as prescribed by your doctor.

- Do not change your dose or stop taking rivaroxaban tablets unless your doctor tells you to.
- Your doctor will tell you how much rivaroxaban tablets to take and when to take it.
- Your doctor may change your dose if needed.
- If you take rivaroxaban tablets for:
  - o **atrial fibrillation:**
    - Take rivaroxaban tablets 1 time a day with your evening meal.
    - If you miss a dose of rivaroxaban tablets, take it as soon as you remember on the same day. Take your next dose at your regularly scheduled time.
  - o **blood clots in the veins of your legs or lungs:**
    - Take rivaroxaban tablets once or twice a day as prescribed by your doctor.
    - Take rivaroxaban tablets with food at the same time each day.
    - If you miss a dose of rivaroxaban tablets:
      - **and take rivaroxaban tablets 2 times a day:** Take rivaroxaban tablets as soon as you remember on the same day. You may take 2 doses at the same time to make up for the missed dose. Take your next dose at your regularly scheduled time.
      - **and take rivaroxaban tablets 1 time a day:** Take rivaroxaban tablets as soon as you remember on the same day. Take your next dose at your regularly scheduled time.
  - o **hip or knee replacement surgery:**
    - Take rivaroxaban tablets 1 time a day with or without food.
    - If you miss a dose of rivaroxaban tablets, take it as soon as you remember on the same day. Take your next dose at your regularly scheduled time.
- If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take rivaroxaban tablets.
- Your doctor will decide how long you should take rivaroxaban tablets. Do not stop taking rivaroxaban tablets without talking with your doctor first.
- Your doctor may stop rivaroxaban tablets for a short time before any surgery, medical or dental procedure. Your doctor will tell you when to start taking rivaroxaban tablets again after your surgery or procedure.
- Do not run out of rivaroxaban tablets. Refill your prescription of rivaroxaban tablets before you run out. When leaving the hospital following a hip or knee replacement, be sure that you will have rivaroxaban tablets available to avoid missing any doses.
- If you take too much rivaroxaban tablets, go to the nearest hospital emergency room or call your doctor right away.

What are the possible side effects of rivaroxaban tablets?

- **See "What is the most important information I should know about rivaroxaban tablets?"**

Tell your doctor if you have any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store rivaroxaban tablets?

- Store rivaroxaban tablets at room temperature between 68°F to 77°F (20° to 25°C).

Keep rivaroxaban tablets and all medicines out of the reach of children.

General information about rivaroxaban tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use rivaroxaban tablets for a condition for which it was not prescribed. Do not give rivaroxaban tablets to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about rivaroxaban tablets. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about rivaroxaban tablets that is written for health professionals.

For more information call **Micro Labs USA Inc.** 1-855-839-8195

What are the ingredients in rivaroxaban tablets?

Active ingredient: rivaroxaban
Inactive ingredients: croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and sodium lauryl sulfate.

The proprietary film coating mixture for rivaroxaban tablets 10 mg tablets is Opadry Pink (03F540164) and contains: ferric oxide red, hypromellose, polyethylene glycol 3350, and titanium dioxide.

The proprietary film coating mixture for rivaroxaban tablets 15 mg tablets is Opadry Brown (03F565105) and contains: ferric oxide red, hypromellose, polyethylene glycol 3350, and titanium dioxide.

The proprietary film coating mixture for rivaroxaban tablets 20 mg tablets is Opadry Brown (03F565106) and contains: ferric oxide red, polyethylene glycol 3350, and titanium dioxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by:
Micro Labs Limited
Goa-403 722, INDIA.

Manufactured for:
Micro Labs USA Inc.
Princeton, NJ 08540

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12.6 QT/QTc Prolongation

In a thorough QT study in healthy men and women aged 50 years and older, no QTc prolonging effects were observed for rivaroxaban (15 mg and 45 mg, single-dose).

13 NON-CLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Rivaroxaban was not carcinogenic when administered by oral gavage to mice or rats for up to 2 years. The systemic exposures (AUCs) of unbound rivaroxaban in male and female mice at the highest dose tested (60 mg/kg/day) were 1-and 2-times, respectively, the human exposure of unbound drug at the human dose of 20 mg/day. Systemic exposures of unbound drug in male and female rats at the highest dose tested (60 mg/kg/day) were 2-and 4-times, respectively, the human exposure.

Rivaroxaban was not mutagenic in bacteria (Ames-Test) or clastogenic in V79 Chinese hamster lung cells *in vitro* or in the mouse micronucleus test *in vivo*.

No impairment of fertility was observed in male or female rats when given up to 200 mg/kg/day of rivaroxaban orally. This dose resulted in exposure levels, based on the unbound AUC, at least 13 times the exposure in humans given 20 mg rivaroxaban daily.

