

From The Medical Letter on Drugs and Therapeutics

An Epinephrine Prefilled Syringe (Symjepi) for Anaphylaxis

The FDA has approved a manually injected, single-dose, prefilled epinephrine syringe (Symjepi – Adamis/Sandoz) for emergency treatment of anaphylaxis. The new device is approved in 0.3- and 0.15-mg strengths for treatment of patients weighing ≥ 30 kg and 15 to 30 kg, respectively; only the 0.3-mg strength is currently available. According to Sandoz, Symjepi will be made available first to institutions and later to the retail market.

Pronunciation Key

Symjepi: sim jep' ee

Epinephrine Auto-Injectors

EpiPen and EpiPen Jr, which are also available generically, have been used effectively for treatment of anaphylaxis for many years (see Table). A generic version of the Adrenaclick auto-injector (no longer manufactured) is also available; it is similar to EpiPen in size and functionality. Auvi-Q, which is the size of a thick credit card, provides visual signals and audio instructions, has an automatic needle retraction system, and appears to be more convenient to carry and easier to use than EpiPen.¹ It is the only auto-injector available in a 0.1-mg strength for use in children weighing 7.5-15 kg.² Because of differences in device design and instructions for use, these 3 auto-injectors are not considered interchangeable, and pharmacists cannot substitute one for another.

The New Device

The Symjepi syringe is stored in a plastic case that is 4.1" long, 1.6" wide, and 0.9" deep (EpiPen in its container is about 5.5" long and 1" in diameter and Auvi-Q is 3.5" long, 2" wide, and 0.5" thick).

The solution should be inspected periodically through a window in the syringe; if the normally clear, colorless solution appears cloudy or has visible particulates or a pink or brown tint, the syringe should be discarded and replaced.

Like epinephrine auto-injectors, Symjepi is injected intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. Before injection, the cap must be removed to expose the needle. Unlike epinephrine auto-injectors, Symjepi syringes require manual injection of the needle and depression of the plunger, which should be pushed down until it clicks; the syringe should then be held in place for two seconds. The single-dose syringe is intentionally overfilled; more than half of the solution will remain in the syringe after use. After the needle is withdrawn, the injection site should be massaged for ten seconds, and the safety guard should be extended manually until it covers the needle.

Clinical Study

In one study, the usability of a Symjepi device filled with saline was compared to that of an EpiPen trainer in 34 untrained adolescents 12-17 years old. All of the subjects tested both devices by simulating injection into a pad placed at the injection site; half of them tested Symjepi first and the other half tested EpiPen first. No use errors were

reported with the Symjepi device compared to 4 (3 were accidental injection into the thumb of the user) with the EpiPen trainer.³

Stability

Epinephrine solutions have a variable, relatively short duration of stability. They should not be exposed to light or to extreme temperatures; they should not be stored in a refrigerator or the glove compartment of an automobile.⁴ As with epinephrine auto-injectors, Symjepi syringes should be replaced before their expiration date.

Table. Epinephrine Products for Anaphylaxis

Epinephrine Injection, USP	Formulations ^a	Cost ^b
Auto-Injectors		
EpiPen (Mylan)	0.3 mg/0.3 mL	\$608.60 ^c
EpiPen Jr	0.15 mg/0.3 mL	608.60 ^c
generic (Mylan, ^d Teva)	0.3 mg/0.3 mL, 0.15 mg/0.3 mL ^f	300.00 ^{c,e}
generic (Impax) ^g	0.3 mg/0.3 mL, 0.15 mg/0.15 mL	395.20 ^{e,h}
Auvi-Q (Kaléo)	0.3 mg/0.3 mL, 0.15 mg/0.15 mL, 0.1 mg/0.1 mL	360.00 ^{e,i}
Syringe		
Symjepi (Adamis/Sandoz)	0.3 mg/0.3 mL, 0.15 mg/0.3 mL ^j	250.00

^a The dose of epinephrine is 0.1 mg for patients who weigh 7.5-15 kg, 0.15 mg for those who weigh 15-30 kg, and 0.3 mg for those who weigh ≥ 30 kg.

^b Approximate WAC for one package containing two auto-injectors. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. February 5, 2019. Reprinted with permission by First Databank, Inc. All rights reserved. ©2019. www.fdbhealth.com/policies/drug-pricing-policy/.

^c Mylan provides free epinephrine auto-injectors to eligible uninsured or underinsured patients who are from families earning up to 400% of the federal poverty level (<https://aspe.hhs.gov/poverty-guidelines>).

^d The Mylan product is an authorized generic drug, which means that it is exactly the same as the approved brand name drug, but is marketed without the brand name on its label.

^e All strengths cost the same.

^f The Teva 0.15-mg strength will be marketed later in 2019.

^g Authorized generic (see footnote 3) of Adrenaclick, which has been discontinued.

^h Both strengths are available at discounted prices at some pharmacies (at CVS pharmacies, the cash price is \$110.00 for a package containing two auto-injectors).

ⁱ The WAC is \$4900, but the manufacturer states that the out-of-pocket cost is \$0 for all commercially insured patients. The cash price for patients without government or commercial insurance is \$360 for those with a household income $\geq$ \$100 000/year and \$0 for those with a household income $<$ \$100 000/year.

^j Only the 0.3-mg strength has been marketed; the launch date for the 0.15-mg strength has not been announced.

Conclusion

Symjepi, the new epinephrine single-dose, prefilled syringe for treatment of anaphylaxis, is priced lower than EpiPen and its generics.

Unlike auto-injectors, Symjepi syringes require the user to manually inject the needle and push down the plunger, which may be difficult for some patients, particularly children.

ARTICLE INFORMATION

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