR ≤2.5**.

INR measurement is not appropriate to measure the anticoagulant activity of Rivaroxaban Clonmel and therefore should not be used for this purpose. Treatment with Rivaroxaban Clonmel only does not require routine coagulation monitoring.

Converting from Rivaroxaban Clonmel to VKA



It is important to ensure adequate anticoagulation while minimising the risk of bleeding during conversion of therapy.

Adults

When converting to VKA, Rivaroxaban Clonmel and VKA should be given concurrently until the **INR ≥2.0**. For the first 2 days of the conversion period, standard initial dosing of VKA should be used followed by VKA dosing guided by INR testing.

INR measurement is not appropriate to measure the anticoagulant activity of Rivaroxaban Clonmel. While patients are on both Rivaroxaban Clonmel and VKA the **INR should not be tested earlier than 24 hours after the previous dose but prior to the next dose of Rivaroxaban Clonmel**. Once Rivaroxaban Clonmel is discontinued, INR values obtained at least 24 hours after the last dose reliably reflect the VKA dosing.

Children

Children who convert from Rivaroxaban Clonmel to VKA need to continue Rivaroxaban Clonmel 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 Clonmel. Co-administration of Rivaroxaban Clonmel and VKA is advised to continue until the INR is ≥ 2.0. Once Rivaroxaban Clonmel is discontinued, INR values obtained at least 24 hours after the last dose reliably reflect the VKA dosing.

Converting from Parenteral Anticoagulants to Rivaroxaban Clonmel

- Patients with a parenteral drug on a fixed dosing scheme such as low-molecular weight heparin (LMWH): Discontinue parenteral drug and start Rivaroxaban Clonmel 0 to 2 hours before the time of the next scheduled administration of the parenteral drug
- Patients with a continuously administered parenteral drug such as intravenous unfractionated heparin: Start Rivaroxaban Clonmel at the time of discontinuation

Converting from Rivaroxaban Clonmel to Parenteral Anticoagulants

Discontinue Rivaroxaban and give the first dose of the parenteral anticoagulant at the time the next Rivaroxaban Clonmel dose would be taken.

Populations Potentially at Higher Risk of Bleeding

Like all anticoagulants, Rivaroxaban Clonmel may increase the risk of bleeding.

Therefore, Rivaroxaban Clonmel is contraindicated in patients:

- With clinically significant active bleeding
- With a 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.
- Receiving concomitant treatment with any other anticoagulants e.g. unfractionated heparin (UFH), LMWHs (enoxaparin, dalteparin, etc.), heparin derivatives (fondaparinux, etc.), oral anticoagulants (warfarin, dabigatran etexilate, apixaban, etc.) except under the circumstances of switching anticoagulant therapy or when UFH is given at doses necessary to maintain an open central venous or arterial catheter.
- With hepatic disease associated with coagulopathy and clinically relevant bleeding risk including Child-Pugh class B and C cirrhotic patients.

Adults Only

Elderly population: The risk of bleeding increases with increasing age.

Several sub-groups of patients are at increased risk of bleeding and should be carefully monitored for

signs and symptoms of bleeding complications.

Treatment decision in these patients should be carried out after assessment of treatment benefit against the risk for bleeding.

Patients with renal impairment

For adults see dosing recommendations for patients with moderate (CrCl 30–49 mL/min) or severe (CrCl 15–29 mL/min) renal impairment. Rivaroxaban Clonmel is to be used with caution in patients with CrCl 15–29 mL/min and in patients with renal impairment concomitantly receiving other medicinal products, that increase Rivaroxaban Clonmel plasma concentrations. Use of Rivaroxaban Clonmel is not recommended in patients with CrCl <15 mL/min.

In children and adolescents no dose adjustment is required with mild renal impairment (glomerular filtration rate: 50-80 mL/min/1.73 m^2), based on data in adults and limited data in paediatric patients.

Rivaroxaban Clonmel 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.

