

Getting started with treatment

Learn how edex[®] can help with erectile dysfunction



Actor portrayal.



What Is edex[®]?

edex[®] is a penile injection used to treat erectile dysfunction (ED) caused by conditions affecting nerves, blood vessels, emotions, and/or a combination of factors.

IMPORTANT SAFETY INFORMATION about edex[®]

Who Should NOT Use edex[®]?

Men who have conditions that might result in long-lasting erections, such as sickle cell anemia or trait, leukemia and tumor of the bone marrow (multiple myeloma) should not use edex[®]. If you have any of these conditions, consult your doctor. Men with penile implants, severe penile curvature or those for whom sexual activity is not advised should not use edex[®]. edex[®] should not be used by women or children.

edex[®] generally should not be used in men who have been told by their healthcare provider to not have sexual activity because of heart problems.

Please see Important Safety Information about edex[®] on pages [8-9](#) and [click here](#) for full Prescribing Information.

edex[®]
(alprostadil for injection)
10 mcg • 20 mcg • 40 mcg

Get to know edex[®]

This brochure can help you learn more about treating your erectile dysfunction (ED) with edex[®].

Please read this information carefully before you prepare and use the edex[®] solution. If you have any questions, ask your doctor. He or she is always your best source of information.

What is edex[®]?

edex[®] is a penile injection used to treat ED caused by conditions affecting nerves, blood vessels, emotions, and/or a combination of factors.



FDA approved for over 2 decades and TSA acceptable



Designed to achieve an erection within 5 to 20 minutes



Customized dose expected to last up to 1 hour



Comes in convenient, single-dose cartridges



No refrigeration required

See page 5 for more information on appropriate storage.

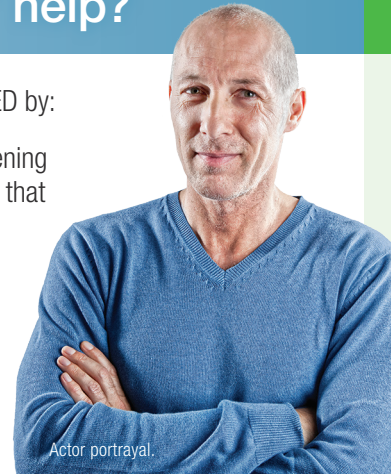
FDA=Food and Drug Administration; TSA=Transportation Security Administration.

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.

How can edex[®] help?

edex[®] works to help men with ED by:

- Relaxing the muscles and opening the blood vessels in the penis that produce an erection
- Allowing the penis to expand and trap blood so it can become erect



Actor portrayal.

Your doctor may prescribe edex[®] if you are not able to take oral treatments for ED.

While edex[®] may help you achieve an erection, it is not a cure for ED. The medical causes of ED should be diagnosed and treated prior to starting treatment, if possible.

IMPORTANT SAFETY INFORMATION about edex[®] (cont)

What Are the Risks of Using edex[®]?

Erections that last more than 6 hours can cause serious damage to the penile tissue and may result in permanent impotence. **Call the prescribing physician right away or, if unavailable, seek professional help immediately if you still have an erection 6 hours after injection.**

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 prescribing physician.

Call your doctor if you notice any redness, lumps, swelling, tenderness, or curvature of the erect penis.

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Getting started

Your doctor should have edex[®] on hand, and will perform your first injection in their office to customize a dose just for you. Your doctor will also:

- Instruct you on how to properly perform self-injections at home
- Make sure you or your partner are fully trained on the proper injection technique before using edex[®] at home
- Prescribe your customized dose of edex[®] for you to use at home



Injecting at home

Once you are well trained on the self-injection procedure, you will be able to perform future injections at home. Be sure to follow your doctor's instructions carefully, and to only inject the dose prescribed.

You should NOT use edex[®] more than 3 times a week. Injections should be administered at least 24 hours apart. Ideally, the injection should be given just prior to foreplay.

It is important to see your doctor for regular check-ups while on edex[®].

If you find that your erection lasts longer than 1 hour or that you are not achieving an erection sufficient for sexual activity while using edex[®], consult your doctor to see if a dose adjustment may be required. Dose adjustments should be made only after consultation with your doctor.

Call your doctor or seek professional help immediately if you have an erection that lasts longer than 6 hours.



