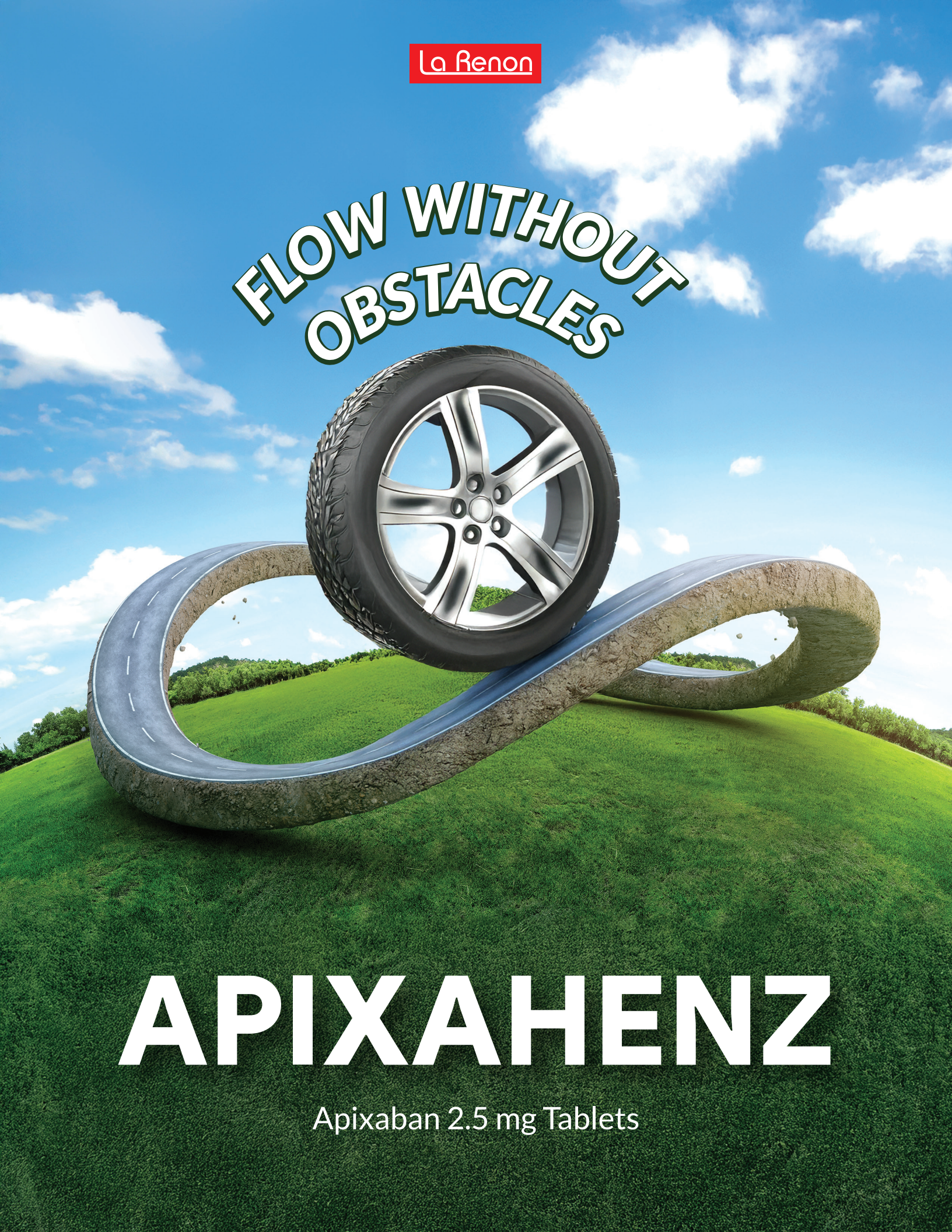
La Renon

FLOW WITHOUT OBSTACLES



APIXAHENZ

Apixaban 2.5 mg Tablets

Associations of Apixaban Dose with Safety and Effectiveness Outcomes in Patients with Atrial Fibrillation and Severe CKD

A retrospective cohort study

Total Patients:

4313

Dose:

Apixaban 5 mg (n=1705) = 5 mg twice daily
Apixaban 2.5 mg (n= 2608) = 2.5 mg twice daily

Inclusion Criteria:

Adult patients with AF and non–dialysis-dependent CKD stage 4/5 (defined as eGFR <30 mL/min/1.73 m^2) who initiated apixaban (5 mg versus 2.5 mg) were eligible for inclusion.