14 CLINICAL STUDIES

14.1 Stroke Prevention in Nonvalvular Atrial Fibrillation

The evidence for the efficacy and safety of rivaroxaban was derived from ROCKET AF, a multi-national, double-blind study comparing rivaroxaban (at a dose of 20 mg once daily with the evening meal in patients with CrCl >50 mL/min and 15 mg once daily with the evening meal in patients with CrCl 30 to <50 mL/min) to warfarin (titrated to INR 2 to 3) to reduce the risk of stroke and non-central nervous system (CNS) systemic embolism in patients with nonvalvular atrial fibrillation (AF). Patients had to have one or more of the following additional risk factors for stroke:

- a prior stroke (ischemic or unknown type), transient ischemic attack (TIA) or non-CNS systemic embolism, or
- 2 or more of the following risk factors:
  - o age ≥75 years,
  - o hypertension,
  - o heart failure or left ventricular ejection fraction ≤35%, or
  - o diabetes mellitus

ROCKET AF was a non-inferiority study designed to demonstrate that rivaroxaban preserved more than 50% of warfarin's effect on stroke and non-CNS systemic embolism as established by previous placebo-controlled studies of warfarin in atrial fibrillation.

A total of 14264 patients were randomized and followed on study treatment for a median of 590 days. The mean age was 71 years and the mean CHADS2 score was 3.5. The population was 60% male, 83% Caucasian, 13% Asian and 1.3% Black. There was a history of stroke, TIA, or non-CNS systemic embolism in 55% of patients, and 38% of patients had not taken a vitamin K antagonist (VKA) within 6 weeks at time of screening. Concomitant diseases of patients in this study included hypertension 91%, diabetes 40%, congestive heart failure 63%, and prior myocardial infarction 17%. At baseline, 37% of patients were on aspirin (almost exclusively at a dose of 100 mg or less) and few patients were on clopidogrel. Patients were enrolled in Eastern Europe (39%); North America (19%); Asia, Australia, and New Zealand (15%); Western Europe (15%); and Latin America (13%). Patients randomized to warfarin had a mean percentage of time in the INR target range of 2 to 3 of 55%, lower during the first few months of the study.

In ROCKET AF, rivaroxaban was demonstrated non-inferior to warfarin for the primary composite endpoint of time to first occurrence of stroke (any type) or non-CNS systemic embolism [HR (95% CI): 0.88 (0.74, 1.03)], but superiority to warfarin was not demonstrated. There is insufficient experience to determine how rivaroxaban and warfarin compare when warfarin therapy is well-controlled.

Table 9 displays the overall results for the primary composite endpoint and its components.

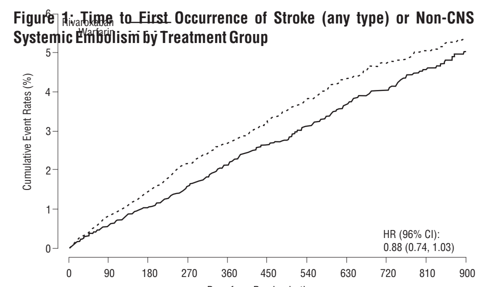
Table 9: Primary Composite Endpoint Results in ROCKET AF Study

Event	Rivaroxaban		Warfarin		Rivaroxaban vs. Warfarin
	N = 7081 n (%)	Event Rate (per 100 pt-yrs)	N = 7090 n (%)	Event Rate (per 100 pt-yrs)	Hazard Ratio (95% CI)
Primary Composite Endpoint*	269 (3.8)	2.1	306 (4.3)	2.4	0.88 (0.74, 1.03)
Stroke	253 (3.6)	2	281 (4)	2.2	
Hemorrhagic Stroke	33 (0.5)	0.3	57 (0.8)	0.4	
Ischemic Stroke	206 (2.9)	1.6	208 (2.9)	1.6	
Unknown Stroke Type	19 (0.3)	0.2	18 (0.3)	0.1	
Non-CNS Systemic Embolism	20 (0.3)	0.2	27 (0.4)	0.2	

* The primary endpoint was the time to first occurrence of stroke (any type) or non-CNS systemic embolism. Data are shown for all randomized patients followed to site notification that the study would end.

Figure 1 is a plot of the time from randomization to the occurrence of the first primary endpoint event in the two treatment arms.

Figure 1: Time to First Occurrence of Stroke (any type) or Non-CNS Systemic Embolism by Treatment Group



Number of Subjects at Risk:
Rivaroxaban 7081 6927 6774 6620 6470 5580 4779 3820 2951 2058 1321
Warfarin 7090 6910 6755 6590 6440 5561 4756 3807 2944 2069 1319

The efficacy of rivaroxaban was generally consistent across major subgroups.

The protocol for ROCKET AF did not stipulate anticoagulation after study drug discontinuation, but warfarin patients who completed the study were generally maintained on warfarin. Rivaroxaban patients were generally switched to warfarin without a period of coadministration of warfarin and rivaroxaban, so that they were not adequately anticoagulated after stopping rivaroxaban until attaining a therapeutic INR. During the 28 days following the end of the study, there were 22 strokes in the 4637 patients taking rivaroxaban vs. 6 in the 4691 patients taking warfarin.

