PATIENT INFORMATION LEAFLET

2946
16.01.24[6]

Vitaros® 3 mg/g cream

(alprostadil)

This medicine is available using the above name but will be referred to as Vitaros throughout this leaflet.

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Vitaros is and what it is used for
2. What you need to know before you use Vitaros
3. How to use Vitaros
4. Possible side effects
5. How to store Vitaros
6. Contents of the pack and other information

1. What Vitaros is and what it is used for

Vitaros is used to treat erectile dysfunction (ED) in men 18 years of age or older. ED is the inability to attain or maintain an erection sufficient for sexual intercourse. There are several causes of ED including medications that you may be taking for other conditions, poor blood circulation in the penis, nerve damage,
emotional problems, too much smoking or alcohol use, and hormonal problems. Often ED is due to more than one cause. Treatments for ED include switching medications, if you are taking a medication that causes ED, prescription medications, medical devices that produce an erection, surgical procedures to correct blood flow to the penis, penile implants and psychological counseling. After application of Vitaros the onset of erection is within 5 to 30 minutes. You should not stop taking any prescription medications, unless told to do so by your doctor.

2. What you need to know before you use Vitaros

Do not use Vitaros
- if you have underlying disorders such as drop in blood pressure when going from a lying/sitting to a standing position, history of a heart attack, and syncope (dizziness).
- if you are allergic to alprostadil or any of the other ingredients of this medicine (listed in section 6).
- if you have a condition that might result in a long-lasting erection or a condition such as sickle cell anaemia or trait, thrombocythemia, polycythemia, multiple myeloma, or leukaemia
- if you have an abnormally formed penis
- if you have an inflammation or infection of the penis
- if you are prone to a venous thrombosis
- if you have a hyperviscosity syndrome which could result in a long-lasting erection
- if you have been told not to have sex for health reasons such as heart problems or a recent stroke.
- if your partner is pregnant, breast feeding or of childbearing potential unless you use a condom barrier.

Warnings and precautions
Talk to your doctor or pharmacist before using Vitaros if you have a history of the following local effects that have been observed with the use of Vitaros:
- Prolonged erections lasting >4 hours (priapism)
- Symptomatic hypotension (dizziness)
- Hepatic and/or renal insufficiency, a lowered dose due to impaired metabolism may be required
- Fainting

A condom should be used in the following situations:
- Your partner is pregnant or breastfeeding
- Your partner is of childbearing potential
- To prevent sexually transmitted diseases
- During oral sex and anal sex

Only latex condoms have been studied. It is not known if condoms made of other materials may be damaged.

Other medicines and Vitaros
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The use of Vitaros with other drugs used to treat Erectile Dysfunction have not been studied. Therefore, if you are taking other drugs for ED, do not combine with Vitaros as there could be signs including dizziness, fainting and prolonged erections. Vitaros has not been tested for use with penile implants or smooth muscle relaxants such as papaverine; drugs used to induce erections such as alpha blocking drugs (e.g. intracavernosal phentolamine, thymoxamine). There is a risk of priapism (painful prolonged abnormal erection) when used in combination.

Although not studied, it is possible that Vitaros may have less of an effect when taken in combination with treatments for high blood pressure, decongestants and appetite suppressants.

If you are taking drugs to prevent blood clots, do not take Vitaros as there may be an increased risk for bleeding or blood found in the urine.

In combination with high blood pressure medication, Vitaros use may increase symptoms of dizziness and fainting, especially in the elderly.

Pregnancy and breast-feeding and fertility
There are no data on the use of Vitaros in pregnant women. Pregnant women should not be exposed to Vitaros.
It is not recommended to use Vitaros while breastfeeding.
It is not known whether Vitaros has an effect on human male fertility.

Driving and using machines
Vitaros may make you feel dizzy or faint. Do not drive or operate machinery within 1 to 2 hours after administration.

Vitaros contains ethanol
This medicine contains 5 mg alcohol (ethanol) in each 100 mg dose which is equivalent to 50 mg/g (5 %w/w). It may cause a burning sensation on damaged skin.

