

edex[®]: Focused on erectile function



Actor portrayal.



edex[®] is an FDA-approved, dual-chamber injection therapy for appropriate patients with erectile dysfunction^{1,2}

INDICATION

edex[®] (alprostadil for injection) is indicated for the treatment of erectile dysfunction due to neurogenic, vasculogenic, psychogenic, or mixed etiology.

IMPORTANT SAFETY INFORMATION about edex[®]

- edex[®] is contraindicated in men with conditions that might predispose them to priapism such as sickle cell anemia or sickle cell trait, multiple myeloma, or leukemia. edex[®] should not be used for the treatment of ED in men with fibrotic conditions of the penis, such as cavernosal fibrosis or Peyronie's disease. Patients with penile implants should not be treated with edex[®].

Please see Important Safety Information continued inside and the accompanying full Prescribing Information.

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

Who may have erectile dysfunction (ED)?

ED is a complex disorder affecting an estimated 30 million men in the US³

- ED often has a multifactorial etiology, including impaired blood circulation in the penis, nerve damage, hormonal imbalances, excessive alcohol use, emotional problems, and certain medications¹
- Men presenting with symptoms of ED should undergo a thorough medical, sexual, and psychosocial history; a physical examination; and selective laboratory testing³

Incidence of ED increases with age⁴



Consider screening for ED in patients who are more likely to have it⁴

- ✓ 51.3% of men with **diabetes**
- ✓ 50% of men with a **history of cardiovascular disease**
- ✓ 44.1% of men with **treated hypertension**
- ✓ 42.6% of men with a **history of benign prostate enlargement**
- ✓ 21.8% of **obese men**
- ✓ 13.1% of current **male smokers**

Treatments for erectile dysfunction, including edex[®], generally should not be used in men for whom sexual activity is inadvisable because of their underlying cardiovascular status.¹

IMPORTANT SAFETY INFORMATION about edex[®] (cont)

- Prolonged erections greater than four hours in duration occurred in 4% of all patients treated up to 24 months. The incidence of priapism (erections greater than 6 hours in duration) was less than 1% with long-term use for up to 24 months. If priapism occurs, the patient should seek immediate medical attention. If priapism is not treated immediately, penile tissue damage and permanent loss of potency may result. To minimize the chances of prolonged erection or priapism, edex[®] should be titrated slowly to the lowest effective dose determined by the physician.
- Intracavernous injections of edex[®] can lead to increased peripheral blood levels of PGE₁ and its metabolites, especially in those patients with significant corpora cavernosa venous leakage. Increased peripheral blood levels of PGE₁ and its metabolites may lead to hypotension and/or dizziness.
- Regular follow-up of patients, with careful examination of the penis at the start of therapy and at regular intervals (eg, 3 months), is strongly recommended to identify any penile changes. Treatment with edex[®] should be discontinued in patients who develop penile angulation, cavernosal fibrosis, or Peyronie's disease. Treatment can be resumed if the penile abnormality subsides.

Considering treatment for your patients with ED

Treatment starts with a discussion between you and your patient^{1,3}

- First, identify and treat underlying treatable medical causes of ED^{1,3}
- Upon the decision to treat ED, counsel patients on treatment options that are not medically contraindicated³
 - The AUA guidelines state that patients may choose to begin with any type of treatment regardless of invasiveness or reversibility
 - Ask patients if they have a preference for oral or ICI

The AUA guidelines support a moderate recommendation of when PDE5i therapy is not an option, or this class of medications is contraindicated, patients should be informed of the benefits and risks of other therapies, including ICI. (Evidence Level: Grade C)³

AUA=American Urological Association; PDE5i=phosphodiesterase type 5 inhibitor; ICI=intracavernosal injections.

edex[®] ICI

For use in men with ED due to a diverse range of etiologies^{1,3}:

- Neurogenic (eg, spinal cord injuries)
- Vasculogenic
- Psychogenic
- Mixed etiology

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10 mcg • 20 mcg • 40 mcg



Actor portrayal.