Few patients in ROCKET AF underwent electrical cardioversion for atrial fibrillation. The utility of rivaroxaban for preventing post-cardioversion stroke and systemic embolism is unknown.

14.2 Treatment of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), and Reduction in the Risk of Recurrence of DVT and of PE

EINSTEIN Deep Vein Thrombosis and EINSTEIN Pulmonary Embolism Studies

Rivaroxaban for the treatment of DVT and/or PE and for the reduction in the risk of recurrence of DVT and of PE was studied in EINSTEIN DVT and EINSTEIN PE, multi-national, open-label, non-inferiority studies comparing rivaroxaban (at an initial dose of 15 mg twice daily with food for the first three weeks, followed by rivaroxaban 20 mg once daily with food) to enoxaparin 1 mg/kg twice daily for at least five days with VKA and then continued with VKA only after the target INR (2 to 3) was reached. Patients who required thrombectomy, insertion of a caval filter, or use of a fibrinolytic agent and patients with creatinine clearance <30 mL/min, significant liver disease, or active bleeding were excluded from the studies. The intended treatment duration was 3, 6, or 12 months based on investigator's assessment prior to randomization.

A total of 8281 (3449 in EINSTEIN DVT and 4832 in EINSTEIN PE) patients were randomized and followed on study treatment for a mean of 208 days in the rivaroxaban group and 204 days in the enoxaparin/VKA group. The mean age was approximately 57 years. The population was 55% male, 70% Caucasian, 9% Asian and about 3% Black. About 73% and 92% of rivaroxaban -treated patients in the EINSTEIN DVT and EINSTEIN PE studies, respectively, received initial parenteral anticoagulant treatment for a median duration of 2 days. Enoxaparin/VKA-treated patients in the EINSTEIN DVT and EINSTEIN PE studies received initial parenteral anticoagulant treatment for a median duration of 8 days. Aspirin was taken as on treatment concomitant antithrombotic medication by approximately 12% of patients in both treatment groups. Patients randomized to VKA had an unadjusted mean percentage of time in the INR target range of 2 to 3 of 58% in EINSTEIN DVT study and 60% in EINSTEIN PE study, with the lower values occurring during the first month of the study.

In the EINSTEIN DVT and EINSTEIN PE studies, 49% of patients had an idiopathic DVT/PE at baseline. Other risk factors included previous episode of DVT/PE (19%), recent surgery or trauma (18%), immobilization (16%), use of estrogen-containing drug (8%), known thrombophilic conditions (6%), or active cancer (5%).

In the EINSTEIN DVT and EINSTEIN PE studies, rivaroxaban was demonstrated to be non-inferior to enoxaparin/VKA for the primary composite endpoint of time to first occurrence of recurrent DVT or non-fatal or fatal PE [EINSTEIN DVT HR (95% CI): 0.68 (0.44, 1.04); EINSTEIN PE HR (95% CI): 1.12 (0.75, 1.68)]. In each study the conclusion of non-inferiority was based on the upper limit of the 95% confidence interval for the hazard ratio being less than 2.

Table 10 displays the overall results for the primary composite endpoint and its components for EINSTEIN DVT and EINSTEIN PE studies.

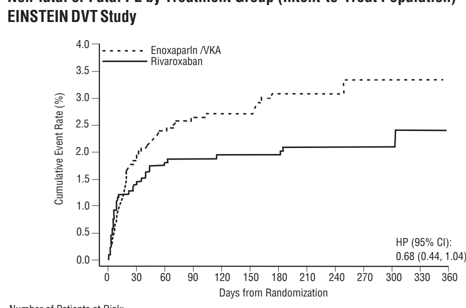
Event	Rivaroxaban 20 mg†	Enoxaparin/ VKA†	Rivaroxaban vs. Enoxaparin/VKA Hazard Ratio (95% CI)
EINSTEIN DVT Study	**N = 1731 n (%)**	**N = 1718 n (%)**	
Primary Composite Endpoint	36 (2.1)	51 (3)	0.68 (0.44, 1.04)
Death (PE)	1 (<0.1)	0	
Death (PE cannot be excluded)	3 (0.2)	6 (0.3)	
Symptomatic PE and DVT	1 (<0.1)	0	
Symptomatic recurrent PE only	20 (1.2)	18 (1)	
Symptomatic recurrent DVT only	14 (0.8)	28 (1.6)	
EINSTEIN PE Study	**N = 2419 n (%)**	**N = 2413 n (%)**	
Primary Composite Endpoint	50 (2.1)	44 (1.8)	1.12 (0.75, 1.68)
Death (PE)	3 (0.1)	1 (<0.1)	
Death (PE cannot be excluded)	8 (0.3)	6 (0.2)	
Symptomatic PE and DVT	0	2 (<0.1)	
Symptomatic recurrent PE only	23 (1)	20 (0.8)	
Symptomatic recurrent DVT only	18 (0.7)	17 (0.7)	

* For the primary efficacy analysis, all confirmed events were considered from randomization up to the end of intended treatment duration (3, 6 or 12 months) irrespective of the actual treatment duration. If the same patient had several events, the patient may have been counted for several components.