3. How to use Vitaros

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

Vitaros should be used as needed to achieve an erection. Each Vitaros AccuDose container is for single use only and should be properly discarded after use.

For an erection: the starting dose should be recommended by a physician.
Do not adjust your dose yourself. Talk to your doctor who will instruct you on proper technique for administration and accomodation of your dose.
Do not apply Vitaros more than 2-3 times a week and only once per 24 hour period.

The onset of effect is within 5 to 30 minutes after administration. The duration of effect is approximately 1 to 2 hours. But, the actual duration can vary from patient to patients.

It is recommended to urinate before applying the drug. After removing the cap, apply all the contents of Vitaros into the opening at the tip of the penis, 5 to 30 minutes before attempting intercourse by following the instructions below:

1.

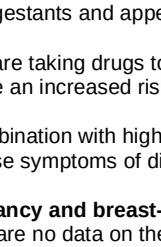
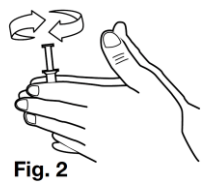


Fig. 1

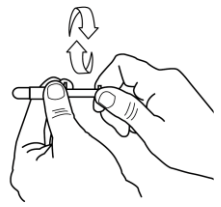
Wash your hands before applying Vitaros. Remove the AccuDose container (see Fig.1) from the sachet by tearing fully down the seal from the middle of the top edge. Save the sachet for discarding the used AccuDose container later.

2.


Fig. 2

Bring the content of the AccuDose container to room temperature by rolling the container between your hands (see Fig. 2). This step can be avoided if the sachet was removed from the refrigerator earlier (within the time limits stated in Section 5 How to store Vitaros) and the contents have already reached room temperature.

3.


Fig. 3

Twist the plunger several times to make sure it will glide easily (see Fig. 3). Then remove the cap from the tip of the AccuDose container.

4.

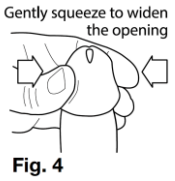


Fig. 4

Grasp the tip of the penis with one hand and gently squeeze to widen the opening at the tip of the penis, while holding it in an upright vertical position (see Fig. 4). Note: if you are not circumcised, first retract and hold the foreskin back prior to widening the opening of the penis

5.

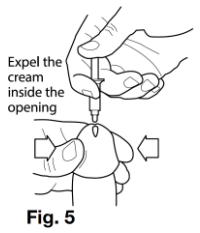


Fig. 5

Hold the barrel of the AccuDose container between your fingers and **without inserting it inside the penis** (see Fig. 5), place the tip of the container as close as possible to the opening at the tip of the penis for the cream to go down the urethra (the tube that leads from the bladder and transports and discharges urine and semen outside the body). Remember to push out all the cream from the AccuDose container. Slowly, but firmly, push down the plunger with your thumb or finger until all the cream is expelled into the opening at the tip of the penis and down the urethra. Note: While it is important that all the cream goes down the urethra, take care **not to insert the tip of the AccuDose container into the opening at the tip of the penis.**

6.

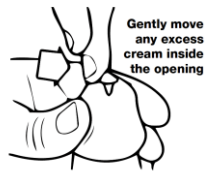


Fig. 6

Hold the penis in an upright position for approximately 30 seconds to allow the cream to penetrate. There will likely be some cream that does not initially fit into the opening at the tip of the penis. Any excess cream covering the opening at the tip of the penis should be gently moved into the opening with the tip of a finger (see Fig. 6). Do not use a second AccuDose to compensate for cream not expelled into the opening at the tip of the penis. Do not urinate immediately after application, due to the risk that drug could come out before the effect takes place.

7. Remember each Vitaros dose is suitable for a single administration only. Replace the cap on the tip of the AccuDose container and place in the opened foil sachet, fold and discard in accordance with local requirements.