About edex[®] (alprostadil for injection)



What is edex[®]?

edex[®] is a penile injection indicated for the treatment of ED due to neurogenic, vasculogenic, psychogenic, or mixed etiology.¹

While edex[®] may help a man achieve an erection, it is not a cure for ED. The medical causes of ED should be diagnosed and treated prior to starting treatment.¹



FDA-approved and TSA-compliant ED treatment^{2,5}



Comes in convenient, single-dose, dual-chamber cartridges¹



Designed to achieve an erection within 5 to 20 minutes¹



No need for external mixing¹
edex[®] is mixed in its sterile dual-chamber cartridge.



Customized dose expected to last up to 1 hour¹

For any erection that lasts longer than 6 hours, instruct patients to contact you or seek professional help immediately.



No refrigeration required¹

Store at 77°F (25°C); temperature variations between 59°F–86°F (15°C–30°C) are allowed. As with any drug product, extremes in temperature should be avoided. Inform patients to not store in checked luggage during air travel or leave in a closed automobile.

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

Mode of action

Alprostadil induces erection by relaxation of trabecular smooth muscle and by dilation of cavernous arteries. This leads to expansion of lacunar spaces and entrapment of blood by compressing the venules against the tunica albuginea, a process referred to as the corporal veno-occlusive mechanism.¹

IMPORTANT SAFETY INFORMATION about edex[®] (cont)

- The safety and efficacy of combinations of edex[®] and other vasoactive agents have not been systematically studied. Therefore, the use of such combinations is not recommended.
- After injection of the edex[®] solution, compression of the injection site for five minutes, or until bleeding stops, is necessary. Patients on anticoagulants, such as warfarin or heparin, may have increased propensity for bleeding after intracavernous injection. Caution should be exercised with concomitant administration of heparin and edex[®].
- edex[®] is not a cure for erectile dysfunction. The underlying treatable medical causes should be diagnosed and treated prior to initiation of therapy. The therapeutic effect of each dose is temporary. edex[®] should be used no more than 3 times per week with at least 24 hours between each dose.

Anatomy of each edex[®] injection¹



*Available in 10 mcg (red tip), 20 mcg (green tip), and 40 mcg (gold tip). 40 mcg shown here.^{1,6}

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10 mcg • 20 mcg • 40 mcg

Efficacy with edex[®]: Erection sufficient for intercourse achieved by most patients¹

STUDY DESIGN

In 2 studies, the safety and efficacy of edex[®] were evaluated in 347 men with a diagnosis of erectile dysfunction due to vasculogenic, neurogenic, and/or mixed etiology. Each study consisted of 3 phases: an in-office dose-titration phase, a 2-week double-blind, crossover phase at home, and an open-label at-home treatment phase that lasted for 12 months (Study 1) or 6 months (Study 2).¹

STUDY 1¹

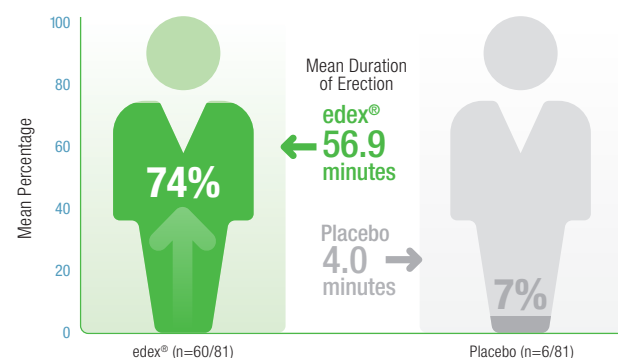
DOSE-TITRATION PHASE n=114

MORE THAN 3 OUT OF 4 men achieved an erection with positive Buckling Test (76%, 87/114)