Patients concomitantly receiving other medicinal products

- Systemic azole-antimycotics (such as ketoconazole, itraconazole, voriconazole and posaconazole) or HIV protease inhibitors (e.g. ritonavir): use of Rivaroxaban Clonmel is not recommended.
- Care is to be taken in patients concomitantly receiving drugs affecting haemostasis such as non-steroidal anti-inflammatory drugs (NSAIDs), ASA, platelet aggregation inhibitors or selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs)
- The interaction with erythromycin, clarithromycin or fluconazole is likely not clinically relevant in most patients but can be potentially significant in high-risk patients (for patients with renal impairment see further above)

Interaction studies have only been performed in adults. The extent of interactions in the paediatric population is not known. The warnings above should be taken into account for the paediatric population.

Patients with other haemorrhagic risk factors

As with other antithrombotics, Rivaroxaban Clonmel 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

Patients with cancer

Patients with malignant disease may simultaneously be at higher risk of bleeding and thrombosis. The individual benefit of antithrombotic treatment should be weighed against risk for bleeding in patients with active cancer dependent on tumour location, antineoplastic therapy and stage of disease. Tumours located in the gastrointestinal or genitourinary tract have been associated with an increased risk of bleeding during Rivaroxaban Clonmel therapy.

In patients with malignant neoplasms at high risk of bleeding, the use of Rivaroxaban Clonmel is contraindicated.

Other Contraindications

Rivaroxaban Clonmel is contraindicated during pregnancy and breastfeeding. Women of childbearing potential should avoid becoming pregnant during treatment with Rivaroxaban Clonmel. Rivaroxaban Clonmel is also contraindicated in case of hypersensitivity to the active substance or to any of the excipients.

Overdose

Due to limited absorption, a ceiling effect with no further increase in average plasma exposure is expected at supratherapeutic doses of 50 mg Rivaroxaban Clonmel and above in adults; however, no data is available at supratherapeutic doses in children. A decrease in the relative bioavailability for increasing doses (in mg/kg bodyweight) was found in children, suggesting absorption limitations for higher doses, even when taken together with food. A specific reversal agent antagonising the pharmacodynamic effect of Rivaroxaban Clonmel is available (refer to the Summary of Product Characteristics of andexanet alfa), however, it is not established in children. The use of activated charcoal to reduce absorption in case of overdose may be considered.

Should a bleeding complication arise in a patient receiving Rivaroxaban Clonmel, the next Rivaroxaban Clonmel administration should be delayed or treatment should be discontinued as appropriate.

Individualised bleeding management may include:

- Symptomatic treatment, such as mechanical compression, surgical intervention, fluid replacement
- Haemodynamic support, blood product or component transfusion
- If bleeding cannot be controlled with the above measures, either the administration of a specific factor Xa inhibitor reversal agent (andexanet alfa) or a specific procoagulant reversal agent, such as prothrombin complex concentrate (PCC), activated prothrombin complex concentrate (APCC) or recombinant factor VIIa (r-FVIIa) should be considered.

However, there is currently very limited clinical experience with the use of these medicinal products in adults and in children receiving Rivaroxaban Clonmel.

Due to the high plasma protein binding, Rivaroxaban Clonmel is not expected to be dialysable.

Coagulation Testing

Rivaroxaban Clonmel does not require routine coagulation monitoring. However, measuring Rivaroxaban Clonmel levels may be useful in exceptional situations where knowledge of Rivaroxaban Clonmel exposure may help to take clinical decisions, e.g. overdose and emergency surgery.

Anti-FXa assays with Rivaroxaban Clonmel specific calibrators to measure Rivaroxaban levels are commercially available. If clinically indicated haemostatic status can also be assessed by prothrombin time (PT) using Neoplastin as described in the SmPC.

The following coagulation tests are increased: PT, activated partial thromboplastin time (aPTT) and calculated PT INR. Since the INR was developed to assess the effects of VKAs on the PT, it is therefore not appropriate to use the INR to measure activity of Rivaroxaban Clonmel.

