

Getting Started on Edex



edex[®]

(alprostadil for injection)

10 mcg • 20 mcg • 40 mcg

An Introduction to Edex®

Edex can only be obtained with a prescription from your doctor. You or your partner should be fully trained on the proper injection technique before using Edex at home. Be sure to use only the dose prescribed by your doctor.

This pamphlet provides a summary of information about your medicine. Please read this information carefully before you prepare the Edex solution. After reading this pamphlet, if you have any questions, talk to your doctor. He or she is always your best source of information.

About Edex

Edex is a drug that is injected into the penis to treat erectile dysfunction, also called impotence. Its active ingredient is alprostadil.

Alprostadil is identical to a naturally occurring substance in the body. Alprostadil widens the blood vessels and increases blood flow into the penis.

Edex is an option for men who do not respond to, or are not candidates for, oral erectile dysfunction therapy.¹

When you use Edex, you can expect it to work in five to 20 minutes.

Edex® is not a cure for erectile dysfunction. The underlying treatable medical causes should be diagnosed and treated prior to starting therapy. The therapeutic effect of each dose is temporary. A common side effect is mild to moderate pain during the injection.

What You Should Know About Edex

How Edex Is Used

Edex is injected into a specific area of the penis. See instructions for Self-Injection in this brochure.

What to Expect from Edex

Edex should produce an erection in five to 20 minutes. The standard goal for treatment is to produce an erection lasting no longer than one hour. You should NOT use Edex more than three times a week. Injections should be administered at least 24 hours apart. Ideally, the injection should be given just prior to foreplay.

People Who Shouldn't Use Edex

Men who have conditions that might result in long-lasting erections should not use Edex. Some of these conditions are sickle cell anemia or trait, leukemia and tumor of the bone marrow (multiple myeloma). If you have any of these conditions, talk to your doctor. Men with penile implants, severe penile curvature or those who have been advised not to engage in sexual activity should not use Edex. Edex should not be used by women or children.

The Risks of Using Edex

Erections that last more than six hours can cause serious damage to the penile tissue and may result in permanent impotence. If you still have an erection six hours after injection, call your doctor immediately or, if unavailable, seek professional help elsewhere.

Side Effects Associated with Edex

A common side effect of Edex is mild to moderate pain during injection. The erection may also be associated with a painful sensation. If you experience severe pain, call the doctor who prescribed Edex. A small amount of bleeding at the injection site may occur. To prevent bruising, apply firm, but gentle, pressure to the injection site for five minutes, continue until bleeding stops. Tell your doctor if you have a condition or are taking a medicine that interferes with blood clotting.

There is a possibility of needle breakage with the use of Edex. To best avoid breaking the needle, you should pay careful attention to your doctor's instructions and try to handle the injection device properly. If the needle breaks during injection and you are able to see and grasp the broken end, you should remove it and contact your doctor. If you cannot see or cannot grasp the broken end, you should promptly contact your doctor.

Other Important Information

- Call your doctor if you see any redness, lumps, swelling, tenderness or curvature of the erect penis.
- Edex offers no protection from sexually transmitted diseases such as HIV (the virus that causes AIDS).
- Small amounts of bleeding at the injection site can increase the risk of transmission of blood-borne diseases between partners.

How to Store Edex

Edex should be stored at approximately 77° F (25° C), however the temperature can vary between 59° to 86° F (15° to 30° C). Avoid extremes in temperature. If you travel with Edex, do NOT store it in your checked luggage during air travel or leave it in a closed car.

Edex should always be used immediately after mixing it.


Using Edex

It is very important that you follow the directions for using Edex carefully. If, after reading the instructions, you have any questions, talk to your doctor or pharmacist.

Edex can only be obtained with a prescription from your doctor. You or your partner should be well trained on the proper injection method before using Edex at home. Be sure to use only the dose prescribed by your doctor.

Edex is available in either a 2- or 6-pack. The 2-pack contains enough supplies for two injections. Each 2-pack includes the following items:

- One reusable Edex injection device
- One reusable carrying case
- Two single-dose, dual-chamber cartridges (one per injection)
- Two sterile needles (one per injection)
- Four alcohol swabs (two per injection)
- A user information sheet

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The 6-pack contains enough supplies for six injections. Each 6-pack includes the following items:

- One reusable Edex injection device
- One reusable carrying case
- Six single-dose, dual-chamber cartridges (one per injection)
- Six sterile needles (one per injection)
- 12 alcohol swabs (two per injection)
- A user information sheet

For each injection, you will need the supplies shown in the diagram below.