Mean Optimum Dose: 13.8 mcg (range 1 to 20 mcg)

Patients Who Achieved Erection Sufficient for Sexual Intercourse



PLACEBO-CONTROLLED PHASE n=81

OPEN-LABEL PHASE n=74

Through 12 months, **ALMOST 9 OUT OF 10** men achieved an erection sufficient for sexual intercourse (88.9%)



STUDY DESIGN (cont)

During the dose-titration phase, individualized optimum doses of edex[®] were established. Erectile response was measured by the Buckling Test to assess axial penile rigidity. A positive Buckling Test was achieved if the erect penis was able to support an axial load of 1.0 kg without buckling of the penile shaft. During the subsequent 2-week double-blind, crossover phase, patients self-injected edex[®] or placebo at home. Thereafter, patients continued to perform self-injections of open-label edex[®] for 6 or 12 months, and the occurrence of an erection sufficient for sexual intercourse was documented following each injection.¹

STUDY 2¹

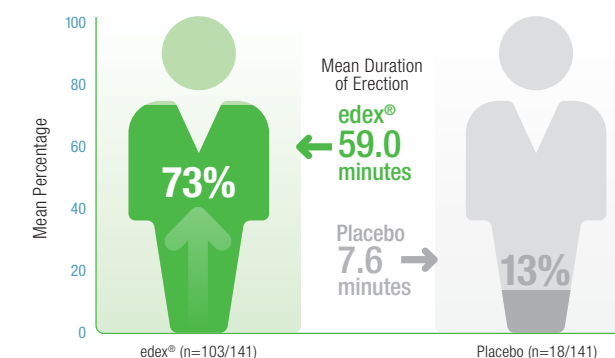
DOSE-TITRATION PHASE n=233

ALMOST 3 OUT OF 4 men achieved an erection with positive Buckling Test (73%, 171/233)



Mean Optimum Dose: 25.9 mcg (range 1 to 40 mcg)

Patients Who Achieved Erection Sufficient for Sexual Intercourse



PLACEBO-CONTROLLED PHASE n=141

OPEN-LABEL PHASE n=139

Through 6 months, **MORE THAN 8 OUT OF 10** men achieved an erection sufficient for sexual intercourse (85.3%)



For the duration of each study, the average dose of edex[®] remained essentially unchanged.¹

IMPORTANT SAFETY INFORMATION about edex[®] (cont)

- edex[®] uses a superfine (29 gauge) needle. As with all superfine needles, the possibility of needle breakage exists. Careful instruction in proper patient handling and injection techniques may minimize the potential for needle breakage.
- **The patient should be instructed not to reuse or to share needles or cartridges. As with all prescription medicines, the patient should not allow anyone else to use his medicine.**

IMPORTANT SAFETY INFORMATION about edex[®] (cont)

- There is a potential for cardiac risk of sexual activity in patients with preexisting cardiovascular disease. Therefore, treatments for erectile dysfunction, including edex[®], generally should not be used in men for whom sexual activity is inadvisable because of their underlying cardiovascular status. In addition, the evaluation of erectile dysfunction should include a determination of potential underlying causes and the identification of appropriate treatment following a complete medical assessment.

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10 mcg • 20 mcg • 40 mcg

A safety profile established in clinical trials up to 24 months¹

Local Adverse Reactions Reported by ≥1% of Patients in All Study Periods ^{1*}	edex [®] (N=1065) % (n)
Penile pain	
During injection	29% (305)
During erection	35% (368)
After erection	30% (317)
Other [†]	11% (116)
Bleeding	15% (158)
Penile angulation	7% (72)
Faulty injection technique [‡]	6% (59)
Hematoma	5% (56)
Penile fibrosis	5% (52)
Prolonged erection	
>4 ≤6 hours	4% (44)
>6 hours	<1% (6)
Ecchymosis	4% (44)
Penis disorder	3% (28)
Cavernous body fibrosis	2% (20)
Erythema	2% (17)
Peyronie's disease	1% (11)

*From 4 edex[®] studies.

