

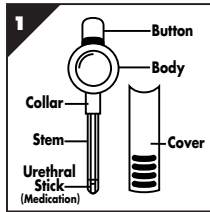


PATIENT INFORMATION

Please read this pamphlet before using MUSE® (alprostadil). This pamphlet is a quick reference source on important information about MUSE for you and your partner. **Before administering MUSE, please review the patient video and education booklet. These materials provide visual instruction and more detailed information as well as practical tips on how to use MUSE.**

WHAT IS MUSE?

MUSE represents a unique approach for the treatment of erectile dysfunction, commonly called impotence. It is based on the discovery that the urethra (the normal pathway for urine) can absorb certain medications into the surrounding erectile tissues thereby creating an erection. There are 4 dose strengths available: 125, 250, 500, and 1000 micrograms. The MUSE applicator (Fig.1) contained in each foil pouch is intended for 1 administration only. Your dose of MUSE will be determined by you and your physician. After administration, the erection process will begin within 5 – 10 minutes, and may last 30 – 60 minutes. However, the actual duration will vary from patient to patient.



WHAT IS MUSE USED FOR?

MUSE is indicated for the treatment of erectile dysfunction. Erectile dysfunction is the inability to attain or maintain an erection sufficient for sexual intercourse.

WHO SHOULD NOT USE MUSE?

You should not use MUSE if you have any of the following:

- Known hypersensitivity to alprostadil (the active medication in MUSE)
- An abnormally formed penis
- Have been advised not to undertake sexual activity
- Conditions that might result in long-lasting erections, such as sickle cell anemia or trait, leukemia, or tumor of the bone marrow (multiple myeloma)
- MUSE should not be used for sexual intercourse with a pregnant woman unless the couple uses a condom barrier.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF MUSE?

The most common side effects that have been observed using MUSE follow:

- Aching in the penis, testicles, legs, and in the perineum (area between the penis and rectum)
- Warmth or burning sensation in the urethra
- Redness of the penis due to increased blood flow
- Minor urethral bleeding or spotting due to improper administration.

Side effects reported less frequently:

- Prolonged erection - **PLEASE NOTE: IF YOUR ERECTION IS RIGID FOR MORE THAN 4 HOURS, CALL YOUR DOCTOR PROMPTLY.**
- Swelling of leg veins
- Light-headedness/Dizziness
- Fainting - **PLEASE NOTE: AFTER USING MUSE, YOU SHOULD AVOID ACTIVITIES, SUCH AS DRIVING OR HAZARDOUS TASKS, WHERE INJURY COULD RESULT IF DIZZINESS OR FAINTING WERE TO OCCUR. IN PATIENTS EXPERIENCING THESE SYMPTOMS, THE SYMPTOMS HAVE USUALLY OCCURRED DURING INITIATION OF THERAPY AND WITHIN ONE HOUR OF MUSE ADMINISTRATION.**
- Rapid pulse.

If you have a history of fainting be sure to discuss this with your doctor prior to using MUSE. If you do experience dizziness or feel faint, this may be due to the lowering of your blood pressure. Lie down immediately and raise your legs. If symptoms persist, call your doctor promptly. Because of the potential for these side effects, MUSE titration should be carried out under medical supervision.

Call your doctor for medical advice about side effects. **To report side effects, contact Meda Pharmaceuticals Inc. at 1-888-367-6873 or contact FDA at 1-800-FDA-1088, fax 1-800-FDA-0178 or online at www.fda.gov/medwatch/report.htm.**

Changing Your Dosage

It is assumed that you and your doctor have determined the proper dose of MUSE. If you suspect that your dose needs to be increased or decreased to achieve the response that works best for you, please call your doctor to determine if your dose needs to be reevaluated. Do not use MUSE more than twice in a 24-hour period.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF MUSE FOR YOUR PARTNER?

The most common reported side effects observed in women whose partners use MUSE are mild vaginal itching or burning. Using a water-based lubricant can help to make vaginal penetration easier. Your partner may want to consult her health care provider if she has not had sexual intercourse for an extended period of time.

IMPORTANT INFORMATION FOR YOU AND YOUR PARTNER

Pregnancy

MUSE has no contraceptive properties.

Because MUSE has not been tested during human pregnancy, it is recommended that couples use adequate contraception if the female partner is of childbearing potential. MUSE should not be used for sexual intercourse with a pregnant woman unless the couple uses a condom barrier.