† Treatment schedule in EINSTEIN DVT and EINSTEIN PE studies: Rivaroxaban 15 mg twice daily for 3 weeks followed by 20 mg once daily; enoxaparin/VKA [enoxaparin: 1 mg/kg twice daily, VKA: individually titrated doses to achieve a target INR of 2.5 (range: 2 to 3)]

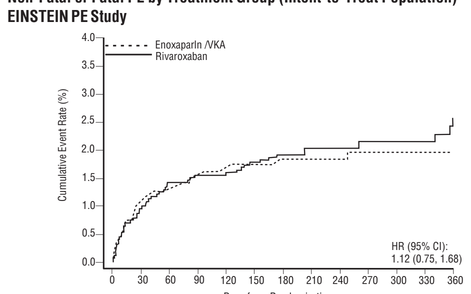
Figures 2 and 3 are plots of the time from randomization to the occurrence of the first primary efficacy endpoint event in the two treatment groups in EINSTEIN DVT and EINSTEIN PE studies, respectively.

Figure 2: Time to First Occurrence of the Composite of Recurrent DVT or Non-fatal or Fatal PE by Treatment Group (Intent-to-Treat Population) – EINSTEIN DVT Study



Number of Patients at Risk:
Enoxaparln /VKA (N- 1718) 1616 1581 1565 1368 1358 1301 380 362 342 325 297 264
Rivaroxaban (N- 1731) 1668 1648 1635 1424 1412 1369 400 369 364 345 309 266

Figure 3: Time to First Occurrence of the Composite of Recurrent DVT or Non-Fatal or Fatal PE by Treatment Group (Intent-to-Treat Population) – EINSTEIN PE Study



Number of Patients at Risk:
Enoxaparln /VKA (N- 2413) 2316 2295 2200 2155 2146 2113 835 787 773 746 722 675
Rivaroxaban (N- 2419) 2350 2321 2311 2180 2167 2133 837 794 785 757 725 672

EINSTEIN Extension Study

Rivaroxaban for reduction in the risk of recurrence of DVT and of PE was studied in the EINSTEIN Extension study, a multi-national, double-blind, superiority study comparing rivaroxaban (20 mg once daily with food) to placebo in patients who had completed 6 to 14 months of treatment for DVT and/or PE following the acute event. The intended treatment duration was 6 or 12 months based on investigator's assessment prior to randomization.

A total of 1196 patients were randomized and followed on study treatment for a mean of 190 days for both rivaroxaban and placebo treatment groups. The mean age was approximately 58 years. The population was 58% male, 78% Caucasian, 8% Asian and about 2% Black. Aspirin was taken as on-treatment concomitant antithrombotic medication by approximately 12% of patients in both treatment groups. In the EINSTEIN Extension study about 60% of patients had a history of proximal index DVT without PE event and 29% of patients had a PE without symptomatic DVT event. About 59% of patients had an idiopathic DVT/PE. Other risk factors included previous episode of DVT/PE (16%), immobilization (14%), known thrombophilic conditions (8%), or active cancer (5%).

In the EINSTEIN Extension study rivaroxaban was demonstrated to be superior to placebo for the primary composite endpoint of time to first occurrence of recurrent DVT or non-fatal or fatal PE [HR (95% CI): 0.18 (0.09, 0.39)].

Table 11 displays the overall results for the primary composite endpoint and its components.

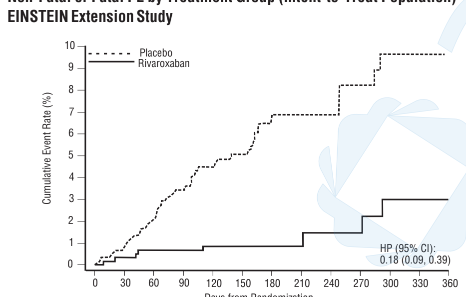
Table 11: Primary Composite Endpoint Results* in EINSTEIN Extension Study - Intent-to-Treat Population

Event	Rivaroxaban 20 mg N = 602	Placebo N = 594 n (%)	Rivaroxaban vs. Placebo Hazard Ratio (95% CI)
Primary Composite Endpoint	8 (1.3)	42 (7.1)	0.18 (0.09, 0.39) p-value = <0.0001
Death (PE)	0	1 (0.2)	
Death (PE cannot be excluded)	1 (0.2)	0	
Symptomatic recurrent PE	2 (0.3)	13 (2.2)	
Symptomatic recurrent DVT	5 (0.8)	31 (5.2)	

* For the primary efficacy analysis, all confirmed events were considered from randomization up to the end of intended treatment duration (6 or 12 months) irrespective of the actual treatment duration.

Figure 4 is a plot of the time from randomization to the occurrence of the first primary efficacy endpoint event in the two treatment groups.

