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

Alprostadil (Alprostadil)

Do not use MUSE:
• You are allergic to alprostadil or any of the other ingredients of MUSE.
• You have had a mini-stroke (transient ischaemic attack) or had a heart attack.
• You have had a heart, lung or chest disorder (in these cases MUSE could result in spread of the disease to your partner)
• You have a disease of your penis, such as Peyronie’s disease.
• You have any inflammation in your penis or urethra (pathway for urine flow) because it contains important information for you.
• You have polycythaemia (increased blood cells).
• You have multiple myeloma (tumour of the bone marrow).
• You have a disease which makes your blood coagulate abnormally, such as polycythaemia vera or essential thrombocythaemia.
• You have anuria (lack of urine production).
• You have a history of bleeding disorders.
• You have been told not to take this medicine for health reasons such as heart problems or a weak artery.

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 or penis.
• If you have a blood borne disease. Administration of MUSE could result in spread of the disease to your partner.
• If you have hepatitis B or C, because this disease can be spread by Sexual contact if you have hepatitis C or a history of drug abuse.
• If you have any problems with your immune system.
• If you have a history of mental illness or addiction.
• If you have had a min-stroke (transient ischaemic attack).
• If you have been told to avoid sexual activity with your partner.
• If you have a history of erectile dysfunction.
• If you use any medicines, especially medicines to treat heart problems, high or low blood pressure, such as a beta blocker.
• If you or your partner are breast feeding.

Possible side effects
You may get a red warm penis that is sensitive to the touch (this is normal). Your erection should last for 30 to 60 minutes. If you feel a burning sensation, it may help to continue to rub with the used applicator head, otherwise continue to rub for a short time.

How to use the applicator
Do not touch the stem and tip of the applicator. 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:
Wrap your middle and ring fingers around the middle of the applicator (Fig. 1).

Step b:
Open the full pouch by tearing fully across the scored edge (Fig. 2).

Step c:
Gently slide out the pouch onto your hand (Fig. 3).

Step d:
Grip the applicator (Fig. 4).

Step e:
Look carefully at the drawing of a penis (Fig. 6a) while sitting or standing, whichever is the more comfortable for you.

Step f:
For a straight up position, preferably stand or walk about for 10 minutes whilst holding the applicator.

Step g:
Put the applicator in the opened foil pouch and fold it for your partner to know it is safe to use.

Step h:
Do not touch the stem of the applicator.

Step i:
Look at the applicator to check there is no medication left in it.

Step j:
Gently and completely push down the button at the top of the applicator (Fig. 7) until it stops.

Step k:
Hold the applicator in this position for 5 seconds.

Step l:
Hold the applicator in the way which is most comfortable for you (Fig. 8).

Step m:
Your erection should last for 30 to 60 minutes. If you feel a burning sensation, it may help to continue to rub with the used applicator head, otherwise continue to rub for a short time.

Storage
Store in a cool dry place, away from direct sunlight and out of reach of children.

Indications
MUSE is used to treat erectile dysfunction (impotence). Your doctor will give you one dose of 500 micrograms.

How to dispose of any unused MUSE
If you have used MUSE more than 7 doses in 1 week.

If you feel you are a different person by taking MUSE, you should stop using it and call your doctor.

If you feel a burning sensation, it may help to continue to rub with the used applicator head, otherwise continue to rub for a short time.

MUSE is not for use by women and children.

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.

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Design by Randelhoff Design
Be careful not to scratch the lining of your urethra which covers the walls of your urethra

- **Step h:**
  - Slowly insert the MUSE stem into your urethra (Fig. 6b). This straightens and opens the urethra
  - Hold the applicator in this position for 5 seconds
  - This ensures the stick is completely released
  - Gently move the applicator from side to side to release any medication left in it until it stops
  - If you feel a burning sensation, it may help to continue to roll your penis until the burning stops

- **Step i:**
  - If you see any medication left in the applicator, gently look carefully at the drawing of a penis (Fig. 6a)
  - If you feel a red or warm penis that is sensitive to the touch due to MUSE use, these measures will help protect the environment

- **Step j:**
  - After use, replace the cover on the applicator
  - Remember, use each MUSE applicator once only
  - Put the applicator in the opened foil pouch and fold it
  - After use, replace the cover on the applicator

- **Step k:**
  - Keep your applicator and pouch 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 foil pouches may be marketed
  - Marketing Authorization Holder
    - In the UK: Mylan Products Ltd, Station Close, Potters Bar, Hertfordshire EN6 3LQ
  - In Ireland - Mylan IRE Healthcare Limited, Unit 35/36, Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland
  - Manufacturer
    - Mylan IRE Healthcare Limited, Unit 35/36, Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland
  - If you have any further questions on the use of MUSE, ask your doctor or pharmacist

7. Commonly asked questions about MUSE

- **How will the use of MUSE affect your sex life?**
  - MUSE may cause some discomfort, discomfort may appear at the start of treatment and may take some time to resolve.
  - You may experience some discomfort when you first begin treatment. It is important to sit, or stand, or sit on your back too soon after administration of MUSE. Use the following measures:
  - **Positioning yourself:**
    - Avoid lying flat
    - Avoid sitting for long periods
    - **Diet:**
    - Avoid eating cold remedies, allergy, sinus medications and appetite suppressants as they may increase the chance of discomfort
    - Use MUSE may cause some burning and itching, which should not last long
  - **How long will the effect of MUSE last?**
    - An erection should begin 5-10 minutes after using MUSE. It should last for more than one hour. If your erection lasts too long, a lower dose may be better
  - **How do I know if I have the correct dose of MUSE?**
    - Your doctor will decide the correct dose for you. If your erection does not last long enough for you to have foreplay and sexual intercourse, you may need to have the dose increased. Do not take a higher dose of MUSE. Benefits of lower dose are:
    - **Erectile dysfunction:**
      - A lower dose may be better
      - **Sexual intercourse:**
        - A lower dose may be better
      - **Factors which may reduce your erection:**
        - Certain medications, e.g. tadalafil (Viagra), doxazosin (Mano), prazosin (Zyban), terazosin (Cialis), bupropion (Wellbutrin), and norepinephrine agonist (Norvasc), may reduce the effectiveness of MUSE
  - **Erections in the past?**
    - The efficacy of MUSE is assessed by asking for the provision of the following measures: factors which may reduce your erection:
      - Some medications, e.g. tadalafil (Viagra), doxazosin (Mano), prazosin (Zyban), terazosin (Cialis), bupropion (Wellbutrin), and norepinephrine agonist (Norvasc), may reduce the effectiveness of MUSE
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      - A lower dose may be better
  - **Sexual dysfunction helpline:**
    - 020 3873 8962
    - Wednesday and Fridays from 10 a.m. to 4 p.m. All calls are confidential and free of charge.
    - Further information on impotence or any aspects of its treatment, you can call the Sexual Dysfunction Helpline at 020 3873 8962
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    - The manufacturer responsible for batch release is Meda
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