



Patient Information

The patient, and caregiver, if possible, should read this information carefully before using Twinject® (TWIN-jehkt). You must know how to use Twinject before you have an emergency. This information contains additional details beyond the quick-reference instructions on the Twinject label. This information does not replace talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about Twinject?

Use Twinject and go to your doctor or emergency room right away for more medical treatment.

- Epinephrine, the active ingredient in Twinject helps treat life-threatening allergic reactions.
- Make sure to tell your doctor about all your medical conditions and allergies.
- Always get medical treatment right away after using Twinject.

Since you cannot predict when a life-threatening allergic reaction will occur, carry Twinject with you at all times.

Look at the medicine in your Twinject regularly. If it looks cloudy (has particles in it), is discolored, or if the expiration date has passed, the Twinject should be replaced. In the event of a life-threatening allergic reaction, you should go ahead and use an out-of-date product, if that is all you have.

After the first and second dose, liquid will remain in the syringe that can't be used and should be discarded with the syringe as outlined in this Patient Information Leaflet.

What is Twinject?

Twinject is an emergency injection ("shot") of epinephrine. It is a medicine used for life-threatening allergic reactions such as severe swelling, breathing problems, or loss of blood pressure. Allergic reactions can be caused by stinging and biting insects (bugs), allergy injections, food, medicines, exercise, or unknown causes.

Life-threatening allergic reactions may show up as closing of your breathing airways, wheezing, sneezing, hoarseness, hives, itching, swelling, skin redness, fast heartbeat, weak pulse, feeling very anxious, confusion, stomach pain, losing control of urine or bowel movements (incontinence), faintness, or "passing out" (unconsciousness).

- Each Twinject can give 2 injections.
- Twinject 0.15mg is for patients who weigh 33-66 pounds (15-30 kg).
- Twinject 0.3mg is for patients who weigh 66 pounds (30 kg) or greater.
- Use of Twinject must be followed by emergency medical care.

Who should not use Twinject?

There are no absolute contraindications to the use of Twinject in a life-threatening allergic reaction. People with certain medical conditions have a higher chance of getting serious side effects from Twinject.

Tell your doctor about all your medical conditions, but especially if you:

- have heart disease or high blood pressure
- have diabetes
- have thyroid conditions
- have asthma
- have depression or other mental disease
- have Parkinson's disease
- are pregnant
- are allergic to any of the ingredients in Twinject

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Some medicines may cause serious side effects if taken while you use Twinject. Some medicines may affect how Twinject works, or Twinject may affect how your other medicines work. Diabetic patients may need to adjust the dose of their diabetes medicines or insulin after using Twinject.

How should I use Twinject?

- **Do NOT remove the green caps until you are ready to use.**
- **Never put thumb, fingers, or hand over the red tip.** The needle comes out of the red tip. Accidental injection into hand or feet may result in the loss of blood flow to these areas. If this happens, go immediately to the nearest emergency room.
- Hold Twinject in the thigh while slowly counting to 10 to make sure all medicine is delivered.
- Twinject is not suitable for patients, or caregivers, with such disabilities as severe debilitating arthritis of the hands, because the use of this product requires some manual dexterity to administer.
- Inject Twinject only into the middle of the outer side of your thigh (upper leg).
- Instructions on how to use Twinject also can be found at www.twinject.com.

What should I avoid while using Twinject?

- Avoid injecting Twinject into your buttock or any other part of your body, other than the middle of the outer side of your thigh (upper leg).
- Avoid injecting Twinject into a vein.

What are the possible side effects of Twinject?

Too much epinephrine (Twinject) can cause dangerously high blood pressure, stroke, or death.

If you take certain medicines, you may develop serious life-threatening side effects from the epinephrine in Twinject. Be sure to tell your doctor about all the medicines you take, especially medicines for asthma.

Patients with certain medical conditions, or who take certain medicines, may get more side effects from Twinject, or the side effects may last longer. This includes patients who take certain types of medicines for asthma, allergies, depression, hyperthyroidism, high blood pressure, and heart disease. Patients with heart disease may feel chest pain (angina). Patients with mental disease or Parkinson's disease may have worsening symptoms of their illness. Twinject (epinephrine) can cause the following reactions. Some reactions can be serious. They usually go away with rest.

Common side effects of Twinject include:

- faster, irregular (wrong) or 'pounding' heartbeat
- throbbing headache
- paleness
- feelings of over excitement, anxiety, or fear
- weakness or shakiness
- dizziness
- nausea and vomiting
- sweating

These are not all the possible side effects of Twinject. For more information, ask your doctor or pharmacist.

