

Randelhoff Design SPECIFICATION BOX FOR LEAFLET		COMPONENT SIZE	FONT SIZES USED
COUNTRY	UKIE	406,4 x 203,2 mm	Futura LT light Futura LT bold Futura LT medium
PRODUCT	MUSE 125, 250, 500, 1000 mcgr	05-11-000005	
PACK SIZE	1 Sachet		
MANUFACTURE CODE	05-11-000005		
MEDA CODE	56UKIE1514251-02	8 pt	
DESIGNED BY	Randelhoff Design		
DATE	27.03.2018		
COMMENTS			
MEDA APPROVAL DATE			
SIGNATURE			



05-11-000005

**Package leaflet: Information for the patient**  
**MUSE® 125, 250, 500 or 1000 micrograms urethral stick**  
 (Alprostadil)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

**What is in this leaflet:**

- What MUSE is and what it is used for
- What you need to know before you use MUSE
- How to use MUSE
- Possible side effects
- How to store MUSE
- Contents of the pack and other information
- Commonly asked questions about MUSE
- Helpful tips for improving your erection

**1. What MUSE is and what it is used for**

MUSE contains alprostadil in an applicator. Alprostadil is identical to a substance called prostaglandin E<sub>1</sub> (PGE<sub>1</sub>) which occurs naturally in the body. The applicator is used to deliver alprostadil into your penis. It acts to widen blood vessels and increases blood flow.

MUSE is used:

- To help you get and maintain an erection when you have insufficient PGE<sub>1</sub>.
- By your doctor to test whether you suffer from impotence. MUSE is not for use by women and children.

**2. What you need to know before you use MUSE**

**Do not use MUSE:**

- If you are allergic to alprostadil or any of the other ingredients of MUSE. These are listed in section 6.
- If your penis is deformed, for example it is bent or severely curved.
- If you have a disease of your penis, such as Peyronie's disease.
- If you have any inflammation in your penis or urethra (pathway for urine to pass out of the penis).
- If you have sickle cell anaemia or traits (abnormal red blood cells).
- If you have leukaemia (cancer of blood cells).
- If you have multiple myeloma (tumour of the bone marrow).
- If you have thrombocythaemia (increase in blood platelets).
- If you have polycythaemia (increased blood cells).
- If you are susceptible to venous thrombosis (blood clots in blood vessels).
- If you have a history of long-lasting erections.
- If you have been told not to have sex for health reasons such as heart problems or a recent stroke.

**Warnings and precautions**

Talk to your doctor before using MUSE:

- If you know that you have a bleeding disorder. Incorrect use of MUSE can cause bleeding in the urethra.
- If you have a blood born disease. Administration of MUSE could result in spread of the disease to your partner.
- If you have a heart, lung or chest disorder (in these cases you also should engage in sexual activity with caution)
- If you have a history of mental illness or addiction
- If you have had a mini-stroke (transient ischaemic attack)
- If you have a penile implant.
- If you have erections lasting 4 hours or longer.**

MUSE will not protect you or your partner from sexually transmitted diseases like chlamydia, gonorrhoea, herpes simplex virus, viral hepatitis, HIV, genital warts or syphilis. Always use a condom to avoid these sexually transmitted diseases.

**Other medicines and MUSE**

You must tell your doctor if you are taking:

- Antihypertensives (medicines to treat high blood pressure). MUSE may affect how well your medicine works.
- Anticoagulants (medicines to thin your blood). You are more likely to get bleeding in the urethra.
- Sympathomimetics (medicines used to treat heart problems and low blood pressure). MUSE may work less effectively.
- Vasoactive medicines (change the diameter of your blood vessels). Your blood pressure may decrease or increase.
- Decongestants (medicines for a cold, hay fever or sinus trouble). MUSE may work less effectively.
- Appetite suppressants (medicines that make you feel less hungry). MUSE may work less effectively.
- Viagra or other medicines for a weak erection. They may change the effect of MUSE.

Tell your doctor if you are taking or have recently taken or might take any other medicines, including any you bought without a prescription.

**Pregnancy and breast feeding**

MUSE should not be used if your female partner is or may be pregnant, unless you use a condom barrier.

Please ask your doctor or pharmacist for advice before using MUSE if your partner is breast feeding.

**Driving and using machines**

**MUSE may make you feel dizzy or faint. Do not drive or operate machinery if you feel dizzy or faint.**

**3. How to use MUSE**

Always use MUSE exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

**How much MUSE to use**

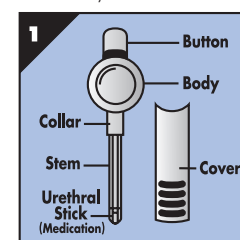
**For an erection:** The usual starting dose is 500 micrograms. If this does not give you an adequate erection, **do not increase your dose yourself.** Talk to your doctor who will try a higher dose.