Outcomes:

Risks of bleeding and stroke/systemic embolism were compared by apixaban dose (5 mg versus 2.5 mg).

Results:

Risk of bleeding and stroke/systemic embolism associated with apixaban dose:

Outcome	Weighted incidence rate (95% CI), events per 100 person-years		Weighted incidence rate difference (95% CI), events per 100 person-years
	5 mg	2.5 mg	5 mg vs 2.5 mg
Any bleeding	4.9 (3.7–6.1)	2.9 (2.2–3.6)	2.0 (0.6 to 3.4)
Stroke/systemic embolism	3.3 (2.3–4.2)	3.0 (2.4–3.7)	0.2 (–1.0 to 1.4)

- Apixaban 5 mg was associated with a higher risk of bleeding (incidence rate 4.9 versus 2.9 events per 100 person-years; incidence rate difference, 2.0 [95% CI, 0.6–3.4] events per 100 person-years).

Conclusion:

Compared with 2.5 mg, use of 5 mg apixaban was associated with a higher risk of bleeding in patients with AF and severe CKD.

Apixaban 2.5 mg is a better choice to reduce the risk of bleeding for patients with AF and non–dialysis dependent CKD stage 4/5

AF=Atrial Fibrillation
Reference: Circulation. 2023;148:1445–1454

Safety and Effectiveness of Apixaban vs. Warfarin in Patients with Severe Renal Impairment

Retrospective, matched cohort study

Total Patients Enrolled: 146 Apixaban Group n=73 Warfarin Group n= 73

Dose:

Apixaban (n=73): 2.5 mg twice daily (n=45), 5 mg twice daily: (n=27), 10 mg twice daily: (n=1)

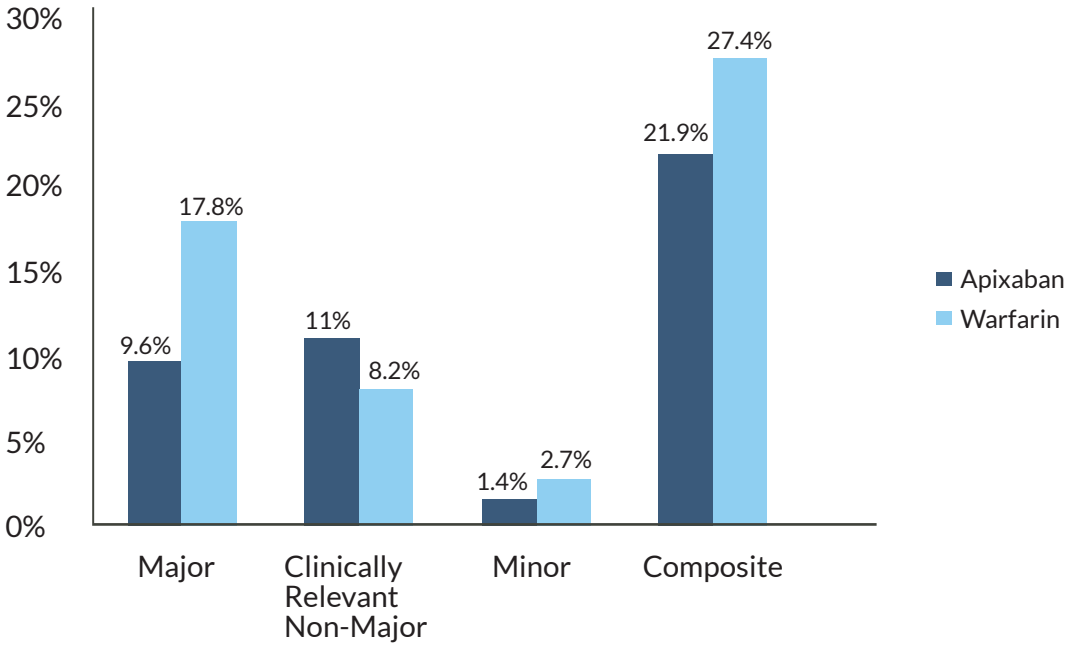
Warfarin (n=73): 4 mg daily

Inclusion Criteria:

- Adults (≥ 18 years) who received apixaban or warfarin during hospitalization
- Creatinine clearance (CrCl) < 25 mL/min or serum creatinine (SCr) > 2.5 mg/dL
- Patients on peritoneal dialysis or Hemodialysis

Results:

Occurrence of clinical outcomes in the patients receiving Apixaban and Warfarin.



