Basic Succinct Statement

SUVIRAY®

Presentation:

Solution for injection, subcutaneous use: 1 mL prefilled syringe contains 70 mg of erenumab.

Indications:

Suviray is indicated for prophylaxis of migraine.

Dosage and administration:

Adults: The recommended dose of Suviray® is 70 mg administered subcutaneously once monthly. Some patients may benefit from a dosage of 140 mg once monthly. Suviray is intended for patient self-administration in the abdomen, thigh, or upper arm. Administration should be performed by an individual who has been trained to administer the product. The needle cover of Suviray prefilled syringe contains dry natural rubber (a derivative of latex), which may cause allergic reactions in individuals sensitive to latex.

Special populations

Pediatric patients: The safety and effectiveness of Suviray have not been studied in pediatric patients.

Geriatric patients: Clinical studies of Erenumab did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Renal impairment: No dose adjustment is necessary in patients with mild to moderate renal impairment.

Hepatic impairment: No clinical studies have been conducted to evaluate the effect of hepatic impairment. Hepatic clearance is not a major clearance pathway for erenumab.

Contraindications:

Serious hypersensitivity to erenumab or to any of the excipients.

Warnings and precautions:

The following adverse reactions have been reported in the post-marketing setting following the use of Erenumab: Serious hypersensitivity reactions, including rash, angioedema, and anaphylaxis, constipation with serious complications, development of hypertension and worsening of pre-existing hypertension have been reported in post-marketing experience, development of Raynaud's phenomenon and recurrence or worsening of pre-existing Raynaud's phenomenon have been reported in the postmarketing setting following the use of CGRP antagonists, including Erenumab.

Pregnancy, lactation, females and males of reproductive potential:

Pregnancy: Safety has not been established. Suviray should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: It is not known whether erenumab is present in human milk. A decision should be made whether to discontinue nursing or discontinue Suviray, taking into account the benefit-risk assessment for the mother and the infant.

Females and males of reproductive potential: No human data are available. There were no adverse effects on surrogate markers of fertility in monkeys.

Adverse drug reactions:

Common (1 to 10%): Injection site reactions, constipation, pruritus.

Uncommon (< 1%): Muscle Spasm

Injections site reactions: including injection site pain, injection site erythema and injection site pruritus. A majority of injection site reactions were mild and transient.

Post-marketing experience: Hypersensitivity reactions including rash, angioedema and anaphylaxis. Constipation with serious complications. Hypertension. Oral mucosal ulceration. Alopecia. Raynaud's phenomenon

Immunogenicity: In pivotal studies the incidence of anti-erenumab antibody was 6.2% for the 70 mg dose (*in vitro* neutralizing activity in 3 patients). There was no impact of anti-erenumab antibody development on efficacy or safety of erenumab.

Interactions:

Erenumab is not metabolized by cytochrome P450 enzymes and is unlikely to cause marked changes in pro-inflammatory cytokines that may impact cytochrome P450 enzyme expression or activity. Interactions with concomitant medications that are substrates, inducers, or inhibitors of cytochrome P450 enzymes are unlikely. Suviray did not affect the pharmacokinetics of a combined oral contraceptive containing ethinyl estradiol and norgestimate and had no effect on the pharmacokinetics of sumatriptan. Concomitant administration of Suviray with sumatriptan had no effect on resting blood pressure compared with sumatriptan alone.

Packs: Suviray 70 mg/ml solution for injection in pre-filled syringe – 1 pre-filled syringe per pack

Before prescribing, please consult full prescribing information available from Novartis Healthcare Private Limited, Inspire BKC, 7th Floor, Bandra Kurla Complex, Bandra (E), Mumbai 400051, Maharashtra, India. Tel +91 22 50243000

WARNING: To be sold by retail on the prescription of a "Registered Neurologist & Psychiatrist".

India BSS dated 31 Jan 2022, revised on 29 Apr 2026 based on the International BSS dated 5 Oct 2020, effective from 29 Apr 2026.