8. Vitaros may be irritating to the eyes. Wash your hands after applying Vitaros.

Children and adolescents
Vitaros is not indicated for children or men below 18 years of age.

If you use more Vitaros than you should
Overdose with Vitaros requiring treatment has not been reported. Overdose with Vitaros may result in a drop in blood pressure, fainting, dizziness, persistent pain in the penis, and possible prolonged erection lasting longer than 4 hours. This can result in permanent worsening or erectile function. Call your doctor promptly if you suffer with any of these effects.

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

4. Possible side effects
Like all medicines, Vitaros can cause side effects, although not everybody gets them.

If you get a long-lasting erection of more than 4 hours, contact your doctor immediately. Your doctor may reduce your dose of Vitaros and disontinue your treatment.

Common side effects (may affect more than 1 in 10 patients):
You:
- mild to moderate local aching, burning or pain and redness of the penis,
- rash,
- genital pruritus,
- penile oedema
- inflammation of the glans penis (balanitis)
- penile tingling, throbbing numbness, burning

Your partner:
- Mild vaginal burning or itching, vaginitis

This effect may be due to the drug or to the act of vaginal penetration. Using a water-based lubricant can help to make vaginal penetration easier.

Uncommon but potentially serious side effects (may affect up to 1 in 100 patients):
You:
- light-headedness/dizziness
- prolonged erection for more than 4 hours
- fainting
- low blood pressure or rapid pulse
- pain at the application site or in extremity
- urethral stenosis
- increase in sensitivity
- penile itching
- genital rash
- scrotal pain
- fullness in genital
- lack of sensation to penis
- Urinary tract inflammation

Your partner: vulvovaginal pruritus
*Increased sexual/physical activity in combination with Vitaros may increase the risk of heart attack or stroke in patients with underlying disease/risk factors (see Section 2).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Duration of side effects:
Most effects are short acting and resolve within 1-2 hours.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Vitaros
Keep this medicine out of the sight and reach of children.

Do not use Vitaros after the expiry date which is stated on the carton, sachet and AccuDose™ container label after Exp.
The expiry date refers to the last day of the month.
Store in a refrigerator (2°C - 8°C).
Do not freeze.
Unopened sachets may be kept out of the refrigerator by the patient, at a temperature below 25°C for up to 3 days prior to use.
At the end of this period, the product should be discarded if not used.

Each dispenser is for single use only.
Once opened, use immediately, discard any unused portion.
Store in the original sachet in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist to throw away medicines you no longer use. These measures will help protect the environment.

If your AccuDose™ fails to work properly or shows any signs of deterioration, you should seek the advice of your pharmacist.

6. Contents of the pack and other information
What Vitaros contains
The active substance is alprostadil
Each single container contains 300 micrograms of alprostadil in 100 mg of cream (3mg/g).

The other ingredients are purified water; ethanol, anhydrous; ethyl laurate; hydroxypropyl guar gum; dodecyl-2-N,N dimethyl-aminopropionate hydrochloride; potassium dihydrogen phosphate; sodium hydroxide, for pH adjustment; phosphoric acid, for pH adjustment.

What Vitaros looks like and contents of the pack
Vitaros is a white to off-white cream supplied in AccuDose™, a single dose container. AccuDose™ is a container consisting of a plunger, barrel, and protective cap.
Each container is provided in a protective sachet.
The sachets are composed of aluminium foil/laminate. The container components are composed of polypropylene and polyethylene.
Available in pack size of 4-unit dose AccuDose™ containers.

MANUFACTURER AND PRODUCT LICENCE HOLDER
Manufactured by
Laphal Industries, Avenue de Provence, 13190 Allauch, France.
Delpharm Huningue SAS, 26, rue de la Chapelle, 68330 Huningue, France.
Centre Specialites Pharmaceutiques, Zac Des Suzots, 35 Rue de La Chapelle, 63450 Saint Amant Tallende, France.