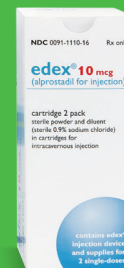
Actor portrayals.

edex[®] does not require refrigeration

edex[®] should be stored at room temperature, 77°F (25°C).

- Temperature can vary between 59°F–86°F (15°C–30°C)
- Avoid extreme temperatures
- Do not store in checked luggage during air travel or leave in a closed car

Always use immediately after mixing.



IMPORTANT SAFETY INFORMATION about edex[®] (cont)

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There is a possibility of needle breakage with the use of edex[®]. To avoid breaking the needle, you should pay careful attention to your doctor's instruction 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.

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Using edex[®] (cont)

It is very important that you follow the instructions for using edex[®] carefully. See instructions for self-injection later on in this brochure. If you have any questions after reading the instructions, talk to your doctor or pharmacist.

edex[®] is available in a 2- or 6-pack

**2
PACK**

Contains enough supplies for 2 injections. Each 2-pack includes the following items:

- 1 reusable edex[®] injection device
 - Do not discard after first injection
- 1 reusable carrying case
- 2 single-dose, dual-chamber cartridges (1 per injection)
- 2 sterile needles (1 per injection)
- 4 alcohol swabs (2 per injection)
- Patient Information

**6
PACK**

Contains enough supplies for 6 injections. Each 6-pack includes the following items:

- 1 reusable edex[®] injection device
 - Do not discard after first injection
- 1 reusable carrying case
- 6 single-dose, dual-chamber cartridges (1 per injection)
- 6 sterile needles (1 per injection)
- 12 alcohol swabs (2 per injection)
- Patient Information

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

IMPORTANT SAFETY INFORMATION about edex[®] (cont)

Other Important Information

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.

There is no approved injectable treatment using multiple medications. In addition, there are no data on the efficacy and safety of these combinations.

Parts of each edex[®] injection



*Available in 10 mcg (red tip), 20 mcg (green tip), and 40 mcg (gold tip). 40 mcg shown here.

IMPORTANT SAFETY INFORMATION about edex[®] (cont)

Using edex[®]

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This information should not take the place of talking with your doctor or healthcare professional. If you have any questions, talk to your doctor or pharmacist.

You are encouraged to report negative side effects of prescription drugs. Contact Endo Pharmaceuticals Inc. at 1-800-462-3636 (ENDO), or FDA at 1-800-FDA-1088 or www.FDA.gov/medwatch.

Please [click here](#) for full Prescribing Information and Patient Information for edex[®].

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Instructions for self-injection

IMPORTANT:

To maintain sterility and avoid contamination, follow these directions carefully.

Each needle and cartridge should be used only once. Safely discard the supplies (see the “Discard Injection Supplies” section on page 17). The edex[®] cartridges contain a solid layer or cake of dry white powder approximately 3/8” 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 appears damaged or the cake is substantially reduced in size.

Before you use edex[®], you should be properly trained by your doctor.

Mix edex[®] just prior to injection. edex[®] should always be used immediately after mixing it. Your dose has been customized for your individual needs, so use only the dose prescribed by your doctor.

Have a clean area available to assemble the items necessary for your injection of edex[®]. 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 or 6 Pack.

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

IMPORTANT SAFETY INFORMATION about edex[®] (cont)

Who Should NOT Use edex[®]?

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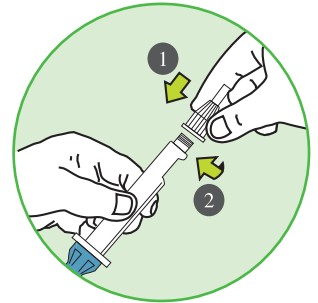
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PREPARE THE INJECTION

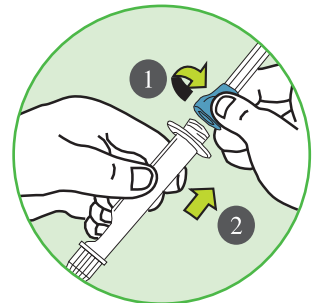
1. Wash your hands thoroughly with soap and water and dry them with a clean towel.
2. Check to see if the seal on the base of the needle is intact. Remove the seal from the base of the needle. Do not touch the exposed needle.