Do not use more than 2 doses in one day (24-hour period) or more than 7 doses in 1 week.

**To test for erectile dysfunction (impotence):** Your doctor will give you one dose of 500 micrograms.

**How to use the applicator**

MUSE consists of an applicator (Fig. 1) for delivering alprostadil into the urethra. Your doctor will show you how to use MUSE and make sure that you can use it yourself. Follow the instructions below carefully:

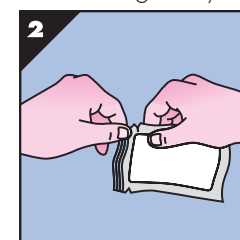


**Step a:**

- Wash your hands and dry them on clean towel
- Urinate and gently shake your penis several times to remove excess urine.** A moist urethra makes inserting MUSE easier

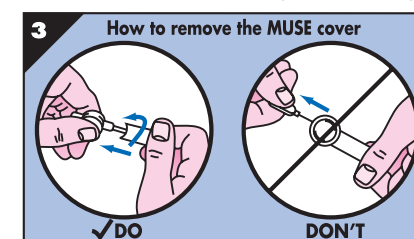
**Step b:**

- Open the foil pouch by tearing fully across the notched edge (Fig. 2)
- Let MUSE slide out of the pouch onto your hand
- Do not grab the applicator**
- Save the pouch for throwing away the used applicator later



**Step c:**

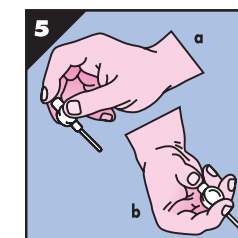
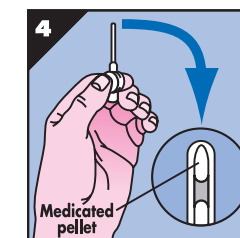
- Remove the protective cover from the end of the applicator by holding the body of the applicator with your thumb and forefinger and twisting (Fig. 3)
- Pull the applicator out of the cover
- Be careful not to touch the applicator stem and tip**
- Save the cover for throwing away the used applicator later



**Step d:**

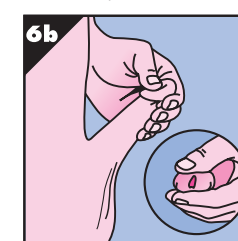
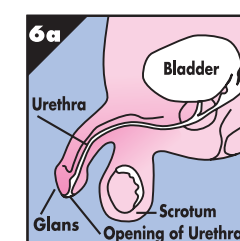
- Check that you can see the medication at the end of the stem (Fig. 4.)

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



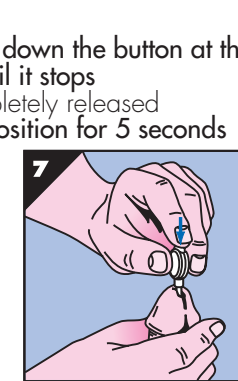
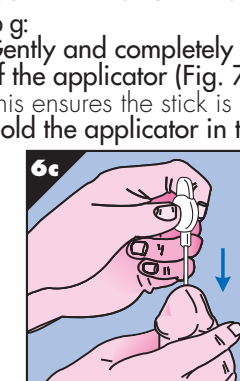
**Step e:**

- Look carefully at the drawing of a penis (Fig. 6a)
- While sitting or standing, whichever is the more comfortable for you, **take several seconds to stretch your penis gently and slowly to its full length**
- Do this with gentle compression from the top to the bottom of the glans (Fig. 6b). This straightens and opens the urethra



**Step f:**

- Slowly insert the MUSE stem** into your urethra up to the collar (Fig 6c)
- If you feel any discomfort or pulling sensation, withdraw the applicator slightly and gently re-insert.

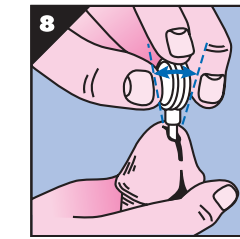


**Step g:**

- Gently and completely push down the button at the top of the applicator (Fig. 7) until it stops**
- This ensures the stick is completely released
- Hold the applicator in this position for 5 seconds**

**Step h:**

- Gently move the applicator from side to side to release the medication (Fig. 8)**
- Be careful not to scratch the lining of your urethra which could cause it to bleed**

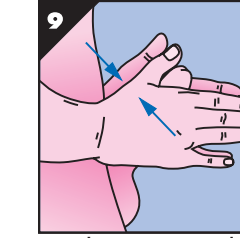


**Step i:**

- Remove the applicator whilst keeping your penis upright
- Look at the applicator to check there is no medication left in it
- Do not touch the stem**
- If you see any medication left in the applicator, gently reinsert it into your urethra**
- Repeat steps g, h and i

**Step k:**

- Hold your penis upright and stretch it to its full length
- Roll your penis firmly between your hands for at least 10 seconds (Fig. 9).** This helps to make sure that the medicine covers the walls of your urethra
- If you feel a burning sensation, it may help to continue to roll your penis until the burning stops**



**Step l:**

- Remember, use each MUSE applicator once only**
- After use, replace the cover on the applicator
- Put the applicator in the opened foil pouch and fold it
- Ask your pharmacist how to dispose of it
- Step m:**
- After you have used MUSE **it is important to sit, or preferably stand or walk about for 10 minutes whilst your erection develops.** This will make your erection better
- Your erection should last for 30 to 60 minutes
- You may get a red warm penis that is sensitive to the touch (this is normal).