Sexually Transmitted Diseases

MUSE will not protect you or your partner from sexually transmitted diseases like chlamydia, gonorrhea, herpes simplex virus, viral hepatitis, human immunodeficiency virus (HIV – the virus that causes AIDS), human papilloma virus (genital warts), and syphilis. Latex condoms can protect against these sexually transmitted diseases.

HOW SHOULD I STORE MUSE?

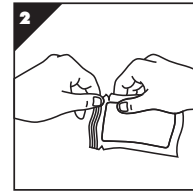
It is recommended that MUSE be stored in a refrigerator. MUSE may be kept at room temperature (less than 30°C/86°F) for up to 14 days prior to use. It is very important that MUSE not be exposed to temperatures above 30°C/86°F since this will make MUSE ineffective. MUSE should not be exposed to high temperatures or placed in direct sunlight.

Storage When Traveling

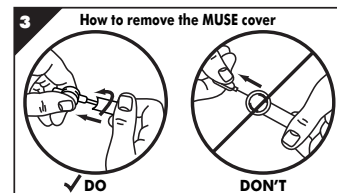
When traveling, store MUSE in a portable ice pack or cooler. Do not store in the trunk of a car or in baggage storage areas where MUSE may be exposed to extremes in temperature.

HOW TO ADMINISTER MUSE:

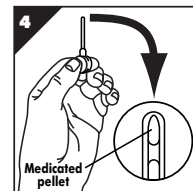
1. Immediately prior to administration, urinate and gently shake the penis several times to remove excess urine. A moist urethra makes administration of MUSE easier. The medicated pellet has been specially developed to dissolve in the small quantity of urine that remains in the urethra after urination.
2. Open the foil pouch by tearing fully across from the notched edge (Fig. 2). Let the MUSE slide out of the pouch. Save the pouch for discarding the MUSE applicator later.



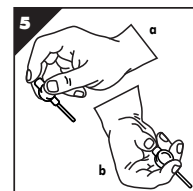
3. To remove the protective cover from the applicator stem (Fig. 3), hold the body of the applicator with your thumb and forefinger. Twist the body and pull out the applicator from the cover, being careful not to push in or pull out the applicator button. Avoid touching the applicator stem and tip. Save the cover for discarding the MUSE applicator later.



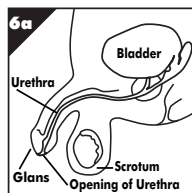
4. Visually inspect the MUSE. The MUSE system is see-through, and you will be able to see the medicated pellet at the end of the stem. Make sure that the pellet is present before insertion (Fig. 4).



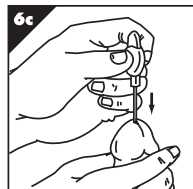
5. Hold the applicator in a way which is the most comfortable for you. (Fig. 5a and 5b)



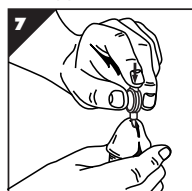
6. Please review Figure 6a, the anatomy of the penis.



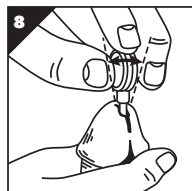
While sitting or standing, whichever is more comfortable for you, take several seconds to gently and slowly stretch the penis upward to its full length, with gentle compression from top to bottom of the glans (Fig. 6b). This straightens and opens the urethra. Slowly insert the MUSE stem into the urethra up to the collar (Fig. 6c). If you feel any discomfort or a pulling sensation, withdraw the applicator slightly and then gently reinsert.



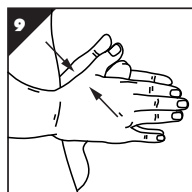
7. Gently and completely push down (Fig. 7) the button at the top of the applicator until it stops. It is important to do this to ensure that the medicated pellet is completely released. Hold the applicator in this position for 5 seconds.



8. Gently rock the applicator from side to side. This will separate the medicated pellet from the applicator tip (Fig. 8). If you apply too much pressure you may scratch the lining of the urethra causing it to bleed.



9. Remove the applicator while keeping the penis upright.
 10. Visually inspect the applicator tip to see that the medication is no longer in the applicator. Do not touch the stem. If you notice some residual medication in the end of the applicator, gently reinsert into the urethra and repeat steps 7, 8, and 9.
 11. Holding the penis upright and stretched to its full length, roll the penis firmly between your hands for at least 10 seconds. This will ensure that the medication is adequately distributed along the walls of the urethra (Fig. 9). If you feel a burning sensation, it may help to continue to roll the penis for an additional 30 – 60 seconds or until the burning subsides.