Figure 4: Time to First Occurrence of the Composite of Recurrent DVT or Non-Fatal or Fatal PE by Treatment Group (Intent-to-Treat Population) – EINSTEIN Extension Study



Number of Patients at Risk:
Placebo (N- 594) 582 570 559 522 468 453 164 138 134 110 93 85
Rivaroxaban (N- 602) 590 583 577 552 503 491 171 138 133 114 92 81

14.3 Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery

Rivaroxaban was studied in 9011 patients (4487 rivaroxaban -treated, 4524 enoxaparin-treated patients) in the RECORD 1, 2, and 3 studies.

The two randomized, double-blind, clinical studies (RECORD 1 and 2) in patients undergoing elective total hip replacement surgery compared rivaroxaban 10 mg once daily starting at least 6 to 8 hours (about 90% of patients dosed 6 to 10 hours) after wound closure versus enoxaparin 40 mg once daily started 12 hours preoperatively. In RECORD 1 and 2, a total of 6727 patients were randomized and 6579 received study drug. The mean age [± standard deviation (SD)] was 63 ± 12.2 (range 18 to 93) years with 49% of patients >65 years and 55% of patients were female. More than 82% of patients were White, 7% were Asian, and less than 2% were Black. The studies excluded patients undergoing staged bilateral total hip replacement, patients with severe renal impairment defined as an estimated creatinine clearance <30 mL/min, or patients with significant liver disease (hepatitis or cirrhosis). In RECORD 1, the mean exposure duration (± SD) to active rivaroxaban and enoxaparin was 33.3 + 7 and 33.6 + 8.3 days, respectively. In RECORD 2, the mean exposure duration to active rivaroxaban and enoxaparin was 33.5 + 6.9 and 12.4 + 2.9 days, respectively. After Day 13, oral placebo was continued in the enoxaparin group for the remainder of the double-blind study duration. The efficacy data for RECORD 1 and 2 are provided in Table 12.

Table 12: Summary of Key Efficacy Analysis Results for Patients Undergoing Total Hip Replacement Surgery -Modified Intent-to-Treat Population

	RECORD 1			RECORD 2		
Treatment Dosage and Duration	Rivaroxaban 10 mg once daily	Enoxaparin 40 mg once daily	RRR*, p-value	Rivaroxaban 10 mg once daily	Enoxaparin† 40 mg once daily	RRR*, p-value
Number of Patients	N = 1513	N = 1473		N = 834	N = 835	
Total VTE	17 (1.1%)	57 (3.9%)	71% (95% CI: 50, 83), p<0.001	17 (2%)	70 (8.4%)	76% (95% CI: 59, 86), p<0.001
Components of Total VTE						
Proximal DVT	1 (0.1%)	31 (2.1%)		5 (0.6%)	40 (4.8%)	
Distal DVT	12 (0.8%)	26 (1.8%)		11 (1.3%)	43 (5.2%)	
Non-fatal PE	3 (0.2%)	1 (0.1%)		1 (0.1%)	4 (0.5%)	
Death (any cause)	4 (0.3%)	4 (0.3%)		2 (0.2%)	4 (0.5%)	
Number of Patients	N = 1600	N = 1587		N = 928	N = 929	
Major VTE‡	3 (0.2%)	33 (2.1%)	91% (95% CI: 71, 97), p<0.001	6 (0.7%)	45 (4.8%)	87% (95% CI: 69, 94), p<0.001
Number of Patients	N = 2103	N = 2119		N = 1178	N = 1179	
Symptomatic VTE	5 (0.2%)	11 (0.5%)		3 (0.3%)	15 (1.3%)	

* Relative Risk Reduction; CI = confidence interval
† Includes the placebo-controlled period of RECORD 2
‡ Proximal DVT, nonfatal PE or VTE-related death

One randomized, double-blind, clinical study (RECORD 3) in patients undergoing elective total knee replacement surgery compared rivaroxaban 10 mg once daily started at least 6 to 8 hours (about 90% of patients dosed 6 to 10 hours) after wound closure versus enoxaparin. In RECORD 3, the enoxaparin regimen was 40 mg once daily started 12 hours preoperatively. The mean age (± SD) of patients in the study was 68 ± 9 (range 28 to 91) years with 66% of patients ≥65 years. Sixty-eight percent (68%) of patients were female. Eighty-one percent (81%) of patients were White, less than 7% were Asian, and less than 2% were Black. The study excluded patients with severe renal impairment defined as an estimated creatinine clearance <30 mL/min or patients with significant liver disease (hepatitis or cirrhosis). The mean exposure duration (± SD) to active rivaroxaban and enoxaparin was 11.9 ± 2.3 and 12.5 ± 3 days, respectively. The efficacy data are provided in Table 13.