**If you use more MUSE than you should**

Contact your doctor for advice. You may get low blood pressure, pain in your penis that does not go away and, very rarely, an erection which lasts for more than 4 hours.

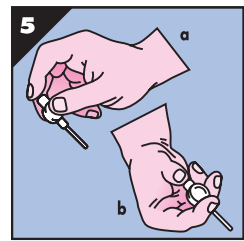
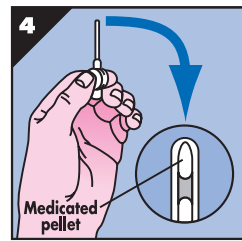
**4. Possible side effects**

Like all medicines, MUSE can cause side effects, although not everybody gets them. They are usually mild and disappear after a short time.

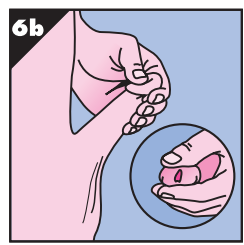
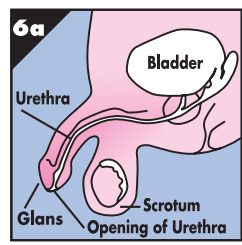
If you experience any of the following symptoms, contact your doctor immediately:

- You have a long lasting erection of more than 4 hours

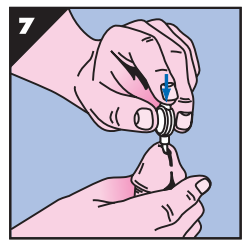
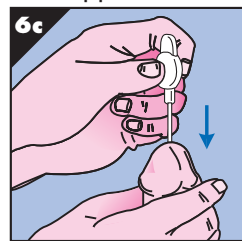
- Hold the applicator in the way which is most comfortable for you (Fig. 5)



- Step e:**
- Look carefully at the drawing of a penis (Fig. 6a)
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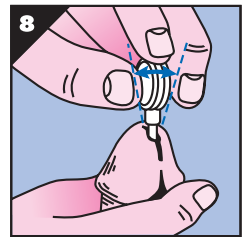


- Step f:**
- Slowly insert the MUSE stem** into your urethra up to the collar (Fig. 6c)
  - If you feel any discomfort or pulling sensation, withdraw the applicator slightly and gently re-insert.



- Step g:**
- Gently and completely push down the button at the top of the applicator (Fig. 7) until it stops**
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  - Hold the applicator in this position for 5 seconds

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**Step i:**

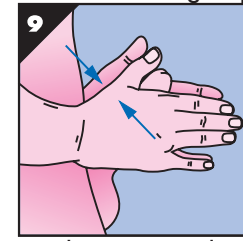
- Remove the applicator whilst keeping your penis upright

**Step j:**

- Look at the applicator to check there is no medication left in it
- Do not touch the stem**
- If you see any medication left in the applicator, gently reinsert it into your urethra**
- Repeat steps g, h and i

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Contact your doctor for advice. You may get low blood pressure, pain in your penis that does not go away and, very rarely, an erection which lasts for more than 4 hours.

#### 4. Possible side effects

Like all medicines, MUSE can cause side effects, although not everybody gets them. They are usually mild and disappear after a short time.

If you experience any of the following symptoms, contact your doctor immediately:

- You have a long lasting erection of more than 4 hours

- Your penis becomes scarred, bent or kinked
- Your testes or scrotum become red, swollen or painful, or develop lumps called spermatocele, which are cysts containing sperm

Very common side effects (affects more than 1 in 10 patients):

- Burning feeling in the urethra
- Painful penis

Common possible side effects (affects less than 1 in 10 patients):

- Headache
- Dizziness
- Muscle spasms
- Low blood pressure
- Minor bleeding in the urethra
- Pain in the testes
- Burning or itching in partner's vagina
- Bruised penis
- Increased erection

- Peyronie's disease (condition resulting in pain and abnormal curvature, shortening or narrowing of the penis).