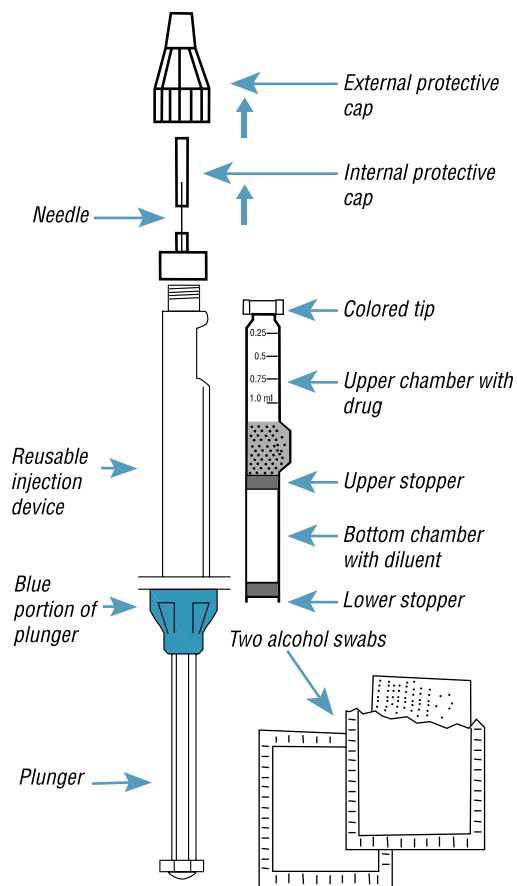


Figure A

IMPORTANT NOTE:

To ensure that Edex is sterile, follow these directions carefully.

Each needle and cartridge should be used only once. Dispose of the supplies safely (see Discarding Edex Injection Supplies section in this brochure). The Edex cartridges contain a solid layer or cake of dry white powder that is about 3/8 of an inch in thickness. A normal cake may appear cracked or crumbled. If the cartridge is damaged, the cake may shrink in size. Do not use the cartridge if it looks damaged or if the cake is substantially reduced in size.

Instructions for Self-Injection

Before you use Edex, you should be properly trained by your doctor. These instructions are not intended to be a substitute for training by your doctor.

Remember to mix Edex just before injection. Your doctor has prescribed the dose that is right for you. Use only the dose prescribed by your doctor.

It is important to have a clean area to assemble the items needed for your Edex injection. The reusable Edex injection device is for use only with the single-dose, dual-chamber cartridges and needles included in the Edex Cartridge 2-Pack and 6-Pack.

READ THE INSTRUCTIONS COMPLETELY BEFORE STARTING YOUR SELF-INJECTION PROCEDURE.

Preparing the Edex Solution

1. Wash your hands thoroughly with soap and water and dry them with a clean towel.

2. Check to see if the seal on the base of the needle is intact. Remove the seal from the base of the needle. Do not touch the exposed needle (Figure B).

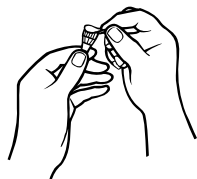


Figure B

3. Attach the needle to the tip of the Edex® injection device by turning clockwise (to the right) until tight (Figure C). **Note: Always attach the needle to the injection device before inserting the cartridge into the injection device.**

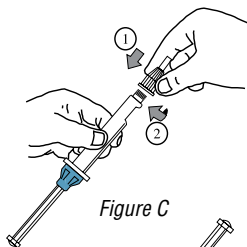


Figure C

4. Turn the blue portion of the plunger counterclockwise (to the left) to unscrew it from the injection device (Figure D).

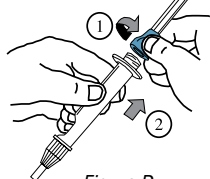


Figure D

5. Pick up the cartridge. Wipe the tip of the cartridge with an alcohol swab. Do not touch the tip of the cartridge after you've cleansed it with the alcohol swab (Figure E).

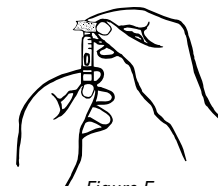


Figure E

6. Insert the cartridge into the injection device with the tip facing toward the attached needle (Figure F). The ridge on the cartridge will need to fit into the groove on the injection device.