[†]Penile pain reported without an association to injection site or erection, such as pain in penis and scrotum, pain in glans penis, and burning penile pain.

[‡]Examples include: injection into glans penis, urethra, or subcutaneously.

- With use up to 24 months, on a per-injection basis, 15% of injections were associated with penile pain. Penile pain was judged by patients to be 80% mild, 16% moderate, and 4% severe¹
- The frequency of penile pain reports decreased over time: 41% of the patients experienced pain during the first 2 months and 3% of the patients experienced pain during Months 21–24¹
- In placebo-controlled studies, penile pain was reported by 31% of patients after edex[®] and by 9% of patients after placebo injection¹
- 4% of patients in 4 clinical studies discontinued due to penile pain⁷
- Discontinuation of therapy due to a side effect in clinical trials was required in approximately 9% of patients treated with edex[®] and in <1% of patients treated with placebo¹

IMPORTANT SAFETY INFORMATION about edex[®] (cont)

- 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.
- edex[®] is not indicated for use in women or pediatric patients.

Systemic Adverse Experiences Reported by ≥1% of Patients ^{1§}	edex [®] (N=1065) % (n)
RESPIRATORY	
Upper respiratory tract infection	5% (58)
Sinusitis	1% (14)
BODY AS A WHOLE	
Influenza-like symptoms	3% (35)
Headache	2% (20)
Infection	2% (18)
Pain	2% (16)
MUSCULOSKELETAL	
Back pain	2% (23)
Leg pain	1% (13)
CARDIOVASCULAR	
Hypertension	2% (17)
Myocardial infarction	1% (13)
Abnormal electrocardiogram (ECG)	1% (12)
METABOLIC/NUTRITIONAL	
Hypertriglyceridemia	2% (17)
Hypercholesterolemia	1% (12)
Hyperglycemia	1% (12)
UROGENITAL	
Prostate disorder	1% (15)
Testicular pain	1% (13)
Inguinal hernia	1% (11)
DERMATOLOGIC	
Skin disorder	1% (14)
SPECIAL SENSES	
Abnormal vision	1% (11)

§From 4 edex[®] studies.

Indication and Important Safety Information

INDICATION

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- Prolonged erections greater than four hours in duration occurred in 4% of all patients treated up to 24 months. The incidence of priapism (erections greater than 6 hours in duration) was less than 1% with long-term use for up to 24 months. If priapism occurs, the patient should seek immediate medical attention. If priapism is not treated immediately, penile tissue damage and permanent loss of potency may result. To minimize the chances of prolonged erection or priapism, edex[®] should be titrated slowly to the lowest effective dose determined by the physician.
- Intracavernous injections of edex[®] can lead to increased peripheral blood levels of PGE₁ and its metabolites, especially in those patients with significant corpora cavernosa venous leakage. Increased peripheral blood levels of PGE₁ and its metabolites may lead to hypotension and/or dizziness.
- Regular follow-up of patients, with careful examination of the penis at the start of therapy and at regular intervals (eg, 3 months), is strongly recommended to identify any penile changes. Treatment with edex[®] should be discontinued in patients who develop penile angulation, cavernosal fibrosis, or Peyronie's disease. Treatment can be resumed if the penile abnormality subsides.
- The safety and efficacy of combinations of edex[®] and other vasoactive agents have not been systematically studied. Therefore, the use of such combinations is not recommended.
- After injection of the edex[®] solution, compression of the injection site for five minutes, or until bleeding stops, is necessary. Patients on anticoagulants, such as warfarin or heparin, may have increased propensity for bleeding after intracavernous injection. Caution should be exercised with concomitant administration of heparin and edex[®].
- edex[®] is not a cure for erectile dysfunction. The underlying treatable medical causes should be diagnosed and treated prior to initiation of therapy. The therapeutic effect of each dose is temporary. edex[®] should be used no more than 3 times per week with at least 24 hours between each dose.
- edex[®] uses a superfine (29 gauge) needle. As with all superfine needles, the possibility of needle breakage exists. Careful instruction in proper patient handling and injection techniques may minimize the potential for needle breakage.