Uncommon possible side effects (affects less than 1 in 100 patients):

- Fainting or feeling faint
- Impaired or enhanced sense of touch
- Swelling of the leg veins
- Leg pain
- Common cold
- Pain in the perineum (between the penis and rectum)
- Increased heart rate
- Widening of your blood vessels and decreased blood pressure which may make you feel lightheaded
- Problems with your blood vessels, such as bleeding from your veins

- Feeling sick
- Skin rash, which may be itchy or red
- Increased sweating
- Need to pass urine more urgently or frequently than normal
- Pain or difficulty in urinating
- Blood in your urine
- Increased levels of creatinine in your blood.
- Priapism (prolonged erection)
- Your testes or scrotum could become red, swollen or painful, or develop lumps called spermatocele, which are cysts containing sperm. The penis could feel numb
- Uncomfortable or painful erections, or no erection at all
- Change in ejaculation
- Swollen or tight foreskin and/or the head of your penis.

Rare possible side effects (affects less than 1 in 1000 patients):

- Urinary tract infection
- Disorders of the penis which may result in your penis becoming scarred, bent or kinked, particularly after long term use of MUSE

Very rare possible side effects (affects less than 1 in 10,000 patients):

- Red or white itchy patches (urticaria)

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this

leaflet. You can also report side effects directly via UK: the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) IRELAND: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [www.hpra.ie](http://www.hpra.ie), e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store MUSE

- Keep out of the sight and reach of children.
- Store unopened pouches in a refrigerator (2-8°C). Prior to use you may remove them from the refrigerator and store them at room temperature (not above 30°C) for a maximum of 14 days.
- Do not use MUSE after the expiry date which is stated on the pouch. The expiry date refers to the last day of that month.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### 6. Contents of the pack and other information

**What MUSE contains**

The active substance in MUSE is alprostadil. Each MUSE urethral stick contains 125 microgram, 250 micrograms, 500 micrograms or 1000 micrograms of alprostadil. The other ingredient is polyethylene glycol 1450 (PEG 1450).

**What MUSE looks like and contents of the pack**

MUSE is a single use applicator for giving alprostadil directly into your urethra (the pathway for urine through the penis). The applicator consists of a urethral stick, stem, collar, body, button and cover as one unit. Each applicator comes in a protective foil pouch.

MUSE comes in packs of 1, 2, 3, 6 or 10 pouches. (Not all packs may be marketed.)

**Marketing Authorisation Holder**

In the UK: Mylan Products Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL, UK

In Ireland: Mylan IRE Healthcare Limited, Unit 35/36, Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland

**Manufacturer**

The manufacturer responsible for batch release is Meda Pharma GmbH & Co KG, Benzstrasse 1, D61352 Bad Homburg, Germany

**Sexual Dysfunction Helpline**

For more information on impotence or any aspects of its treatment, you can call:

The Sexual Dysfunction Association, on 0870 774 3571 (UK only) or email [info@sda.uk.net](mailto:info@sda.uk.net). The Association's address is Suite 301, Emblem House, London Bridge Hospital, 27 Tooley Street, London SE1 2PR. The Helpline is open on Mondays, Wednesdays and Fridays from 10 a.m. to 4 p.m. All calls are answered in the strictest confidence.

#### 7. Commonly asked questions about MUSE

**•Will the use of MUSE hurt?** Inserting MUSE may cause you some discomfort. Urinating before using MUSE, stretching your penis to its full length and using MUSE repeatedly will reduce the chance of discomfort. Using MUSE may cause some burning and aching, which should not last long.

**•How long will the effect of MUSE last?** An erection should begin 5 to 10 minutes after using MUSE. It should last for about 30 to 60 minutes. However, this will vary from patient to patient.

**•What will the erection be like? How will it compare with the erections in the past?** MUSE should produce an erection for sexual intercourse. The erection may not be the same as those you had in the past. There may be some mild pain and aching in the penis or groin and your erection may continue after orgasm. Your penis may feel warm and become red because MUSE increases blood flow in it.

**•How do I know if I have the correct dose of MUSE?** You and your doctor will decide the correct dose for you. If your erection does not last enough for you to have foreplay and sexual intercourse, you may need to have the dose increased. Or, if your erection lasts too long, a lower dose may be better for you. Tell your doctor if you think your dose needs to be changed.

**•After my erection is over, will my penis feel sensitive?** Your penis may be red and feel warm and sensitive to the touch for a few hours. This is normal.

#### 8. Helpful tips for improving your erection

**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 (which 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. You should sit, stand or walk about for 10 minutes before sexual intercourse.
- Urination or dribbling immediately following administration may result in loss of medication from the urethra.
- Using medications that contain decongestants, such as cold remedies, allergy, sinus medications and appetite suppressants, may lessen the effect of MUSE.

If you have any further questions on the use of MUSE, ask your doctor or pharmacist.

This leaflet was last revised in 05/2018.

If this leaflet is difficult to see or read or you would like it in a different format, please contact:

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In Ireland - Mylan IRE Healthcare Limited, Unit 35/36, Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland

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