- Apixaban showed a major bleeding incidence of 9.6%, compared to 17.8% with warfarin.
- Apixaban was associated with composite bleeding in 21.9% of patients, versus 27.4% in the warfarin group.
- Based on the results of this study, apixaban seems to be a reasonable alternative to warfarin in patients with severe renal dysfunction who prefer a target-specific anticoagulant.

Apixaban is a safe and effective alternative to warfarin for patients with severe renal impairment

CrCl = creatinine clearance, SCr = serum creatinine concentration

Reference: Pharmacotherapy. 2017 Apr;37(4):412-419

APIXAHENZ

Apixaban 2.5 mg Tablets

Background:

Atrial fibrillation (AF) is common in CKD patients, with prevalence ranging from 13% to nearly 50%, depending on the stage of CKD. Treating patients with AF in patients with advanced CKD can be particularly challenging as CKD is associated with higher risk of both thrombotic and bleeding events. Direct oral anticoagulants (DOACs) are partially eliminated through the kidneys to varying extents and initial trials validating their effectiveness excluded individuals with advanced kidney disease (creatinine clearance <25). Among the DOACs, Apixaban undergoes the least renal excretion, making it a preferred choice when it comes to stroke prevention in dialysis patients with AF.

Description:

APIXAHENZ (Apixaban) is an oral, direct Factor Xa (FXa) inhibitor used as an anticoagulant. APIXAHENZ is available as: **APIXAHENZ-2.5** (Apixaban 2.5 mg) Tablet.

Indication:

APIXAHENZ is indicated:

- To reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.
- For the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE).
- For the treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE following initial therapy.

Mechanism of Action:

Apixaban is an oral, reversible, and selective active site inhibitor of FXa. It does not require antithrombin III for antithrombotic activity. Apixaban inhibits free and clot bound FXa, and prothrombinase activity. Apixaban has no direct effect on platelet aggregation but indirectly inhibits platelet aggregation induced by thrombin. By inhibiting FXa, apixaban decreases thrombin generation and thrombus development.

Dosage:

Reduction of risk of stroke and systemic embolism in nonvalvular atrial fibrillation

- The recommended dose is 5 mg orally twice daily.
- In patients with at least 2 of the following characteristics: age ≥80 years, body weight ≤60 kg, or serum creatinine ≥1.5 mg/dL, the recommended dose is 2.5 mg orally twice daily.

Treatment of DVT and PE:

- The recommended dose is 10 mg taken orally twice daily for 7 days, followed by 5 mg taken orally twice daily.

Reduction in the risk of recurrent DVT and PE following initial therapy:

- The recommended dose is 2.5 mg taken orally twice daily.

Benefits:

- Safer and more effective than warfarin in patients with severe renal impairment
- Lower risk of major bleeding compared to warfarin in CKD and dialysis patients
- Fast onset of action
- Low potential for food or drug interactions
- Lack of requirement for routine monitoring during clinical use

References:
Blood (2023) 142 (Supplement 1): 2638. I Circulation. 2022;146:1735–1745 I BMC Nephrol 25, 338 (2024). I Clinical Pharmacokinetics (2019) 58:1265–1279
Kidney Int.2010;77:1098–1106 I Apixaban Label Claim, Reference ID: 3961165

La Renon Healthcare Private Limited
207-208, Iscon Elegance | Circle P | Prahlad Nagar Cross Roads
S.G. Highway, Ahmedabad-380015 | Gujarat, India.
Phone: + 91-79-6616-8998 / 2693-6656 | Fax: +91-79-6616-8998
E-mail: info@larenon.com | Web: www.larenon.com

Scan for more Prescribing Information

I am: _____
Call me on: _____
Mail me at: _____