Procured from within the EU by Product Licence holder
Star Pharmaceuticals Ltd., 5 Sandridge Close, Harrow, Middlesex, HA1 1XD. Repackaged by Servipharm Ltd.

POM	PL 20636/2946

Leaflet revision and issue date (Ref) 16.01.24[6]

Vitaros is a trademark of SIMPLE PHARMA I LIMITED.

Other Sources of Information
Detailed information on this medicine is available on the MHRA website: http://www.mhra.gov.uk

EFFECTS AFTER APPLICATION:
Vitaros requires between 5 to 30 minutes to begin working before you can have sexual intercourse. After administration you can engage in foreplay, which helps arousal and the process of developing an erection. An effective dose of Vitaros should produce an erection sufficient for sexual intercourse. The duration of the effect is approximately 1 to 2 hours. However, the actual duration will vary from patient to patient and the dose of the drug. Vitaros may not create an erection comparable to those you experienced when you were younger. Some patients may experience some mild pain, a burning sensation, and aching in the penis or groin area. Also, your erection may continue for a time after orgasm or ejaculation. After your erection is over your penis may feel full, warm, and somewhat sensitive to the touch. These effects are normal and may last for a few hours.

ADDITIONAL INFORMATION AND PRACTICAL TIPS:
You and your doctor will determine the appropriate dose of Vitaros. 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, if an erection lasts longer than desired or if the side effects are not well tolerated you may need your dose reduced. Call your doctor if you suspect that you may require an adjustment of your dose.

Factors that may enhance your erection:
- Being well rested.
- Sexual foreplay with your partner or self-stimulation while sitting or lying after application of Vitaros.
- Pelvic exercises such as tightening and releasing your pelvic and buttock muscles. These are the muscles you use to stop urination.
- Various positions that may favour and not restrict blood flow to the penis.

Factors which may reduce your erection:
- Anxiety, fatigue, tension, and too much alcohol.
- Urination immediately after application may result in loss of medication.

Blind or partially sighted?
Is this leaflet hard to see or read?
Call 020 8423 2111 to obtain the leaflet in a format suitable for you.

PATIENT INFORMATION LEAFLET

2946
16.01.24[6]

Alprostadil 3 mg/g cream

This medicine is available using the above name but will be referred to as Alprostadil throughout this leaflet.

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Alprostadil is and what it is used for
2. What you need to know before you use Alprostadil
3. How to use Alprostadil
4. Possible side effects
5. How to store Alprostadil
6. Contents of the pack and other information

1. What Alprostadil is and what it is used for

Alprostadil is used to treat erectile dysfunction (ED) in men 18 years of age or older. ED is the inability to attain or maintain an erection sufficient for sexual intercourse. There are several causes of ED including medications that you may be taking for other conditions, poor blood circulation in the penis, nerve damage,
emotional problems, too much smoking or alcohol use, and hormonal problems. Often ED is due to more than one cause. Treatments for ED include switching medications, if you are taking a medication that causes ED, prescription medications, medical devices that produce an erection, surgical procedures to correct blood flow to the penis, penile implants and psychological counseling. After application of Alprostadil the onset of erection is within 5 to 30 minutes. You should not stop taking any prescription medications, unless told to do so by your doctor.

2. What you need to know before you use Alprostadil

Do not use Alprostadil
- if you have underlying disorders such as drop in blood pressure when going from a lying/sitting to a standing position, history of a heart attack, and syncope (dizziness).
- if you are allergic to alprostadil or any of the other ingredients of this medicine (listed in section 6).
- if you have a condition that might result in a long-lasting erection or a condition such as sickle cell anaemia or trait, thrombocythemia, polycythemia, multiple myeloma, or leukaemia
- if you have an abnormally formed penis
- if you have an inflammation or infection of the penis
- if you are prone to a venous thrombosis
- if you have a hyperviscosity syndrome which could result in a long-lasting erection
- if you have been told not to have sex for health reasons such as heart problems or a recent stroke.
- if your partner is pregnant, breast feeding or of childbearing potential unless you use a condom barrier.

