

Summary Public Assessment Report

EpiPen Twist, EpiPen Jr. Twist (adrenaline tartrate)

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EpiPen Twist, EpiPen Jr. Twist
adrenaline tartrate, adrenaline

Solution for injection in pre-filled pen, 300 mikrogram, 150 mikrogram

This is a summary of the public assessment report (PAR) for EpiPen Twist, EpiPen Jr. Twist. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is EpiPen Twist, EpiPen Jr. Twist and what is it used for?

The product is a medicine with 'well-established use'. This means that the medicinal use of the active substance of the product is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

EpiPen Twist, EpiPen Jr, is a sterile solution in a pre-filled syringe in an auto-injector for emergency injection into the muscle (intramuscular).

EpiPen Twist, EpiPen Jr, is to be used for the emergency treatment of severe allergic reactions (anaphylaxis) caused by allergens in e.g. insect stings or bites, foods, drugs and other allergens as well as triggered by exercise or by unknown causes.

How does EpiPen Twist, EpiPen Jr. Twist work?

The medicine in the EpiPen Twist, EpiPen Jr, is adrenaline (epinephrine) which is an adrenergic drug. It works directly on the cardiovascular (heart and circulation) system and respiratory (lung) system, countering the potentially fatal effects of anaphylaxis by rapidly constricting the blood vessels, relaxing muscles in the lungs to improve breathing, reducing swelling and stimulating heartbeat.

Anaphylactic reaction may occur within minutes after exposure and consist of: itching of the skin; raised rash (like a nettle rash); flushing; swelling of the lips, throat, tongue, hands and feet; wheezing; hoarseness; nausea; vomiting; abdominal cramps and in some cases, loss of consciousness.

The reaction is the result of the body trying to protect itself from the allergen (the foreign substance that causes the allergy) by releasing chemicals into the blood stream. Sometimes the cause of the allergic reaction is not known.

How is EpiPen Twist, EpiPen Jr. Twist used?

The pharmaceutical form is solution for injection.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of EpiPen Twist, EpiPen Jr. Twist have been shown in studies?

As adrenaline tartrate, adrenaline is a well-known substance, and its use in the treatment of severe allergic reactions (anaphylaxis) caused by allergens in e.g. insect stings or bites, foods, drugs and other allergens as well as triggered by exercise or by unknown causes, is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of adrenaline tartrate, adrenaline in the treatment of the above-mentioned indication.

What are the possible side effects from EpiPen Twist, EpiPen Jr. Twist?

For the full list of restrictions, see the package leaflet.

Why is EpiPen Twist, EpiPen Jr. Twist approved?

The Swedish Medical Products Agency decided that the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of EpiPen Twist, EpiPen Jr. Twist?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Additional risk minimisation measures (including educational material)

The educational material should contain the following key elements:

- Training device which should allow prescribers and patient/carers to familiarise themselves with the device and the administration procedure of the prescribed adrenaline Auto-Injector before its actual use.
The training device mimics the precise step of use of the active device without containing the active substance or a needle and offer the possibility to be reset and used repeatedly.
- Instructional audio-visual material which explains in detail how the product is to be used and the different steps for administration.
- Checklist for prescribers aiming to facilitate the discussion between the prescriber and the patient and to provide sufficient information on the optimal way of use, administration, and storage of the product.

For more details, please see the full PAR for EpiPen Twist, EpiPen Jr. Twist on the following website: [MRI - Home](#).

Other information about EpiPen Twist, EpiPen Jr. Twist

The full PAR for EpiPen Twist, EpiPen Jr. Twist can be found on the following website: [MRI - Home](#). For more information about treatment with EpiPen Twist, EpiPen Jr. Twist, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-07.