Dosing or treatment decisions should not be based on results of INR except when converting from Rivaroxaban Clonmel to VKA as described above.

Dosing Overview in Adults

Indication[1,2]	Dosing[1,2]	Special Populations[1,2]
Stroke prevention in adult patients with non-valvular atrial fibrillation[a]	**Rivaroxaban Clonmel 20 mg once daily**	In patients with impaired renal function with CrCl 15–49 mL/min[b] **Rivaroxaban Clonmel 15 mg once daily** PCI with stent placement For a maximum of 12 months **Rivaroxaban Clonmel 15 mg once daily** plus a P2Y12 inhibitor (e.g. clopidogrel) PCI with stent placement in patients with impaired renal function with CrCl 30–49 mL/min[b] **Rivaroxaban 10 mg once daily** plus a P2Y12 inhibitor (e.g. clopidogrel)
Treatment of **DVT** and **PE**[c], and prevention of recurrent DVT and PE in adult patients	Treatment and prevention of recurrence, day 1–21 **Rivaroxaban Clonmel 15 mg twice daily** Prevention of recurrence, from day 22 onwards **Rivaroxaban Clonmel 20 mg once daily** Extended prevention of recurrence, from month 7 onwards **Rivaroxaban 10 mg once daily** Extended prevention of recurrence, from month 7 onwards **Rivaroxaban Clonmel 20 mg once daily** in patients at high risk of recurrent DVT or PE, such as those: • with complicated comorbidities • who have developed recurrent DVT or PE on extended prevention with Rivaroxaban 10 mg	In patients with impaired renal function with CrCl 15–49mL/min[b] Treatment and prevention of recurrence, day 1–21 **Rivaroxaban Clonmel 15 mg twice daily** Thereafter Rivaroxaban Clonmel 15mg once daily instead of **Rivaroxaban Clonmel 20mg once daily** if patient's assessed risk for bleeding outweighs risk for recurrence. When the recommended dose is **Rivaroxaban 10 mg once daily**, no dose adjustment is necessary

Rivaroxaban Clonmel 15 mg and 20 mg must be taken with food[1,2]

For patients who are unable to swallow whole tablets, **Rivaroxaban Clonmel** tablets may be crushed and mixed with water or apple puree immediately prior to use and administered orally.

[a]With one or more risk factors, such as congestive heart failure, hypertension, age ≥75 years, diabetes mellitus, prior stroke or transient ischaemic attack.

[b]Use with caution in patients with creatinine clearance 15–29 mL/min and in patients with renal impairment when concomitantly receiving other medicinal products that increase Rivaroxaban Clonmel plasma concentration.

[c]Not recommended as an alternative to unfractionated heparin in patients with PE who are haemodynamically unstable or may receive thrombolysis or pulmonary embolectomy.

Dosing Overview in Children and Adolescents

For dosing for the treatment of VTE and prevention of recurrence in paediatric patients, please refer to page 6.

ASA, acetylsalicylic acid; CrCl, creatinine clearance; DVT, deep vein thrombosis; HIV, human immunodeficiency virus; INR, international normalised ratio; LMWH, low-molecular-weight heparin; NSAID, non-steroidal anti-inflammatory drug; NVAF, non-valvular atrial fibrillation; PCI, percutaneous coronary intervention; PE, pulmonary embolism; SmPC, Summary of Product Characteristics; VKA, vitamin K antagonist; VTE, venous thromboembolism; UFH, unfractionated heparin.

References

1. Clonmel Healthcare Ltd. Rivaroxaban Clonmel 15 mg film-coated tablets Summary of Product Characteristics. Available at www.hpra.ie.
2. Clonmel Healthcare Ltd. Rivaroxaban Clonmel 20 mg film-coated tablets Summary of Product Characteristics. Available at www.hpra.ie.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance at www.hpra.ie.

Adverse events may also be reported to Clonmel Healthcare Ltd. via medicalinformation@clonmel-health.ie or 052 6177777

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