3. Attach the needle to the tip of the edex[®] injection device by turning clockwise until tight. **Note: Always attach the needle to the injection device before inserting the cartridge into the injection device.**



4. Turn the blue portion of the plunger counterclockwise to unscrew it from the injection device.



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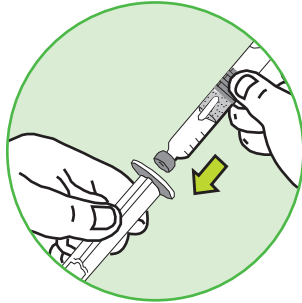
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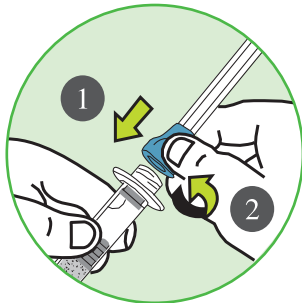
5. Pick up the cartridge and wipe the tip of the cartridge with an alcohol swab. Do not touch the tip of the cartridge after it has been cleansed with the alcohol swab.



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

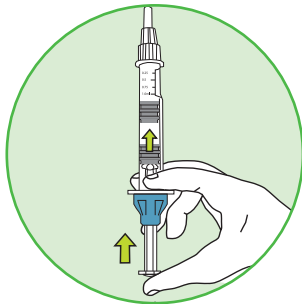


7. Attach the plunger to the injection device by turning the blue portion of the plunger clockwise until tight.



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

9. To prepare the drug solution, slowly push the plunger until the 2 gray rubber stoppers touch. Gently move the injection device in a back and forth motion until the drug has dissolved and the solution is clear. The solution may initially appear cloudy due to small air bubbles. Do not use the solution if it remains cloudy, is colored, or contains particles.



Watch a step-by-step instructional video for the injection procedure at edex.com/video



Actor portrayal.

IMPORTANT SAFETY INFORMATION about edex® (cont)

What Are the Risks of Using edex®?

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Side Effects Associated with edex®

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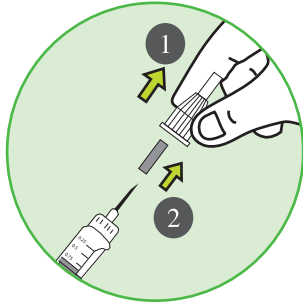
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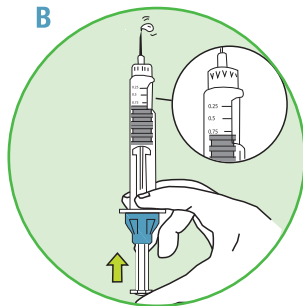
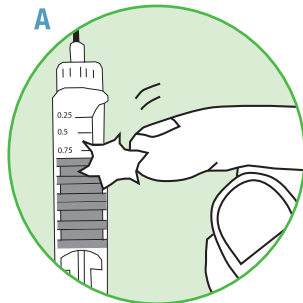
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Continued on next page

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. Do not turn the protective caps counterclockwise as this will loosen the needle. Do not discard 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.



11. Gently tap the cartridge so that air bubbles float to the top of the solution (Part A). Carefully push the plunger until a drop of solution appears at the end of the needle (Part B).
Note: The plunger pushes the rubber stoppers forward; the rubber stoppers cannot be pulled back with the plunger.



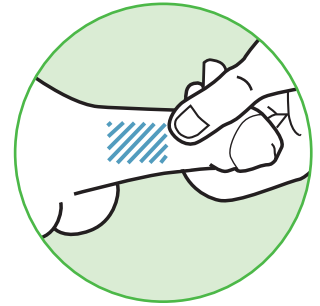
IMPORTANT SAFETY INFORMATION about edex® (cont)

A small amount of bleeding at the injection site may occur. To prevent bruising, apply firm pressure at the injection site for 5 minutes; continue until bleeding stops. Tell your doctor if you have a condition or are taking a medicine that interferes with blood clotting.

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.
13. Set the injection device down on a clean, level surface and do not allow the needle to touch anything.

SELECT INJECTION SITE

14. Choose an injection site mid-shaft on one side of the penis. Avoid visible blood vessels. With each use of edex®, alternate the side of the penis and vary the site of the injection. 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 that you can clearly see the selected injection site. Wipe the injection site with a new alcohol swab. Do not discard this swab; you will need to use it later.



Continued on next page

IMPORTANT SAFETY INFORMATION about edex® (cont)

There is a possibility of needle breakage with the use of edex®. To avoid breaking the needle, you should pay careful attention to your doctor's instruction 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.