Table 13: Summary of Key Efficacy Analysis Results for Patients Undergoing Total Knee Replacement Surgery -Modified Intent-to-Treat Population

	RECORD 3		
Treatment Dosage and Duration	Rivaroxaban 10 mg once daily	Enoxaparin 40 mg once daily	RRR*, p-value
Number of Patients	N = 813	N = 871	
Total VTE	79 (9.7%)	164 (18.8%)	48%(95% CI: 34, 60), p<0.001
Components of events contributing to Total VTE			
Proximal DVT	9 (1.1%)	19 (2.2%)	
Distal DVT	74 (9.1%)	154 (17.7%)	
Non-fatal PE	0	4 (0.5%)	
Death (any cause)	0	2 (0.2%)	
Number of Patients	N = 895	N = 917	
Major VTE†	9 (1%)	23 (2.5%)	60% (95% CI: 14, 81), p = 0.024
Number of Patients	N = 1206	N = 1226	
Symptomatic VTE	8 (0.7%)	24 (2%)	

* Relative Risk Reduction; CI = confidence interval
† Proximal DVT, nonfatal PE or VTE-related death

16 HOW SUPPLIED/STORAGE AND HANDLING

Rivaroxaban Tablets are available in the strengths and packages listed below:

- 10 mg tablets are light red colored, round, biconvex, film coated tablets, with engraving 10 on one face and other face plain. The tablets are supplied in the packages listed:

Bottles of 30	NDC 42571-260-30
Bottles of 50	NDC 42571-260-18
Bottles of 90	NDC 42571-260-90
Bottles of 120	NDC 42571-260-12
Carton of 10x10 Unit-dose Tablets	NDC 42571-260-11

- 15 mg tablets are red colored, round, biconvex, film coated tablets, with engraving 15 on one face and other face plain. The tablets are supplied in the packages listed:

Bottles of 30	NDC 42571-261-30
Bottles of 90	NDC 42571-261-90
Carton of 10x10 Unit-dose Tablets	NDC 42571-261-11

- 20 mg tablets are brown red colored, round, biconvex, film coated tablets, with engraving 20 on one face and other face plain. The tablets are supplied in the packages listed:

Bottles of 30	NDC 42571-262-30
Bottles of 90	NDC 42571-262-90
Carton of 10x10 Unit-dose Tablets	NDC 42571-262-11

Store at 25°C (77°F) or room temperature; excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Keep out of the reach of children.

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide).

17.1 Instructions for Patient Use

- Advise patients to take rivaroxaban only as directed.
- Remind patients to not discontinue rivaroxaban without first talking to their healthcare professional.
- Advise patients with atrial fibrillation to take rivaroxaban once daily with the evening meal.
- Advise patients with DVT and/or PE to take rivaroxaban 15 mg or 20 mg tablets with food at approximately the same time every day *[see Dosage and Administration (2.4)]*.
- Advise patients who cannot swallow the tablet whole to crush rivaroxaban tablet and combine with a small amount of applesauce followed by food *[see Dosage and Administration (2.8)]*.
- For patients requiring an NG tube or gastric feeding tube, instruct the patient or caregiver to crush the rivaroxaban tablet and mix it with a small amount of water before administering via the tube *[see Dosage and Administration (2.8)]*.
- If a dose is missed, advise the patient to take rivaroxaban as soon as possible on the same day and continue on the following day with their recommended daily dose regimen.

17.2 Bleeding Risks

- Advise patients to report any unusual bleeding or bruising to their physician. Inform patients that it might take them longer than usual to stop bleeding, and that they may bruise and/or bleed more easily when they are treated with rivaroxaban *[see Warnings and Precautions (5.2)]*.
- If patients have had neuraxial anesthesia or spinal puncture, and particularly, if they are taking concomitant NSAIDs or platelet inhibitors, advise patients to watch for signs and symptoms of spinal or epidural hematoma, such as back pain, tingling, numbness (especially in the lower limbs), muscle weakness, and stool or urine incontinence. If any of these symptoms occur, advise the patient to contact his or her physician immediately *[see Boxed Warning]*.

17.3 Invasive or Surgical Procedures

Instruct patients to inform their healthcare professional that they are taking rivaroxaban before any invasive procedure (including dental procedures) is scheduled.

17.4 Concomitant Medication and Herbals

Advise patients to inform their physicians and dentists if they are taking, or plan to take, any prescription or over-the-counter drugs or herbals, so their healthcare professionals can evaluate potential interactions *[see Drug Interactions (7)]*.

17.5 Pregnancy and Pregnancy-Related Hemorrhage

- Advise patients to inform their physician immediately if they become pregnant or intend to become pregnant during treatment with rivaroxaban *[see Use in Specific Populations (8.1)]*.
- Advise pregnant women receiving rivaroxaban to immediately report to their physician any bleeding or symptoms of blood loss *[see Warnings and Precautions (5.7)]*.

17.6 Nursing

Advise patients to discuss with their physician if they are nursing or intend to nurse during anticoagulant treatment *[see Use in Specific Populations (8.3)]*.

