**Vitaros**

**3 mg/g**

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. 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 this in the Leaflet?

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

Vitaros is available in two dosage strengths of 200 and 300 mcg alprostadil in 100 mg of cream. Vitaros is used to treat erectile dysfunction (ED) in men 18 years of age or older. ED is the inability to maintain or achieve 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 medical problems. Other 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 increase blood flow to the penis; and surgery. Vitaros can improve 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 heart attack or stroke, severe liver disease, or heart failure.
- 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 thrombocytopenia, polycythaemia, multiple myeloma, or leukaemia.
- If you have an abnormal formation of penis
- If you have an infection or inflammation of the penis
- If you are prone to a venous thrombosis.
- If you have a hyper sensitivity syndrome which could result in a long-lasting erection.
- If you have been told not to 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.

**Warning and precautions**

Talk to your doctor or pharmacist before using Vitaros if you have the history of any of the other local effects that can be induced with the use of Vitaros:

- prolonged erections lasting 24* hours (priapism)
- Symptomatic hypotension (dizziness)
- headache and other symptoms of low blood pressure, a lowered dose due to impaired metabolism may be required

Fainting

A condom should be used in the following situations:

- If you are prone to a venous thrombosis.
- If you have a hyper sensitivity syndrome which could result in a long-lasting erection.
- If you have been told not to 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.

**Other medicines and Vitaros**

Tell your doctor or pharmacist if you are taking, have recently taken or may take any other medicines.

The use of Vitaros with other drugs 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 erection. Vitaros is not been tested for use with penile implants or smooth muscle relaxants such as papaverine; drugs used to reduce erections such as alpha blocking drugs (e.g. intracavernosal phentolamine, trimetaphan). There is a risk of priapism (prolonged abnormal erection) when used in combination.

- If taken in combination, it may cause a drop in blood pressure or rapid pulse
- Cardiovascular problems
- Your partner is of childbearing potential unless you use a condom barrier.
- If you are prone to a venous thrombosis.
- If you have a hyper sensitivity syndrome which could result in a long-lasting erection.
- If you have been told not to 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.

**Children and adolescents**

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

If you use more VITAROS than you should:

**Stop use**

Overdose with Vitaros has not been reported. However, if you take extra doses of Vitaros, you may experience an erection sufficient for sexual intercourse. The duration of the effect is approximately 1 to 2 hours. However, the duration may vary from person to person and the dose and the patient. The patient may not create an erection compatible 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 Vataros use your penis may be more sensitive to 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 need 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 tolerable you may need to have your dose reduced. Ask your doctor if you suspect that you may need 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.

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