Symjepi™ (epinephrine) – New drug approval

- On June 15, 2017, Adamis announced the FDA approval of Symjepi (epinephrine) 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.

- Anaphylaxis is a serious, sometimes life-threatening allergic reaction. The most common anaphylactic reactions are to foods, insect stings, medications and latex. Up to 8% of U.S. children under the age of 18 have a food allergy, and approximately 38% of those with a food allergy have a history of severe reactions.

- 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 were anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and/or respiratory difficulties.

- The recommended dose of Symjepi is one syringe (0.3 mg/3 mL) in patients weighing ≥ 30 kg injected intramuscularly or subcutaneously into the anterolateral aspect of the thigh with the needle facing downwards.

    — The Symjepi syringe can be injected through clothing if necessary.
    — In young children who may be uncooperative and kick or move during an injection, caregivers should hold the leg firmly in place and limit movement prior to and during an injection.
    — With severe persistent anaphylaxis, repeat injections with an additional Symjepi may be necessary.

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- Adamis plans to launch Symjepi in the second half of 2017. Symjepi will be available as a single pack containing one single-dose pre-filled syringe for manual injection, containing 0.3 mg/0.3 mL epinephrine sterile solution for injection, and as a two-pack, containing two pre-filled syringes.