

Symjepi[™] (epinephrine) – New formulation approval

- On September 27, 2018, the [FDA approved](#) Adamis' [Symjepi \(epinephrine\)](#) 0.15 mg injection for the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (eg, order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (eg, triatoma, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (eg, radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.
 - Symjepi is intended for immediate administration in patients who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions.
 - Anaphylactic reactions may occur within minutes after exposure and consist of flushing, apprehension, syncope, tachycardia, thready or unobtainable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhea and abdominal cramps, involuntary voiding, wheezing, dyspnea due to laryngeal spasm, pruritus, rashes, urticaria or angioedema.
 - Symjepi is intended for immediate administration as emergency supportive therapy only and is not a substitute for immediate medical care.
- Previously, Symjepi was only approved as a 0.3 mg injection. Epinephrine for the emergency treatment of allergic reactions is also available as [Auvi-Q[®]](#), [EpiPen[®]](#), and EpiPen Jr.
- Warnings and precautions of Symjepi include emergency treatment, injection-related complications, serious infections at the injection site, allergic reactions associated with sulfite, and disease interactions.
- The most common adverse reactions with Symjepi use include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and/or respiratory difficulties.
- Selection of the appropriate dosage strength (Symjepi 0.3 mg or Symjepi 0.15 mg) is determined according to patient body weight:
 - Patients ≥ 30 kg (approximately 66 pounds or more): Symjepi 0.3 mg
 - Patients 15 to 30 kg (33 pounds to 66 pounds): Symjepi 0.15 mg
- Symjepi is injected intramuscularly or subcutaneously into the anterolateral aspect of the thigh with the needle facing downwards. It can be injected through clothing if necessary.
- The prescriber should carefully assess each patient to determine the most appropriate dose of epinephrine, recognizing the life-threatening nature of the reactions for which this drug is indicated.
- Adamis' launch plans for Symjepi 0.15 mg single-dose prefilled syringes are pending.