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**PATIENT INFORMATION LEAFLET**  
**MUSE® (alprostadil)**

Before using MUSE, please read this leaflet carefully; it contains important information for you and your partner about using MUSE. Ask your doctor or pharmacist for help if anything in this leaflet is not clear, or if you want more information.

Please keep the leaflet so that you can refer to it again.

**WHAT IS MUSE?**

The name of your medication is MUSE. It consists of a single use applicator for administering the active ingredient alprostadil, directly into your urethra, the pathway for urine through the penis. Alprostadil is suspended in the single excipient, macrogol, to form a urethral stick which is contained in the tip of the applicator. There are four dose strengths available containing either 125, 250, 500 or 1000 micrograms of alprostadil. Your doctor will decide with you which strength is right for you.

MUSE is supplied in packs containing either 1 or 6 foil pouches, each pouch contains one dose of MUSE.

**HOW DOES MUSE WORK?**

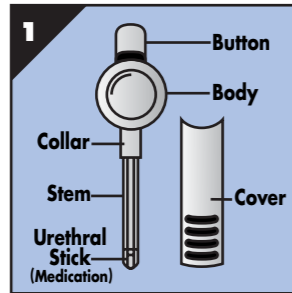
Alprostadil is identical to a natural substance in your body called prostaglandin E<sub>1</sub>. Alprostadil is absorbed from the urethra into the surrounding tissues where it increases the flow of blood into the penis, causing an erection.

**WHO MAKES MUSE?**

MUSE is manufactured by VIVUS Inc. at 735/745 Airport Road in Lakewood, NJ 08701, USA.

The site of batch release is Abbott Laboratories Ltd., Queenborough, Kent, ME11 5EL, UK.

The Marketing Authorisation holder is Meda Pharmaceuticals, Castle Donington, Derbyshire, DE74 2TZ, UK.



**WHAT IS MUSE USED FOR?**

MUSE is for use in men with a primarily organic (physical) cause of weak erections or impotence. Your doctor may also administer MUSE when testing your erectile function.

**WHO SHOULD NOT USE MUSE?**

You should not use MUSE if any of the following apply:

- You have previously had a bad reaction to a medicine containing alprostadil (the active medication in MUSE).
  - You have an abnormally formed penis.
  - You have a condition that might result in having long-lasting erections, such as sickle cell disease, leukaemia, or tumour of the bone marrow (multiple myeloma), or you have a history of long-lasting erections.
  - You have been advised not to undertake sexual activity maybe because you have an unstable heart condition or have had a recent stroke.
  - If your female partner is, or may be pregnant, you should use a condom barrier when you use MUSE.
  - MUSE should not be used by women or children.
- MUSE has not been tested in patients who have impotence primarily of psychogenic (psychological) origin.

**IMPORTANT INFORMATION FOR YOU AND YOUR PARTNER**

- **Pregnancy:** MUSE has no contraceptive properties. Because MUSE has not been tested during human pregnancy or in couples trying to achieve pregnancy, it is recommended that adequate contraception is used if the female partner is of childbearing potential.
- **Sexually transmitted diseases:** MUSE will not protect you or your partner from sexually transmitted diseases like chlamydia, gonorrhoea, herpes simplex virus, viral hepatitis, HIV (which causes AIDS), genital warts or syphilis. Latex condoms can protect against these diseases.

**ARE YOU TAKING OTHER MEDICINES OR DO YOU HAVE A PENILE IMPLANT?**

Make sure that your doctor knows about all other medicines you are taking, whether these are prescribed or bought from the chemist. If you are taking anticoagulants - medicines to thin your blood - or medicines which affect your blood pressure, tell your doctor this before starting to use MUSE. Medicines that contain decongestants such as cold remedies and some treatments for hayfever or sinus trouble may block the effects of MUSE. Appetite suppressants may have the same effect.

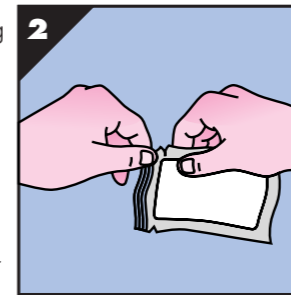
If you have a penile implant, or are taking other products for weak erections or impotence, discuss this with your doctor before you use MUSE.

**HOW TO USE MUSE**

- Your doctor will show you how to use MUSE and your dose of MUSE will be determined by you and your doctor. If MUSE does not work first time, it may be because you need a higher dose and will need to step up to the next strength. The maximum dose available is 1000 micrograms. Consult your doctor if you suspect your dose needs to be changed.
- Use one dose of MUSE as needed to achieve an erection.
- Unopened pouches of MUSE should be stored in a refrigerator (2-8°C). However, you may wish to store the product at room temperature (below 30°C for up to 14 days) before use as this may make insertion more comfortable.
- The instructions below tell you how to administer MUSE; in order for MUSE to be at its most effective, you will need to follow these carefully.

