

## PACKAGE LEAFLET: INFORMATION FOR THE USER

Vitaros 300 micrograms, cream  
alprostadil

Read the entire 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.

Do not pass this medicine on to others. It may harm them, even if their symptoms 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. Contact your doctor or pharmacist.

### Contents of this leaflet

1. What is Vitaros and what is it used for?
2. When should you not use this medicine or be extra careful?
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### 1. WHAT IS VITAROS AND WHAT IS IT USED FOR?

Vitaros is used to treat erectile dysfunction (erectile dysfunction, ED). ED is the inability to get or maintain an erection sufficient for sexual intercourse. There are various causes of ED, including medications you take for other conditions, poor blood circulation in the penis, nerve damage, emotional problems, excessive smoking or alcohol use, and hormonal issues. Often, ED has more than one cause. Treatments for ED include switching to other medications if you are taking a drug that causes ED, prescription medications, medical devices that help you achieve an erection, surgical procedures that correct blood flow to the penis, penile implants, and psychological counseling.

### 2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAUTIOUS WITH IT?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.
- You have underlying disorders such as a drop in blood pressure from standing up quickly from a sitting or lying position, sometimes with dizziness (orthostatic hypotension), a heart attack, or sudden loss of consciousness, fainting (syncope).
- You have a condition that could result in a prolonged erection, or a condition such as sickle cell anemia or tendency to sickle cell formation, thrombocythemia, polycythemia, multiple myeloma, or leukemia.
- You have an abnormally shaped penis.
- You have an inflammation or infection of the penis.
- You are prone to venous thrombosis.
- You have a hyperviscosity syndrome that could result in a prolonged erection.
- You have been advised not to have sex for health reasons such as heart problems or a recent stroke.

- Your partner can conceive children unless you use a condom.

When should you be extra cautious with this medicine?

Contact your doctor or pharmacist before using this medicine if you have a history of the following local effects observed with the use of this medicine:

- long-lasting, often painful erection (priapism)
- symptomatic hypotension (dizziness)
- liver and/or kidney failure, a reduced dose may be necessary due to decreased metabolism
- fainting

In the following situations, you should use a condom:

- your partner is pregnant or breastfeeding
- your partner can conceive children
- to prevent sexually transmitted diseases
- during oral and anal sex.

Research has only been conducted on latex condoms together with this medicine.

Are you using any other medicines?

Are you using any other medicines besides Vitaros, or have you recently done so, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist.

The safety and efficacy of Vitaros used together with other medicines for erectile dysfunction, particularly treatment with PDE5 inhibitors, have not been studied. Therefore, do not use this medicine with PDE5 inhibitors.

Patients who are simultaneously treated with medicines for high blood pressure may have a greater risk of low blood pressure; this is especially true for the elderly.

Pregnancy, breastfeeding, and fertility

There is no data on the use of this medicine in pregnant women. Pregnant women should not be exposed to this medicine.

It is not recommended to use this medicine during the period of breastfeeding.

It is not known whether this medicine has an effect on male fertility.

Driving and using machines

This medicine may make you dizzy or you may faint. Do not drive or operate machines within 1 to 2 hours after administration.

Vitaros contains ethanol

This medicine contains 5 mg of alcohol (ethanol) per 100 mg dose unit, equivalent to 50 mg/g (5% w/w). This medicine may cause a burning sensation on your skin if your skin is damaged.

### 3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

This medicine should be used as needed to achieve an erection. Each package of this medicine is for single use only and should be disposed of properly after use.

For an erection: the initial dose is advised by a doctor. Do not change your dose yourself. Talk to your doctor, who will instruct you on the correct technique for administration and dose adjustment.

Do not apply this medicine more than 2-3 times a week and only once a day (24-hour period).

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

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

1. Wash your hands before applying this medication. Remove the single-use container from the foil pouch by tearing along the full length from the middle of the top. Take the single-use container out of the pouch (see figure 1). Keep the pouch to later dispose of the used single-use container.

2. Bring the contents of the single-use package to room temperature by rolling the package between your hands (see figure 2). This step can be skipped if the sachet was previously removed from the refrigerator (within the time limits as indicated in section 5 "How to store this medicine?") and the contents are already at room temperature.

3. Turn the plunger several times to ensure it slides easily (see figure 3). Then remove the cap from the tip of the single-use package.

4. Gently squeeze to widen the opening.

Gently squeeze to widen the opening.

5. Hold the cylinder of the single-use container between your fingers, and without inserting it into the penis (see figure 5), place the tip of the container as close as possible to the opening at the top of the penis to allow the cream to enter the urethra. Remember to push all the cream out of the single-use container. Slowly but surely press the plunger gently down with your thumb or finger until all the cream is brought into the opening at the top of the penis and into the urethra. Note: While it is important that all the cream enters the urethra, the tip of the single-use container should not be inserted into the opening of the penis.

6.

6. Do not urinate immediately after application as the medication risks coming out before it takes effect. Push excess cream into the opening.

7.

7. Remember that each Vitaros dose is suitable for only one administration. Replace the cap on the tip of the single-use container and place it in the opened foil pouch, fold it, and dispose of it as regular household waste.

8. This medicine can be irritating to the eyes. Wash your hands after applying this medicine.

Use in children and adolescents up to 18 years

This medicine is not indicated for children or men under 18 years of age.