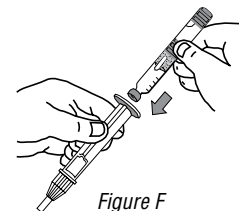


Figure F

7. Attach the plunger to the injection device by turning the blue portion of the plunger clockwise (to the right) until tight (Figure G).

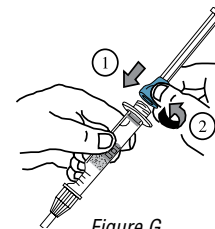


Figure G

8. Hold the injection device in an upright position with the needle pointing up.

9. Prepare the drug solution by slowly pushing the plunger until the two gray rubber stoppers touch (Figure H). Then, gently move the injection device in a back and forth motion until the drug has dissolved and the solution is clear. At first the solution may appear cloudy due to small air bubbles. Do not use the solution if it remains cloudy, is colored or contains particles.

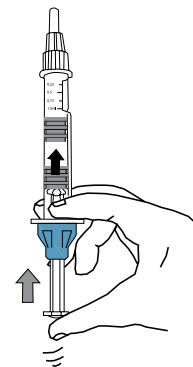


Figure H

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10. While holding the injection device with the needle pointing up, carefully remove the external and internal protective caps from the needle by pulling them straight off (Figure I). Do not turn the protective caps counterclockwise (to the left) because this will loosen the needle. Do not throw away the large external protective cap; you will need to use it later. Do not touch the exposed needle or allow the needle to touch anything.

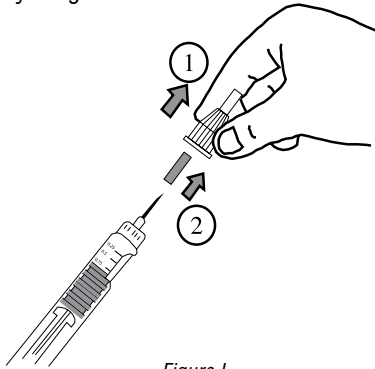


Figure I

11. Now, gently tap the cartridge so that air bubbles float to the top of the solution (Figure J). Carefully push the plunger until a drop of solution appears at the end of the needle (Figure K). **Note: The plunger pushes the rubber stoppers forward; the rubber stoppers cannot be pulled back with the plunger.**
12. Push the plunger until the upper rim of the top stopper reaches the correct volume mark for your prescribed dose. Excess solution will be expelled through the needle.

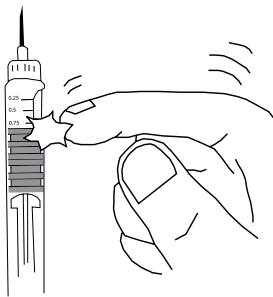


Figure J

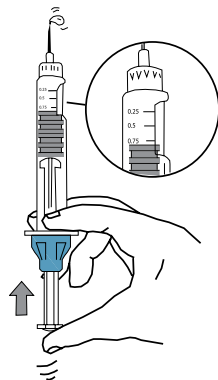


Figure K

13. Set the injection device down on a clean, level surface. Do not let the needle touch anything.

How to Select an Injection Site

14. Choose an injection site mid-shaft on one side of the penis. Be sure to avoid any blood vessels you can see. Every time you use Edex, go to a different side of the penis and change the site of the injection (Figure L). If your penis is not circumcised, pull the foreskin back. Grasping the head of the penis with your thumb and forefinger, stretch it lengthwise along your thigh so you can clearly see the selected injection site. Wipe the injection site with a new alcohol swab. Do not throw away the swab; you will need to use it later.

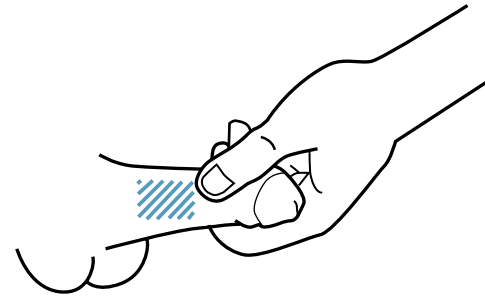


Figure L

Injecting Edex

15. Pick up the injection device and reposition the penis, as in step 14, to keep it from moving during the injection.

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16. Hold the injection device as shown in the figure below (Figure M). Be sure not to touch the plunger at this time. Position the needle horizontally and gently insert the needle into the selected injection site until the needle is almost completely inserted into the penis (Figure M). Now, place your thumb on the plunger and inject the solution slowly over a period of 5 to 10 seconds (Figure N).