How should I store Twinject?

The medicine in Twinject can be damaged by light. Therefore, keep it in the carrying case provided. Keep it at room temperature and protect it from freezing. Do not refrigerate.

Keep Twinject with you at all times.

Check your Twinject regularly to be sure:

- it has not expired
- the medicine in Twinject is not cloudy, discolored, or has particles in it.

Replace the Twinject if needed.

General information about the safe and effective use of Twinject.

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use Twinject for a condition for which it was not prescribed. Do not give Twinject to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about Twinject. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about Twinject that is written for health professionals.

Patient Directions for Use

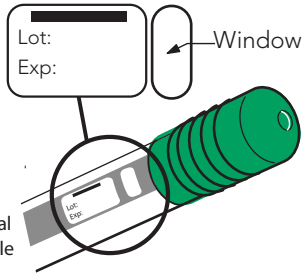
Before Use Make Sure Medicine Is Ready When You Need It

Look at the medicine in the Twinject regularly. If it looks cloudy, is discolored, has particles in it, or if the expiration date has passed, the Twinject should be replaced.

In the event of a life-threatening allergic reaction, you should go ahead and use an out-of-date or discolored product, if that is all you have.

Do NOT remove GREEN caps until you are ready to use the Twinject.

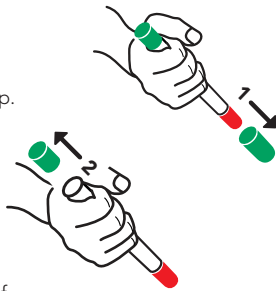
The following instructions should be followed for both Twinject 0.15mg and Twinject 0.3mg. Additional video instructions on the use of Twinject are available at www.twinject.com.



FIRST DOSE

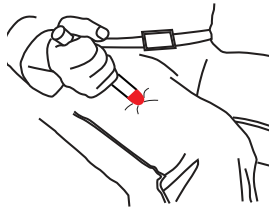
STEP A

- Pull off **GREEN** end cap with the [1]; you will now see a **RED** tip. Never put thumb, finger, or hand over the **RED** tip.
- Pull off **GREEN** end cap with [2].



STEP B

- Put the **RED** tip against the middle of the outer side of your thigh (upper leg) as shown. It can go through clothes.
- Press down hard until the needle enters your thigh (upper leg) through your skin. Hold it in place while slowly counting to 10.
- Remove the Twinject from your thigh.
- Check the **RED** tip, if the needle is exposed you received the dose. If needle is not visible, repeat First Dose step B.



Get emergency medical help right away.

Call 911

- **Immediately prepare for the second dose.**

It is very important to monitor symptoms closely after the first dose is given, including watching for new symptoms. If new symptoms have appeared or symptoms have not improved within about 10 minutes, a second dose is needed.



SECOND DOSE

STEP A

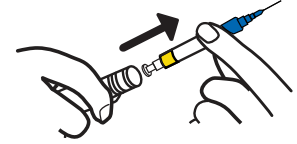
- Unscrew and remove the **RED** tip.



Be careful of the exposed needle.

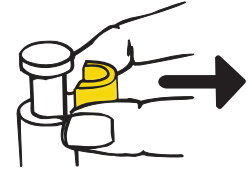
STEP B

- Grab the **BLUE** plastic to pull the syringe out of the barrel (do not touch the needle).



STEP C

- Slide the **YELLOW** collar off the plunger. Be careful not to pull up on the plunger while removing the **YELLOW** collar.

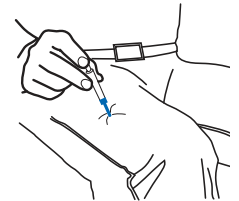


STEP D

- If your symptoms have not improved within about 10 minutes since the first injection, you need a second dose.



- Put the needle into your thigh (upper leg), through your skin, as shown.
- Push the plunger down all the way until it cannot go any further.
- Remove the Twinject from your skin.
- Get emergency medical help right away.
- If a second dose is not needed and after professional medical attention is received, throw away the unused medicine as directed in the after use/disposal directions of this leaflet.
- After the first and second dose, liquid will remain in the syringe that can't be used.



AFTER USE/DISPOSAL

- Put the syringe, needle first into the carrying case.
- Put the other half of the carrying case on and close it.
- Give your used Twinject to a healthcare worker for proper disposal. Do NOT throw away in a regular trash can.



Rx only

Manufactured for and Distributed by:
Shionogi Pharma, Inc.,
Atlanta, GA 30328 USA

 **SHIONOGI PHARMA, INC.**

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