1. First wash your hands and dry them on a clean towel. Then **immediately before administration**, urinate and gently shake the penis several times to remove excess urine. A moist urethra makes insertion of MUSE easier and the medication has been specially designed to dissolve in the moisture that remains in the urethra after urination.

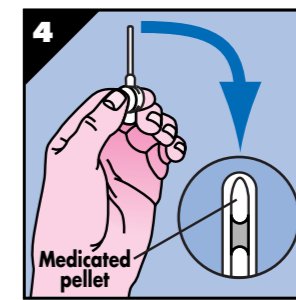
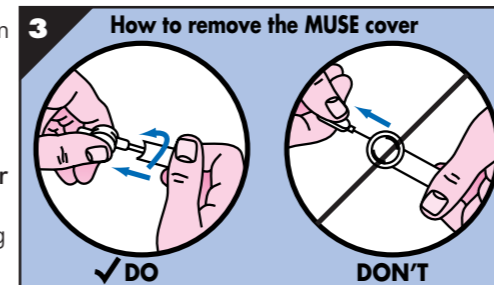
2. Open the foil pouch by tearing fully across the notched edge (Fig. 2). Let MUSE slide out of the pouch - do not remove by grasping the applicator. Save the pouch for discarding the MUSE applicator later.



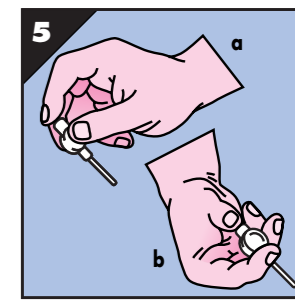
3. To remove the protective cover from the applicator stem (Fig. 3), hold the body of the applicator with your thumb and forefinger. Twist the body and pull out the applicator from the cover.

**Be careful not to push in or pull out the applicator button.**

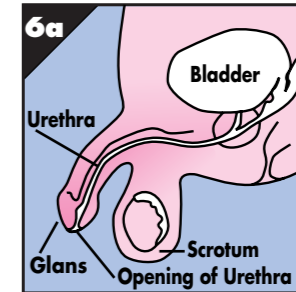
Avoid touching the applicator stem and tip. Save the cover for discarding the MUSE applicator later.



4. Check that you can see the medication at the end of the stem.

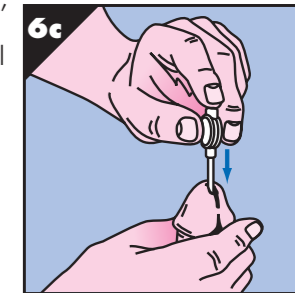
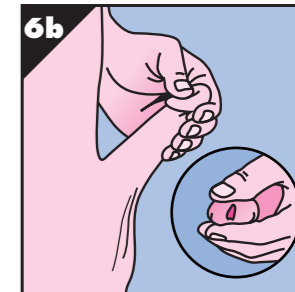


5. Hold the applicator in the way which is most comfortable to you (Fig. 5a and 5b).

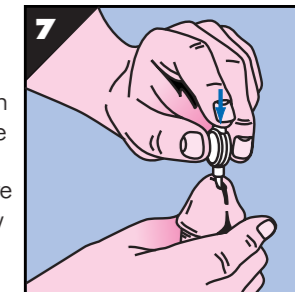


6. Look carefully at Fig. 6a which shows the anatomy of the penis. While **sitting** or **standing**,

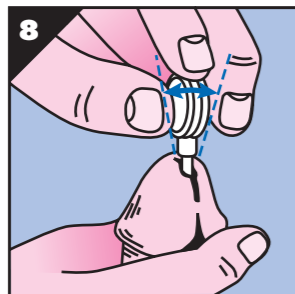
whichever is the more comfortable for you, take several seconds to gently and slowly stretch the penis upward to its full length, with gentle compression from top to bottom of the glans (Fig. 6b). This straightens and opens the urethra. **Slowly insert the MUSE stem into the urethra, up to the collar**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



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



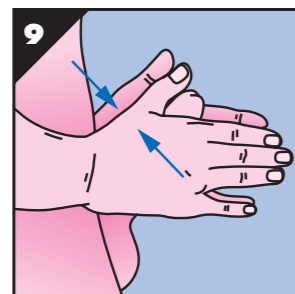
**8. Gently** rock the applicator from side to side. This will release the medication from the tip of the applicator (Fig. 8). Be careful not to scratch the lining of the urethra which could cause it to bleed.



**9.** Remove the applicator while keeping the penis upright.

**10.** Look at the applicator tip to check that the medication has separated from the applicator. Do not touch the stem. If you see any medication left at the end of the applicator, gently re-insert it into the urethra and repeat steps 7, 8 and 9.

**11.** Holding the penis upright and stretched to its full length, roll (massage) the penis firmly between your hands for **at least** 10 seconds (Fig. 9). This will ensure that the medication is properly distributed along the walls of the urethra. If you feel a burning sensation, it may help if you continue rolling the penis for an additional 30-60 seconds or until the burning subsides.