Warnings and precautions
Talk to your doctor or pharmacist before using Alprostadil if you have a history of the following local effects that have been observed with the use of Alprostadil:
- Prolonged erections lasting >4 hours (priapism)
- Symptomatic hypotension (dizziness)
- Hepatic and/or renal insufficiency, a lowered dose due to impaired metabolism may be required
- Fainting

A condom should be used in the following situations:
- Your partner is pregnant or breastfeeding
- Your partner is of childbearing potential
- To prevent sexually transmitted diseases
- During oral sex and anal sex

Only latex condoms have been studied. It is not known if condoms made of other materials may be damaged.

Other medicines and Alprostadil
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The use of Alprostadil with other drugs used to treat Erectile Dysfunction have not been studied. Therefore, if you are taking other drugs for ED, do not combine with Alprostadil as there could be signs including dizziness, fainting and prolonged erections. Alprostadil has not been tested for use with penile implants or smooth muscle relaxants such as papaverine; drugs used to induce erections such as alpha blocking drugs (e.g. intracavernosal phentolamine, thymoxamine). There is a risk of priapism (painful prolonged abnormal erection) when used in combination.

Although not studied, it is possible that Alprostadil may have less of an effect when taken in combination with treatments for high blood pressure, decongestants and appetite suppressants.

If you are taking drugs to prevent blood clots, do not take Alprostadil as there may be an increased risk for bleeding or blood found in the urine.

In combination with high blood pressure medication, Alprostadil use may increase symptoms of dizziness and fainting, especially in the elderly.

Pregnancy and breast-feeding and fertility
There are no data on the use of Alprostadil in pregnant women. Pregnant women should not be exposed to Alprostadil.
It is not recommended to use Alprostadil while breastfeeding.
It is not known whether Alprostadil has an effect on human male fertility.

Driving and using machines
Alprostadil may make you feel dizzy or faint. Do not drive or operate machinery within 1 to 2 hours after administration.

Alprostadil contains ethanol
This medicine contains 5 mg alcohol (ethanol) in each 100 mg dose which is equivalent to 50 mg/g (5 %w/w). It may cause a burning sensation on damaged skin.

3. How to use Alprostadil

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

Alprostadil should be used as needed to achieve an erection. Each Alprostadil AccuDose container is for single use only and should be properly discarded after use.

For an erection: the starting dose should be recommended by a physician.
Do not adjust your dose yourself. Talk to your doctor who will instruct you on proper technique for administration and accomodation of your dose.
Do not apply Alprostadil more than 2-3 times a week and only once per 24 hour period.

The onset of effect is within 5 to 30 minutes after administration. The duration of effect is approximately 1 to 2 hours. But, the actual duration can vary from patient to patients.

It is recommended to urinate before applying the drug. After removing the cap, apply all the contents of Alprostadil into the opening at the tip of the penis, 5 to 30 minutes before attempting intercourse by following the instructions below:

1.

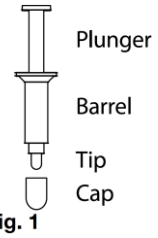
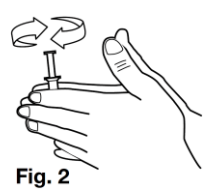


Fig. 1

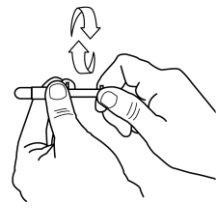
Wash your hands before applying Alprostadil. Remove the AccuDose container (see Fig.1) from the sachet by tearing fully down the seal from the middle of the top edge. Save the sachet for discarding the used AccuDose container later.

2.


Fig. 2

Bring the content of the AccuDose container to room temperature by rolling the container between your hands (see Fig. 2). This step can be avoided if the sachet was removed from the refrigerator earlier (within the time limits stated in Section 5 How to store Alprostadil) and the contents have already reached room temperature.

3.