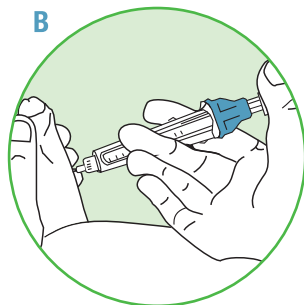
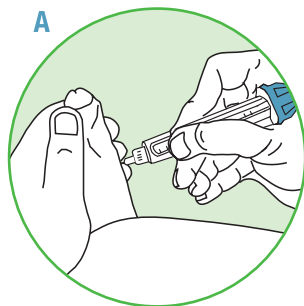
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INJECT edex[®]

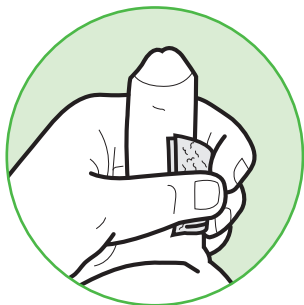
15. Pick up the injection device and reposition the penis as in Step 14 to keep it from moving during the injection.

16. Hold the injection device as shown here (Part A). Do not 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. Now place your thumb on the plunger (Part B) and inject the solution slowly over a period of 5 to 10 seconds.



17. If the solution does not 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. Withdraw needle from penis. Immediately apply firm but gentle pressure with the alcohol swab to the injection site for 5 minutes to prevent bruising. Continue to apply firm pressure until bleeding stops. If bleeding continues or recurs after applying pressure, abstain from intercourse.



Please see additional Important Safety Information on pages 8-9 and [click here](#) for full Prescribing Information.

DISCARD INJECTION SUPPLIES

19. Carefully place the large external protective cap on the needle. Remove the needle from the injection device by turning counterclockwise.
20. Remove the cartridge from the injection device by turning the blue portion of the plunger counterclockwise.
21. Discard your 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. **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.

As with all prescription medicines, do not allow anyone else to use your medication. Proper injection technique and individual dose titration are essential for the safe use of this product.

IMPORTANT SAFETY INFORMATION about edex[®] (cont)

Other Important Information

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The edex[®] Savings Card

The edex[®] Savings Card can help you save on your prescription for edex[®]*

- Each card provides savings of up to \$75 per eligible prescription on out-of-pocket costs that exceed \$15
- Savings apply to each of your next 12 prescriptions written for 6 or more injections of edex[®]

How does the edex[®] Savings Card work?

- Your doctor will provide a prescription for edex[®]
- If you are eligible to participate in this program, you must visit **edex.com** to activate your card before the prescription is filled
- Your copay amount or the cost of your prescription will be reduced accordingly

Download your edex[®] Savings Card

- To download and activate, visit **edex.com** and click on “Savings & Support”



Eligibility Requirements:

- You must be a male patient who is at least 18 years of age
- You must present an activated card to the pharmacist along with your prescription to participate in this program
- If you have any questions regarding your eligibility or benefits, or if you wish to discontinue your participation, call the edex[®] Savings Card Program at 1-888-203-7915 (Monday–Friday, 8 AM–8 PM EST)
- When you use this card, you are certifying that you understand the program rules, regulations, and terms and conditions
- You are not eligible if your prescriptions are paid by any state or other federally funded programs, including, but not limited to, Medicare or Medicaid, Medigap, VA, DoD or TRICARE, or where prohibited by law
- You must comply with the terms above

*Subject to eligibility. Restrictions apply. See Eligibility Requirements above.

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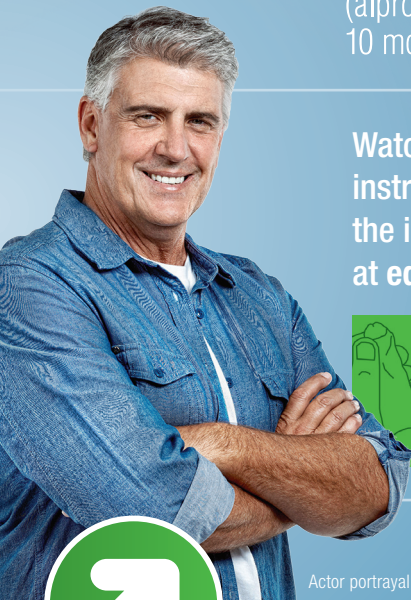
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Rx Only

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