**12.** Remember, each MUSE applicator is for single administration only. After use, replace the cover on the MUSE applicator, place it in the opened foil pouch, and fold and discard it 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 will enhance your erection.**

#### HOW OFTEN CAN I USE MUSE?

You can use MUSE twice in any 24 hour period and up to 7 times in a 7 day period, but do not use it more often than this.

#### QUESTIONS COMMONLY ASKED ABOUT MUSE

**• Will the use of MUSE hurt?**

You may feel some discomfort from insertion, although with repeated use, administration will become easier.

Urinating before administration and making sure you stretch your penis to its full length will reduce the chance of discomfort. In addition, the medication in MUSE may cause some burning and aching, which should go away in a short period of time.

**• How long will the effect of MUSE last?**

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

**• What will the erection be like?**

**How will it compare with the erections in the past?**

An effective dose of MUSE should produce an erection sufficient for sexual intercourse. MUSE may not create an erection such as those you experienced in the past; there may be some mild pain and aching in the penis or groin and your erection may continue after orgasm.

Because MUSE increases local blood flow, your penis may feel warm and become red.

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

You and your doctor will determine the appropriate dose of MUSE. If your erection cannot be maintained for the time you need to have foreplay and sexual intercourse, you may need to have the dose increased. Alternatively, if your erection lasts too long, you may require a dose decrease. Consult your doctor if you suspect your dose needs to be changed.

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

Your penis may feel warm, full and sensitive to the touch for a few hours. This is normal.

#### 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, e.g. tightening and releasing your pelvic and buttock muscles (the muscles you use to stop urination).

**Factors which may reduce your erection:**

- Anxiety, fatigue, tension or 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. It is important to sit, stand or walk about for 10 minutes before you assume positions for sexual intercourse.
- 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.

Your doctor may review your treatment from time to time.

#### WHAT ARE THE POSSIBLE SIDE-EFFECTS OF MUSE?

The most common side-effects that have been observed by men using MUSE are:

- Aching in the penis, testicles, legs and perineum (the area between the penis and the rectum).
- Warmth or a burning sensation in the urethra.
- Minor urethral bleeding due to incorrect administration.

The following side-effects may also occur but they are less common:

- Swelling of the leg veins.
- Headache.
- Light-headedness/dizziness.
- Fainting.
- Rapid pulse.
- Rarely, prolonged erection, changes to your penis (e.g. curvature of the penis), or urinary tract infection may occur.
- Very rarely, rash and allergic skin reactions may occur.

**Please note:** if your erection is rigid for 4 hours or more, call your doctor promptly.

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 men experiencing these symptoms, the symptoms have usually occurred during the initiation of treatment and within one hour of MUSE administration.

If you notice any other symptoms or changes while you are using MUSE, or you are at all concerned, speak to your doctor or chemist.

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

The most common side-effects in women whose partners use MUSE are vaginal itching or burning. Using a water-based lubricant can help to make vaginal penetration easier.

#### WHAT TO DO IF YOUR ERECTION LASTS LONGER THAN DESIRED

Application of ice packs to the inner thigh may shorten the duration of the erection since the cold will restrict the flow of blood to the penis. If used, ice packs should be applied

alternately to each inner thigh for no longer than 10 minutes. If the dose is too high, you may also notice that your pulse rate increases or you feel dizzy or faint. If this happens, immediately lie down and raise your legs. If symptoms persist, call your doctor.

**If you have a rigid erection that lasts longer than four hours, you should speak to the doctor who prescribed MUSE to you straight away. If you cannot contact this doctor or any other doctor in his practice or clinic, then go to the hospital casualty department.**

#### HOW SHOULD I STORE MUSE?

Do not use MUSE after the expiry date shown on the pack.

**MUSE should not be exposed to high temperatures (i.e. above 30°C) or to direct sunlight since it will become ineffective. Store unopened pouches in a refrigerator (2-8°C) and only keep at room temperature (below 30°C) for up to 14 days before use. If travelling, do not leave MUSE in a car or anywhere else where it may be exposed to high temperatures.**

#### REMEMBER

This medicine is for YOU. Only a doctor can prescribe it for you. Never give it to others, even if their symptoms are the same as yours as it may not be suitable for them.

The information in this leaflet applies only to MUSE and is a summary of the information available. If you require further information or you have any questions, speak to your doctor or chemist.

#### IMPOTENCE ASSOCIATION HELPLINE

If you would like more information on impotence or any aspects of treatment, you can call:

The Impotence Association Helpline on 020 8767 7791. The Helpline is open on weekdays from 9a.m. to 5p.m. All calls are answered in the strictest confidence.

The Impotence Information Bureau, 7 Lower Fitzwilliam Street, Dublin 2, Ireland on 1570 111838.

This leaflet was revised in January 2003

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**MEDA**

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