Fig. 3

Twist the plunger several times to make sure it will glide easily (see Fig. 3). Then remove the cap from the tip of the AccuDose container.

4.

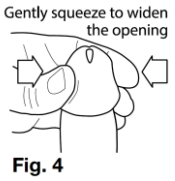


Fig. 4

Grasp the tip of the penis with one hand and gently squeeze to widen the opening at the tip of the penis, while holding it in an upright vertical position (see Fig. 4). Note: if you are not circumcised, first retract and hold the foreskin back prior to widening the opening of the penis

5.

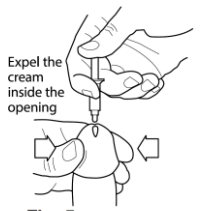


Fig. 5

Hold the barrel of the AccuDose container between your fingers and **without inserting it inside the penis** (see Fig. 5), place the tip of the container as close as possible to the opening at the tip of the penis for the cream to go down the urethra (the tube that leads from the bladder and transports and discharges urine and semen outside the body). Remember to push out all the cream from the AccuDose container. Slowly, but firmly, push down the plunger with your thumb or finger until all the cream is expelled into the opening at the tip of the penis and down the urethra. Note: While it is important that all the cream goes down the urethra, take care **not to insert the tip of the AccuDose container into the opening at the tip of the penis.**

6.

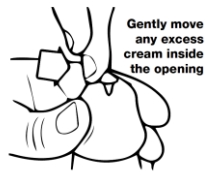


Fig. 6

Hold the penis in an upright position for approximately 30 seconds to allow the cream to penetrate. There will likely be some cream that does not initially fit into the opening at the tip of the penis. Any excess cream covering the opening at the tip of the penis should be gently moved into the opening with the tip of a finger (see Fig. 6). Do not use a second AccuDose to compensate for cream not expelled into the opening at the tip of the penis. Do not urinate immediately after application, due to the risk that drug could come out before the effect takes place.

7. Remember each Alprostadil dose is suitable for a single administration only. Replace the cap on the tip of the AccuDose container and place in the opened foil sachet, fold and discard in accordance with local requirements.

8. Alprostadil may be irritating to the eyes. Wash your hands after applying Alprostadil.

Children and adolescents
Alprostadil is not indicated for children or men below 18 years of age.

If you use more Alprostadil than you should
Overdose with Alprostadil requiring treatment has not been reported. Overdose with Alprostadil may result in a drop in blood pressure, fainting, dizziness, persistent pain in the penis, and possible prolonged erection lasting longer than 4 hours. This can result in permanent worsening or erectile function. Call your doctor promptly if you suffer with any of these effects.

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

4. Possible side effects
Like all medicines, Alprostadil can cause side effects, although not everybody gets them.

If you get a long-lasting erection of more than 4 hours, contact your doctor immediately. Your doctor may reduce your dose of Alprostadil and disontinue your treatment.

Common side effects (may affect more than 1 in 10 patients):
You:
- mild to moderate local aching, burning or pain and redness of the penis,
- rash,
- genital pruritus,
- penile oedema
- inflammation of the glans penis (balanitis)
- penile tingling, throbbing numbness, burning

Your partner:
- Mild vaginal burning or itching, vaginitis

This effect may be due to the drug or to the act of vaginal penetration. Using a water-based lubricant can help to make vaginal penetration easier.

Uncommon but potentially serious side effects (may affect up to 1 in 100 patients):
You:
- light-headedness/dizziness
- prolonged erection for more than 4 hours
- fainting
- low blood pressure or rapid pulse
- pain at the application site or in extremity
- urethral stenosis
- increase in sensitivity
- penile itching
- genital rash
- scrotal pain
- fullness in genital
- lack of sensation to penis
- Urinary tract inflammation

Your partner: vulvovaginal pruritus
*Increased sexual/physical activity in combination with Alprostadil may increase the risk of heart attack or stroke in patients with underlying disease/risk factors (see Section 2).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Duration of side effects:
Most effects are short acting and resolve within 1-2 hours.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Alprostadil
Keep this medicine out of the sight and reach of children.

