

Zeneo® Hydrocortisone Autoinjector FAQ

What is an autoinjector?

A single use medical device designed to deliver a specific dose of a particular drug.

When will it be available?

The company expects to file an application with the Food and Drug Administration (FDA) in 2023. The commercial availability is yet to be determined.

What will it cost?

We will determine the price closer to launch of the product. However, we expect to be guided by the same principle in place now. If a patient needs the product, we will do what we can to support the patient regardless of their ability to pay.

Will it be approved for kids?

The feasibility of a drug device combination for children is being considered. The product requires evaluation and approval by the FDA prior to market availability.

What is a needleless autoinjector?

The Zeneo® is a single-use device that propels the medicine through the skin in less than a tenth of a second. You may obtain more information about Zeneo and its developer, Crossject, at www.crossject.com

How is it different than other autoinjector devices?

The primary difference between Zeneo and other autoinjectors is that Zeneo delivers drug using a needleless technology and other devices deliver drug using needles for injection.

What is the indication of use?

The Zeneo hydrocortisone drug/device combination product is still in development and therefore, an indication hasn't been granted. However, the proposed indication requested in the application will be for use as a rescue medication for the management of acute adrenal crisis.

In what setting may the drug/device be used?

The setting of potential use of the drug device combination is wherever emergent treatment of adrenal crisis is required, for example, home, school, hospital, EMT, etc. The final use settings will be determined by the FDA as part of the approval.

Are there going to be any clinical trials required?

Yes, the development plan for this drug device product is under discussion.

Are there going to be any human factor studies required?

Yes, the development plan for this drug device product is under discussion.

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Is there pain associated with the administration of drug using the needleless autoinjector?

Testing of the Zeneo Autoinjector with drugs other than hydrocortisone have shown that the discomfort felt by the patient is similar to that of typical needle injections.

What are the side effects of the treatment?

Although the Zeneo hydrocortisone product has not been evaluated, we anticipate that the side effect profile will be similar to other emergency use forms of hydrocortisone, such as SoluCortef. The Crossject Zeneo hydrocortisone drug/device combination product is under development and therefore, has not be evaluated or approved by the Food and Drug Administration.