

Prescribing Information

VAZKEPA® ▼ (ICOSAPENT ETHYL) 998 MG SOFT CAPSULES

Prescribers should refer to the Summary of Product Characteristics (SmPC) before prescribing.

Indication: Vazkepa is indicated to reduce the risk of cardiovascular events in adult statin-treated patients at high cardiovascular risk with elevated triglycerides (≥ 150 mg/dL; ≥ 1.7 mmol/L) and either: established cardiovascular disease, or diabetes and at least one other cardiovascular risk factor.

Dosage: Adults: two 998 mg capsules twice daily. Oral administration, taken with or following a meal. Swallow capsules whole. Do not break, crush, dissolve, or chew. Elderly (≥ 65 years): No dose adjustment necessary based on age.

Renal impairment: No dose reduction is recommended. Hepatic impairment: No dose reduction is recommended.

Contraindications: Hypersensitivity to the active substance, soya, peanut or to any of the excipients.

Special warnings and precautions: Allergies to fish/shellfish: Vazkepa is obtained from fish oil. It is not known whether patients with allergies to fish and/or shellfish are at increased risk of an allergic reaction to Vazkepa. Vazkepa should be used with caution in patients with known hypersensitivity to fish and/or shellfish. Hepatic impairment: In patients with hepatic impairment, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) concentrations should be monitored as clinically indicated before the start of treatment and at appropriate intervals during treatment. Atrial fibrillation or flutter: Vazkepa was associated with an increased risk of atrial fibrillation or flutter requiring hospitalisation in a double-blind placebo-controlled trial. The incidence of atrial fibrillation was greater in patients with a previous history of atrial fibrillation or flutter. Patients, particularly those with a relevant medical history, should be monitored for clinical evidence of atrial fibrillation or atrial flutter. Electrocardiographic evaluation should be performed when clinically indicated. Bleeding: Treatment with Vazkepa has been associated with an increased incidence of bleeding. Patients taking Vazkepa in combination with antithrombotic agents, i.e., antiplatelet agents, including acetylsalicylic acid, and/or anticoagulants, may be at increased risk of bleeding and should be monitored periodically.

Interactions: Vazkepa was studied with the following medicinal products which are typical substrates of cytochrome P450 enzymes: omeprazole, rosiglitazone, warfarin and atorvastatin. No interactions were observed.

Pregnancy / lactation: Limited human data on use during pregnancy are available. Use of Vazkepa during pregnancy should be avoided unless the benefit of use outweighs the potential risk to the foetus. It is not known whether Vazkepa is excreted in human milk. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Vazkepa therapy considering the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Side effects: Refer to SmPC for full list of undesirable effects. Very common ($\geq 1/10$): bleeding; Common ($\geq 1/100$ to $< 1/10$): gout, atrial fibrillation or flutter, constipation, eructation, rash, musculoskeletal pain, peripheral oedema; Uncommon ($\geq 1/1000$ to $< 1/100$): hypersensitivity, dysgeusia. Not Known: pharyngeal swelling.

Legal Category: Prescription only medicine (POM).

Pack quantities: Vazkepa is available in HDPE bottles containing 120 soft capsules.

Basic NHS price: £144.21 per 120 soft capsules.

Marketing Authorisation Holder: Recordati Industria Chimica e Farmaceutica S.p.A., Via Matteo Civitali, 1, 20148 Milan, Italy

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Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/>
Adverse events should also be reported to Recordati Pharmaceuticals Limited by e-mail: Local-Safety@recordati.com or by calling +44 (0)1491 576 336