Do not use Alprostadil after the expiry date which is stated on the carton, sachet and AccuDose™ container label after Exp.
The expiry date refers to the last day of the month.
Store in a refrigerator (2°C - 8°C).
Do not freeze.
Unopened sachets may be kept out of the refrigerator by the patient, at a temperature below 25°C for up to 3 days prior to use.
At the end of this period, the product should be discarded if not used.

Each dispenser is for single use only.
Once opened, use immediately, discard any unused portion.
Store in the original sachet in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist to throw away medicines you no longer use. These measures will help protect the environment.

If your AccuDose™ fails to work properly or shows any signs of deterioration, you should seek the advice of your pharmacist.

6. Contents of the pack and other information
What Alprostadil contains
The active substance is alprostadil
Each single container contains 300 micrograms of alprostadil in 100 mg of cream (3mg/g).

The other ingredients are purified water; ethanol, anhydrous; ethyl laurate; hydroxypropyl guar gum; dodecyl-2-N,N dimethyl-aminopropionate hydrochloride; potassium dihydrogen phosphate; sodium hydroxide, for pH adjustment; phosphoric acid, for pH adjustment.

What Alprostadil looks like and contents of the pack
Alprostadil is a white to off-white cream supplied in AccuDose™, a single dose container. AccuDose™ is a container consisting of a plunger, barrel, and protective cap.
Each container is provided in a protective sachet.
The sachets are composed of aluminium foil/laminate. The container components are composed of polypropylene and polyethylene.
Available in pack size of 4-unit dose AccuDose™ containers.

MANUFACTURER AND PRODUCT LICENCE HOLDER
Manufactured by
Laphal Industries, Avenue de Provence, 13190 Allauch, France.
Delpharm Huningue SAS, 26, rue de la Chapelle, 68330 Huningue, France.
Centre Specialites Pharmaceutiques, Zac Des Suzots, 35 Rue de La Chapelle, 63450 Saint Amant Tallende, France.

Procured from within the EU by Product Licence holder
Star Pharmaceuticals Ltd., 5 Sandridge Close, Harrow, Middlesex, HA1 1XD. Repackaged by Servipharm Ltd.

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Other Sources of Information
Detailed information on this medicine is available on the MHRA website: http://www.mhra.gov.uk

EFFECTS AFTER APPLICATION:
Alprostadil requires between 5 to 30 minutes to begin working before you can have sexual intercourse. After administration you can engage in foreplay, which helps arousal and the process of developing an erection. An effective dose of Alprostadil should produce an erection sufficient for sexual intercourse. The duration of the effect is approximately 1 to 2 hours. However, the actual duration will vary from patient to patient and the dose of the drug. Alprostadil may not create an erection comparable to those you experienced when you were younger. Some patients may experience some mild pain, a burning sensation, and aching in the penis or groin area. Also, your erection may continue for a time after orgasm or ejaculation. After your erection is over your penis may feel full, warm, and somewhat sensitive to the touch. These effects are normal and may last for a few hours.

ADDITIONAL INFORMATION AND PRACTICAL TIPS:
You and your doctor will determine the appropriate dose of Alprostadil. 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, if an erection lasts longer than desired or if the side effects are not well tolerated you may need your dose reduced. Call your doctor if you suspect that you may require an adjustment of your dose.

Factors that may enhance your erection:
- Being well rested.
- Sexual foreplay with your partner or self-stimulation while sitting or lying after application of Alprostadil.
- Pelvic exercises such as tightening and releasing your pelvic and buttock muscles. These are the muscles you use to stop urination.
- Various positions that may favour and not restrict blood flow to the penis.

Factors which may reduce your erection:
- Anxiety, fatigue, tension, and too much alcohol.
- Urination immediately after application may result in loss of medication.

Blind or partially sighted?
Is this leaflet hard to see or read?
Call 020 8423 2111 to obtain the leaflet in a format suitable for you.