- **The patient should be instructed not to reuse or to share needles or cartridges. As with all prescription medicines, the patient should not allow anyone else to use his medicine.**
- There is a potential for cardiac risk of sexual activity in patients with preexisting cardiovascular disease. Therefore, treatments for erectile dysfunction, including edex[®], generally should not be used in men for whom sexual activity is inadvisable because of their underlying cardiovascular status. In addition, the evaluation of erectile dysfunction should include a determination of potential underlying causes and the identification of appropriate treatment following a complete medical assessment.
- 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.
- edex[®] is not indicated for use in women or pediatric patients.
- This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.
- The most common local adverse reactions were penile pain during and/or after injection and during erection and bleeding.
- The patient should call his doctor if he sees any redness, lumps, swelling, tenderness or curvature of the erect penis.

Please see the accompanying full Prescribing Information for edex[®].

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

Actor
portrayal.

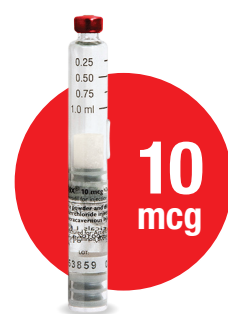
References: 1. edex[®] [package insert]. Malvern, PA: Endo Pharmaceuticals Inc. 2. Food and Drug Administration, US Department of Health and Human Services. Approved drug products with therapeutic equivalence evaluations, 38th edition. 2018. <https://www.fda.gov/downloads/drugs/developmentapprovalprocess/ucm071436.pdf>. Accessed May 22, 2018. 3. Burnett AL, Nehra A, Breau RH, et al. Erectile dysfunction: AUA guideline. *J Urol*. 2018 [Epub ahead of print]. 4. Selvin E, Burnett AL, Platz EA. Prevalence and risk factors for erectile dysfunction in the US. *Am J Med*. 2007;120(2):151-157. 5. Transportation Security Administration, US Department of Homeland Security. Disabilities and medical conditions. Department of Homeland Security website. <https://www.tsa.gov/travel/special-procedures>. Accessed May 29, 2018. 6. Data on file. DOF-EX-02. Endo Pharmaceuticals Inc; June 21, 2018. 7. Data on file. DOF-EX-01. Endo Pharmaceuticals Inc; April 27, 2018.

Dosage range for edex[®]

The dosage range of edex[®] for the treatment of ED is 1 mcg to 40 mcg, as determined in clinical studies¹:

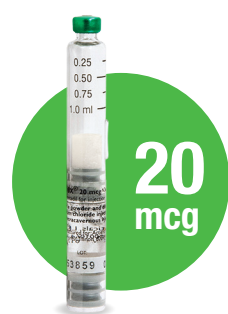
- In a study with a dose range of 1–20 mcg, the mean dose was 10.7 mcg at the end of the dose titration period
- In 2 studies with a dose range of 1–40 mcg, the mean dose was 21.9 mcg at the end of the dose titration period
- Doses greater than 40 mcg have not been studied

Available strengths and measurements^{1,6}



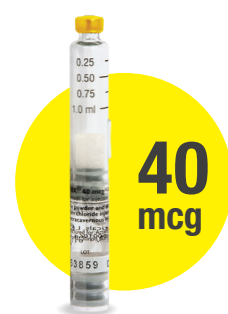
10 mcg

- 0.25 mL = 2.5 mcg
- 0.5 mL = 5.0 mcg
- 0.75 mL = 7.5 mcg
- 1.0 mL = 10 mcg



20 mcg

- 0.25 mL = 5 mcg
- 0.5 mL = 10 mcg
- 0.75 mL = 15 mcg
- 1.0 mL = 20 mcg



40 mcg

- 0.25 mL = 10 mcg
- 0.5 mL = 20 mcg
- 0.75 mL = 30 mcg
- 1.0 mL = 40 mcg

- Available in either **2 PACK** OR **6 PACK**
- Convenient, single-dose cartridges¹

