NOVARTIS

PASURTA® (erenumab)

70 mg/mL Solution for injection in a prefilled syringe

Basic Succinct Statement (BSS)
Version 2.3

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This material is only meant for Healthcare Professionals

PASURTA® 70 mg/mL Solution for injection in a prefilled syringe

Important note: Before prescribing, consult full prescribing information.

Presentation:

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

Indications:

Pasurta is indicated for prophylaxis of migraine in adults who have at least 4 migraine days per month.

Dosage and administration:

Adults: The recommended dose of Pasurta is 70 mg administered subcutaneously once monthly. Some patients may benefit from a dosage of 140 mg once monthly. Pasurta is intended for patient self-administration in the abdomen, thigh, or, if someone else is giving the injection, also into the outer area of the upper arm. Administration should be performed by an individual who has been trained to administer the product. The needle cover of Pasurta prefilled syringe contain dry natural rubber, which may cause allergic reactions in individuals sensitive to latex.

Special populations

Pediatric patients: The safety and effectiveness of Pasurta have not been studied in pediatric patients.
Geriatric patients: No dose adjustment is necessary as the pharmacokinetics of Pasurta are not affected by age.
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 Pasurta.

Contraindications:

Serious hypersensitivity to erenumab or to any of the excipients.

Warnings and precautions:

Serious hypersensitivity reactions, including rash, angioedema, and anaphylactoid reactions have been reported in post-marketing experience.

Adverse drug reactions:

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

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 anaphylactoid reactions. Constipation with serious complications.

Immunogenicity: In pivotal studies the incidence of anti-erenumab antibody was 6.3% for the 70 mg dose (*in vitro* neutralizing activity in 3 patients) and 2.6% for the 140 mg dose (no patients with *in vitro* neutralizing activity). There was no impact of anti-erenumab antibody development on efficacy or safety of Pasurta.

Interactions:

Pasurta 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. Pasurta 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 Pasurta with sumatriptan had no effect on resting blood pressure compared with sumatriptan alone.