17.7 Females of Reproductive Potential

Advise patients who can become pregnant to discuss pregnancy planning with their physician *[see Use in Specific Populations (8.6)]*.

Manufactured by:
Micro Labs Limited
Goa-403 722, INDIA.

Manufactured for:
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Princeton, NJ 08540

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MEDICATION GUIDE
Rivaroxaban (RIV-a-ROX-a-ban) Tablets

Read this Medication Guide before you start taking rivaroxaban tablets and each time you get a refill.

There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about rivaroxaban tablets?

- **For people taking rivaroxaban tablets for atrial fibrillation:**

  People with atrial fibrillation (an irregular heart beat) are at an increased risk of forming a blood clot in the heart, which can travel to the brain, causing a stroke, or to other parts of the body. Rivaroxaban tablets lower your chance of having a stroke by helping to prevent clots from forming. If you stop taking rivaroxaban tablets, you may have increased risk of forming a clot in your blood.

  Do not stop taking rivaroxaban tablets without talking to the doctor who prescribes it for you. Stopping rivaroxaban tablets increases your risk of having a stroke.

  If you have to stop taking rivaroxaban tablets, your doctor may prescribe another blood thinner medicine to prevent a blood clot from forming.

- **Rivaroxaban tablets can cause bleeding** which can be serious, and rarely may lead to death. This is because rivaroxaban tablets are a blood thinner medicine that reduces blood clotting. While you take rivaroxaban tablets you are likely to bruise more easily and it may take longer for bleeding to stop.

  You may have a higher risk of bleeding if you take rivaroxaban tablets and take other medicines that increase your risk of bleeding, including:
  - aspirin or aspirin containing products
  - non-steroidal anti-inflammatory drugs (NSAIDs)
  - warfarin sodium (Coumadin®, Jantoven®)
  - any medicine that contains heparin
  - clopidogrel (Plavix®)
  - other medicines to prevent or treat blood clots

Tell your doctor if you take any of these medicines. Ask your doctor or pharmacist if you are not sure if your medicine is one listed above.

Call your doctor or get medical help right away if you develop any of these signs or symptoms of bleeding:

- unexpected bleeding or bleeding that lasts a long time, such as:
  - o nose bleeds that happen often
  - o unusual bleeding from the gums
  - o menstrual bleeding that is heavier than normal or vaginal bleeding
- bleeding that is severe or you cannot control
- red, pink or brown urine
- bright red or black stools (looks like tar)
- cough up blood or blood clots
- vomit blood or your vomit looks like "coffee grounds"
- headaches, feeling dizzy or weak
- pain, swelling, or new drainage at wound sites

- **Spinal or epidural blood clots (hematoma).** People who take a blood thinner medicine (anticoagulant) like rivaroxaban tablets, and have medicine injected into their spinal and epidural area, or have a spinal puncture have a risk of forming a blood clot that can cause long-term or permanent loss of the ability to move (paralysis). Your risk of developing a spinal or epidural blood clot is higher if:
  - o a thin tube called an epidural catheter is placed in your back to give you certain medicine
  - o you take NSAIDs or a medicine to prevent blood from clotting
  - o you have a history of difficult or repeated epidural or spinal punctures
  - o you have a history of problems with your spine or have had surgery on your spine

If you take rivaroxaban tablets and receive spinal anesthesia or have a spinal puncture, your doctor should watch you closely for symptoms of spinal or epidural blood clots. Tell your doctor right away if you have back pain, tingling, numbness, muscle weakness (especially in your legs and feet), loss of control of the bowels or bladder (incontinence).

- **Rivaroxaban tablets are not for patients with artificial heart valves.**

See "What are the possible side effects of rivaroxaban tablets?" for more information about side effects.

What are rivaroxaban tablets?

- Rivaroxaban tablets are prescription medicine used to:
  - o reduce the risk of stroke and blood clots in people who have a medical condition called atrial fibrillation. With atrial fibrillation, part of the heart does not beat the way it should. This can lead to the formation of blood clots, which can travel to the brain, causing a stroke, or to other parts of the body.
  - o treat blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism) and reduce the risk of them occurring again
  - o reduce the risk of forming a blood clot in the legs and lungs of people who have just had hip or knee replacement surgery

It is not known if rivaroxaban tablets are safe and effective in children.

Who should not take rivaroxaban tablets?

Do not take rivaroxaban tablets if you:

- currently have certain types of abnormal bleeding. Talk to your doctor before taking rivaroxaban tablets if you currently have unusual bleeding.
- are allergic to rivaroxaban or any of the ingredients in rivaroxaban tablets. See the end of this leaflet for a complete list of ingredients in rivaroxaban tablets.

What should I tell my doctor before taking rivaroxaban tablets?