12. Remember, each MUSE is good for a single administration only. Replace the cover on the MUSE applicator, place in the opened foil pouch, fold, and discard as normal household waste.

After you have administered MUSE, it is important to sit, or preferably stand or walk about for 10 minutes while the erection is developing. This increases blood flow to the penis and will enhance your erection.

ADDITIONAL INFORMATION AND PRACTICAL TIPS

Factors Which May Enhance Your Erection:

- Being well rested and relaxed
- Sexual foreplay with your partner or self-stimulation while sitting or standing
- Pelvic exercises (for example, Kegel exercises) — these consist of tightening and releasing your pelvic and buttock muscles. These are the muscles you use to stop urination
- Various positions that may favor blood flow into the penis. Please refer to the patient starter booklet and video for illustrative examples.

Factors Which May Reduce Your Erection:

- Anxiety, fatigue, tension, and too much alcohol
- Lying on your back too soon after administration of MUSE may decrease blood flow to the penis and result in loss of erection
- Urination or dribbling immediately following administration may result in loss of medication from the urethra
- Using medications that contain decongestants, such as over-the-counter cold remedies, allergy, sinus medications, and appetite suppressants, may block the effect of MUSE.

COMMONLY ASKED QUESTIONS ABOUT MUSE

Will insertion of MUSE hurt?

At first, you may feel some minor discomfort from insertion. Urinating prior to administration will reduce the chance of discomfort or abrasions and is important for dissolving the medicated pellet. Be sure to straighten your penis to its full length when inserting the MUSE applicator. With repeated use, administration will become much easier.

What are the side effects associated with MUSE?

Most of the side effects reported in men are relatively minor and include burning and aching in the penis and groin. Rarely noted are prolonged erection, light-headedness, dizziness, fainting, rapid pulse, and swelling of the leg veins. If you feel dizzy, light-headed, faint, or experience rapid pulse, lie down immediately and raise your legs. If symptoms persist, call your doctor promptly. Because of the potential for these side effects, MUSE titration should be carried out under medical supervision.

(See also: “WHAT ARE THE POSSIBLE SIDE EFFECTS OF MUSE?” on the other side.)

In women, mild vaginal itching and burning have been observed.

After I administer MUSE, can we immediately lie down and begin sexual activity?

You can begin sexual activity, but having the man lie down, especially on his back shortly after administration, is not recommended. This will reduce blood flow to the penis and may reduce the erection. It is important to sit, stand or walk about for 10 minutes after administration. Many couples have used this time to incorporate various types of foreplay. After this initial period, you can assume different positions leading to sexual intercourse. Some couples have noticed that the erection is better maintained in positions that favor blood flow into the penis during intercourse.

Please review the video and patient starter booklet available from your doctor which illustrates various positions that will enhance your erection.

How long will the effect of MUSE last?

An erection should begin within 5 – 10 minutes after administering MUSE. The duration of effect is approximately 30 – 60 minutes. However, the actual duration will vary from patient to patient.

What will the erection be like? How will it compare to the erections I had when I was younger?

An effective dose of MUSE should produce an erection sufficient for sexual intercourse. MUSE may not create an erection such as those you experienced when you were younger. Some patients may experience some mild pain and aching in the penis or groin area. Also, your erection may continue after orgasm.

How do I know if I have the correct dose of MUSE?

You and your physician will determine the appropriate dose of MUSE. If your erection cannot be maintained for the time needed to have foreplay and sexual intercourse, you may need to have your dose increased. Similarly, an erection that lasts longer than desired may require a dose decrease. Call your doctor if you suspect you may require a dosing adjustment.

After my erection is over, will my penis feel sensitive?

Your penis may feel full, warm, and somewhat sensitive to the touch. These effects are normal and may last a few hours.

Can I reuse MUSE?

No. MUSE is intended for single-dose application only.

How do I dispose of the MUSE applicator?

After you have administered MUSE, replace the cover on the applicator, place in the opened foil pouch, fold, and discard as normal household waste.

If my erection lasts longer than desired, what should I do?

Note: Call your doctor promptly if you have a rigid erection that lasts more than 4 hours.

An application of ice packs to the inner thigh may shorten the duration of the erection, since the cold will restrict blood flow to the penis. If used, ice packs should be applied alternately to each inner thigh for a period not exceeding 10 minutes.

How often can I safely use MUSE?

MUSE should not be used more than twice per day.

If you have any additional questions about MUSE, please call the toll free patient information line at Meda Pharmaceuticals Inc.

1-888-367-MUSE (1-888-367-6873), or visit the MUSE product web site, <http://www.muserx.net>

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