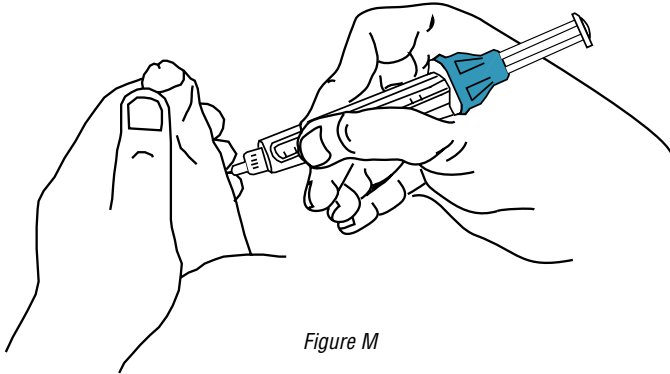


Figure M

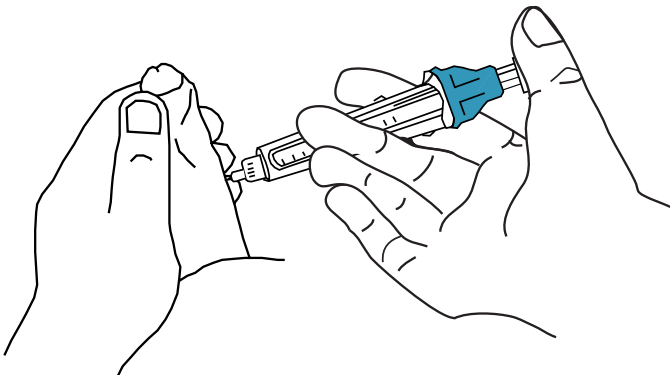


Figure N

17. If the solution doesn't inject easily, or if you immediately experience a burning pain at the injection site, reposition the needle by advancing it slightly or by partially withdrawing it until the solution can be injected easily and painlessly.
18. Next, withdraw the needle from the penis. Immediately apply firm but gentle pressure with the alcohol swab to the injection site for five minutes to prevent bruising (Figure O). Keep applying firm pressure until the bleeding stops. If bleeding continues or recurs after applying pressure, do not engage in sexual intercourse.

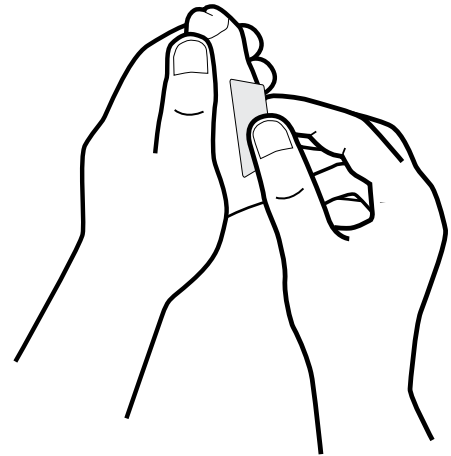


Figure O

Discarding Edex Injection Supplies

19. Carefully place the large external protective cap on the needle. Remove the needle from the injection device by turning counterclockwise (to the left).
20. Remove the cartridge from the injection device by turning the blue portion of the plunger counterclockwise (to the left).
21. Discard the needle in a special container for disposal of sharp medical supplies. Ask your doctor or pharmacist where you can obtain these special containers. Follow the directions on your disposal container for proper disposal procedures.

Important note: Do not reuse or share needles.

22. Clean the reusable injection device with warm water and a mild soap after each use. Once the injection device is dry, place it in the carrying case.

And remember: Do not allow anyone else to use your medication. The correct injection technique and individual dose titration are essential for the safe use of Edex.

This information is not intended to take the place of your healthcare professional. He or she is always your best source of information. Ask your doctor if Edex® is right for you.

References:

1. Montorsi F, Salonia A, Deho F, et al. Pharmacological management of erectile dysfunction. BJU Int. 2003;91(5): 446-54.

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➔ A Reliable Choice.

- Edex is FDA-approved
- Fast-acting (onset in 5-20 minutes)
- Long-lasting (up to one hour)
- Comes in pre-measured, single dose cartridges
- No refrigeration required

Erections that last more than six hours can cause serious damage to the penile tissue and may result in permanent impotence. If you still have an erection six hours after injection, call your doctor immediately or, if unavailable, seek professional help elsewhere. Please see page 4 for additional safety information.

To report an adverse experience or side effect, please call Actient Pharmaceuticals at 1-866-931-0717

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