Have you used too much of this medicine?

As far as is known, overdose with this medicine does not cause side effects that are so severe that they need to be treated. Overdose with this medicine can lead to a drop in blood pressure, fainting, dizziness, prolonged pain in the penis, and possibly a long-lasting, painful erection that lasts longer than four hours. This can lead to a permanent reduction in your ability to get and/or maintain an erection. Call your doctor immediately if you suffer from any of these side effects.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you get a prolonged erection lasting more than 4 hours, contact your doctor immediately. Your doctor may lower your dose of this medicine and stop your treatment.

Side effects that occur frequently (in less than 1 in 10 users):

You:

- rash
- mild to moderate local burning sensation, burning feeling or pain, and redness of the penis
- itching of the genitals or genital discomfort
- increased erection
- fluid retention in the penis
- inflammation of the glans of the penis (balanitis)
- tingling, throbbing sensation, numbness of the penis

Your partner:

- slight burning sensation or itching of the vagina, vaginitis.
- This may be due to the medication but also due to the intercourse itself. In that case, using a water-based lubricant may help.

Side effects that sometimes occur (in less than 1 in 100 users):

You:

- increased sensitivity
- lightheadedness/dizziness
- fainting
- low blood pressure or rapid heartbeat
- pain at the application site or in arms or legs
- narrowing of the urethra

- urinary tract infection
- itching of the penis
- rash on the genitals
- pain in the scrotum
- fullness of the genital organ
- excessive stiffness
- lack of sensation of the penis

Your partner:

- itching at the vulva and vagina.

### Reporting side effects

If you experience side effects, contact your doctor. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

## 5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.

Store in the refrigerator (2°C-8°C).

Do not freeze.

Unopened sachets can be stored by the patient outside the refrigerator, 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. Each package is for single use only.

Use immediately once opened, discard any unused portion.

Store in the original sachet to protect from light.

Do not use this medicine after the expiry date. It can be found on the box, sachet, and container after "Exp.". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed responsibly and will not enter the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

What substances are in this medicine?

- The active substance in this medicine is alprostadil.  
Each single-use pack contains 300 micrograms of alprostadil in 100 mg cream.
- The other substances in this medicine are purified water, anhydrous ethanol, ethyl laurate, hydroxypropyl guar gum, dodecyl-2-N,N-dimethylaminopropionate hydrochloride, potassium dihydrogen phosphate, sodium hydroxide for pH adjustment, phosphoric acid for pH adjustment.

What does Vitaros look like and what is in a pack?

Vitaros is a white to off-white cream. Vitaros is supplied in sachets with 1 single-use container. The single-use container is a device consisting of a plunger, a cylinder, and a protective cap in a protective sachet. Each single-use container contains 100 mg of cream and is also an applicator. Vitaros is available in boxes with 4 single-use containers. The sachets are made of aluminum foil/laminate. The components of the container are made of polypropylene and polyethylene.

Marketing authorization holder and manufacturer

Marketing authorization holder

The Simple Pharma Company Limited,  
Ground Floor, 71 Lower Baggot St,  
Dublin D02 P593,  
Ireland

Manufacturers

Copea Pharma Europe Limited,  
Medici House, Unit 2, Ashbourne Manufacturing Park,  
Ashbourne, Co. Meath, A84 KH58,  
Ireland

Registered under:  
RVG 115134.

This medicine is registered in EEA member states under the following names:

Netherlands:	Vitaros 300 micrograms, cream
Austria:	Vitaros 0.3% (3mg/g) – Cream
Belgium:	Vytaros 3 mg/g cream
Germany:	Vitaros 300 Micrograms/100 mg Cream
Denmark:	Vitaros
Finland:	Vitaros
Iceland:	Vitaros
Luxembourg:	Vytaros 3 mg/g cream
Norway:	Vitaros
Sweden:	Vitaros

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#### EFFECTS AFTER APPLICATION

Vitaros takes between 5 and 30 minutes to start working, allowing you to engage in sexual intercourse. After administration, you can engage in foreplay, which stimulates 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 depending on the patient and the dosage of the medication. Vitaros may not create an erection similar to what you experienced when you were younger. Some patients may experience mild pain or a burning and stinging sensation in the area of the penis or groin. Your erection may also persist for a period after orgasm or ejaculation. After your erection subsides, your penis may feel full, warm, and somewhat sensitive. These effects are normal and may last for a few hours.

## FURTHER INFORMATION AND PRACTICAL TIPS

You and your doctor will determine the appropriate Vitaros dose. If your erection does not last long enough to have foreplay and intercourse, your dose may need to be increased. And if an erection lasts longer than desired or if the side effects are not well tolerated, your dose may need to be reduced. Call your doctor if you suspect you may need an adjustment to your dose.

### Factors that can improve your erection

- Being well-rested.
- Sexual foreplay with your partner or self-stimulation while sitting or lying down after applying Vitaros.
- Pelvic exercises such as tightening and relaxing your pelvic and buttock muscles. These are the muscles you use to stop urination.
- Various positions that are beneficial for blood flow to the penis and do not restrict it.

### Factors that can reduce your erection

- Anxiety, fatigue, tension, and too much alcohol.
- Urinating immediately after application can result in loss of the medication.