It's important that you determine the lowest, yet effective, dose of edex[®] for each patient. Dosing selection is based on your patient's response to edex[®], which begins in your office during the patient's initial injection(s) and self-injection training.¹ The patient is advised not to exceed the optimum edex[®] dose determined in your office.¹

IMPORTANT SAFETY INFORMATION about edex[®] (cont)

- This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.
- The most common local adverse reactions were penile pain during and/or after injection and during erection and bleeding.
- The patient should call his doctor if he sees any redness, lumps, swelling, tenderness or curvature of the erect penis.

12 Please see Important Safety Information on pages 10-11 and the accompanying full Prescribing Information.

Treatment starts with titration and patient training in your office

STEP 1: Initial dosage titration in your office

Establish and prescribe the proper dose of edex[®] for the patient's use at home. Erections should not exceed a duration of 1 hour.¹

FOR ED OF VASCULOGENIC, PSYCHOGENIC, OR MIXED ETIOLOGY¹

- Titration should begin at 2.5 mcg
- **If partial response:** may increase dose by 2.5 mcg to a dose of 5 mcg, followed by increments of 5–10 mcg, depending upon erectile response, until dose produces an erection suitable for intercourse (not exceeding 1 hr)
- **If no response:** may increase dose to 7.5 mcg, followed by increments of 5–10 mcg

FOR ED OF PURE NEUROGENIC ETIOLOGY (SPINAL CORD INJURY)¹

- Titration should begin at 1.25 mcg
- Dose may be increased by 1.25 mcg to a dose of 2.5 mcg, followed by an increment of 2.5 mcg to a dose of 5 mcg, and then in 5-mcg increments until dose that produces an erection suitable for intercourse (not exceeding 1 hr)

- Patient must stay in your office until complete detumescence occurs¹
- If no response: the next higher dose may be given within 1 hour¹
- If there is a response: there should be at least a 1-day interval before next dose is given¹

See STEP 2 on next page

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



Actor portrayals.

13

Treatment starts with titration and patient training in your office (cont)

The first injections of edex[®] must be done at the physician's office by medically trained personnel. Self-injection therapy by the patient can be started only after the patient is properly instructed and well trained in the self-injection technique.¹

STEP 2: Train and counsel your patients on the self-injection procedure and appropriate storage for edex[®]

Once your patient is well trained on the self-injection procedure, he will be able to perform future injections at home. Be sure to instruct the patient to follow your instructions carefully, and to only inject the dose prescribed.¹

The patient should be instructed not to reuse or to share needles or cartridges. As with all prescription medicines, the patient should not allow anyone else to use his medicine.¹

- 1** Thoroughly instruct and train the patient on how to properly perform intracavernous self-injections and appropriate discarding of injection supplies, as outlined in the Patient Information pamphlet.¹
- 2** Carefully assess the patient's skill and competence with the self-injection procedure.¹

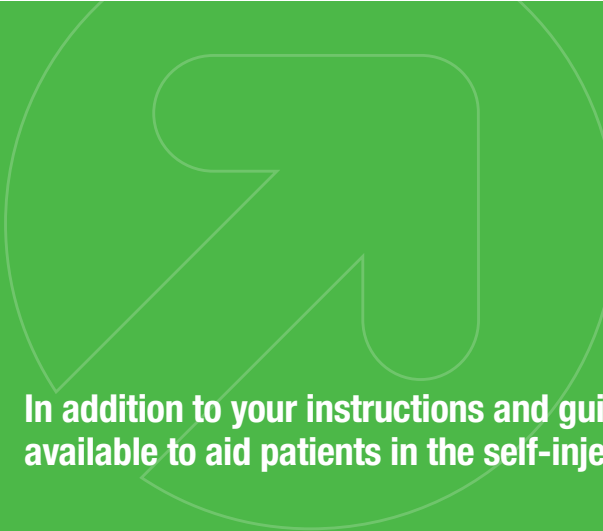
Inform the patient that the injection should be given:

 - Just prior to foreplay, and that he may expect an erection to occur within 5 to 20 minutes after the injection of edex[®]
 - No more than 3 times a week, with at least 24 hours between injections
- 3** Tell your patient what to do if he experiences an erection that lasts¹:
 - Longer than 1 hour (or if he is not achieving an erection sufficient for sexual activity): Contact you to see if a dose adjustment may be required
 - Longer than 6 hours: Contact you or seek professional help immediately
- 4** Counsel your patients on the possible side effects of edex[®] and about the protective measures that are necessary to guard against the spread of sexually transmitted disease.¹
 - 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

IMPORTANT SAFETY INFORMATION about edex[®] (cont)

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14 Please see Important Safety Information on pages 10-11 and the accompanying full Prescribing Information.



In addition to your instructions and guidance, these resources are available to aid patients in the self-injection procedure.

edex[®] Patient Brochure

- Use to aid in patient training in the office
- Send one home with patients for a detailed refresher on injecting edex[®] at home



edex[®] Step-by-Step Instructional Video

Direct patients to edex.com/video so they can look back to see how the self-injection is performed.



Actor portrayal.

Please see the full Prescribing Information for complete instructions on administering edex[®], training your patients on the self-injection procedure, and patient counseling guidance.

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10 mcg • 20 mcg • 40 mcg

15

edex[®]: Focused on erectile function



FDA-approved and TSA-compliant^{2,5}



Rapid onset—should produce an erection within 5 to 20 minutes that can be expected to last up to 1 hour¹



Convenient, single-dose cartridges in 10, 20, or 40 mcg¹

- Available in 2- and 6-cartridge packages
- Require no refrigeration and no external mixing
- Train patients on the self-injection procedure and appropriate storage

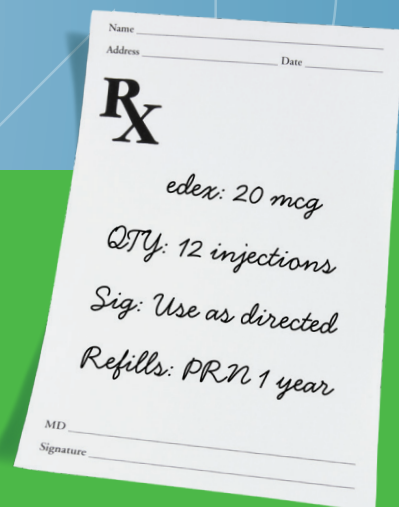


In clinical trials, 73%–74% of patients achieved an erection sufficient for intercourse with edex^{®1}



Office and patient resources

- Copay card
- Product samples
- Instructional video on edex.com



The edex[®] Savings Card can help patients save on their prescription for edex^{®*}

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

- 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 patient's next 12 prescriptions written for 6 or more injections of edex[®]

Eligibility Requirements:

- Must be a male patient who is at least 18 years of age
- Patient must present an activated card to the pharmacist along with a prescription to participate in this program
- If patient has any questions regarding eligibility or benefits, or if patient wishes to discontinue participation, call the edex[®] Savings Card Program at 1-888-203-7915 (Monday–Friday, 8 AM–8 PM EST)

- When using this card, patient is certifying that patient understands the program rules, regulations, and terms and conditions
- Not eligible if the 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
- Patient must comply with the terms above

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edex[®]

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10 mcg • 20 mcg • 40 mcg



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