Before you take rivaroxaban tablets, tell your doctor if you:

- have ever had bleeding problems
- have liver or kidney problems
- have any other medical condition
- are pregnant or plan to become pregnant. It is not known if rivaroxaban tablets will harm your unborn baby. Tell your doctor right away if you become pregnant while taking rivaroxaban tablets. If you take rivaroxaban tablets during pregnancy tell your doctor right away if you have any bleeding or symptoms of blood loss.
- are breastfeeding or plan to breastfeed. It is not known if rivaroxaban tablets passes into your breast milk. You and your doctor should decide if you will take rivaroxaban tablets or breastfeed.

Tell all of your doctors and dentists that you are taking rivaroxaban tablets. They should talk to the doctor who prescribed rivaroxaban tablets for you before you have any surgery, medical or dental procedure.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Some of your other medicines may affect the way rivaroxaban tablets works. Certain medicines may increase your risk of bleeding. See **"What is the most important information I should know about rivaroxaban tablets?"**

Especially tell your doctor if you take:

- ketoconazole (Nizoral®)
- itraconazole (Onmel™, Sporanox®)
- ritonavir (Norvir®)
- lopinavir/ritonavir (Kaletra®)
- indinavir (Crixivan®)
- carbamazepine (Carbatrol®, Equetro®, Tegretol®, Tegretol®-XR, Teril™, Epitol®)
- phenytoin (Dilantin-125®, Dilantin®)
- phenobarbital (Solfoton™)
- rifampin (Rifater®, Rifamate®, Rimactane®, Rifadin®)
- St. John's wort (Hypericum perforatum)

Ask your doctor if you are not sure if your medicine is one listed above.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take rivaroxaban tablets?

- Take rivaroxaban tablets exactly as prescribed by your doctor.
- Do not change your dose or stop taking rivaroxaban tablets unless your doctor tells you to.
- Your doctor will tell you how much rivaroxaban tablets to take and when to take it.
- Your doctor may change your dose if needed.
- If you take rivaroxaban tablets for:
  - o **atrial fibrillation:**
    - Take rivaroxaban tablets 1 time a day with your evening meal.
    - If you miss a dose of rivaroxaban tablets, take it as soon as you remember on the same day. Take your next dose at your regularly scheduled time.
  - o **blood clots in the veins of your legs or lungs:**
    - Take rivaroxaban tablets once or twice a day as prescribed by your doctor.
    - Take rivaroxaban tablets with food at the same time each day.
    - If you miss a dose of rivaroxaban tablets:
      - **and take rivaroxaban tablets 2 times a day:** Take rivaroxaban tablets as soon as you remember on the same day. You may take 2 doses at the same time to make up for the missed dose. Take your next dose at your regularly scheduled time.
      - **and take rivaroxaban tablets 1 time a day:** Take rivaroxaban tablets as soon as you remember on the same day. Take your next dose at your regularly scheduled time.
  - o **hip or knee replacement surgery:**
    - Take rivaroxaban tablets 1 time a day with or without food.
    - If you miss a dose of rivaroxaban tablets, take it as soon as you remember on the same day. Take your next dose at your regularly scheduled time.
- If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take rivaroxaban tablets.
- Your doctor will decide how long you should take rivaroxaban tablets. Do not stop taking rivaroxaban tablets without talking with your doctor first.
- Your doctor may stop rivaroxaban tablets for a short time before any surgery, medical or dental procedure. Your doctor will tell you when to start taking rivaroxaban tablets again after your surgery or procedure.
- Do not run out of rivaroxaban tablets. Refill your prescription of rivaroxaban tablets before you run out. When leaving the hospital following a hip or knee replacement, be sure that you will have rivaroxaban tablets available to avoid missing any doses.
- If you take too much rivaroxaban tablets, go to the nearest hospital emergency room or call your doctor right away.

What are the possible side effects of rivaroxaban tablets?

- **See "What is the most important information I should know about rivaroxaban tablets?"**

Tell your doctor if you have any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store rivaroxaban tablets?

- Store rivaroxaban tablets at room temperature between 68°F to 77°F (20° to 25°C).

Keep rivaroxaban tablets and all medicines out of the reach of children.

General information about rivaroxaban tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use rivaroxaban tablets for a condition for which it was not prescribed. Do not give rivaroxaban tablets to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about rivaroxaban tablets. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about rivaroxaban tablets that is written for health professionals.

For more information call **Micro Labs USA Inc.** 1-855-839-8195

What are the ingredients in rivaroxaban tablets?

Active ingredient: rivaroxaban
Inactive ingredients: croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and sodium lauryl sulfate.

The proprietary film coating mixture for rivaroxaban tablets 10 mg tablets is Opadry Pink (03F540164) and contains: ferric oxide red, hypromellose, polyethylene glycol 3350, and titanium dioxide.

The proprietary film coating mixture for rivaroxaban tablets 15 mg tablets is Opadry Brown (03F565105) and contains: ferric oxide red, hypromellose, polyethylene glycol 3350, and titanium dioxide.

The proprietary film coating mixture for rivaroxaban tablets 20 mg tablets is Opadry Brown (03F565106) and contains: ferric oxide red, polyethylene glycol 3350, and titanium dioxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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