

Package leaflet: Information for the user

Invicorp 25 micrograms / 2 mg solution for injection

aviptadil/phentolamine mesilate

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

1. What Invicorp is and what it is used for

The active components in Invicorp (aviptadil and phentolamine mesilate) affect the flow of blood in and out of the penis. In broad outline, phentolamine mesilate increases the flow of blood into the penis, while aviptadil reduces the flow of blood from the penis.

If you suffer from an erectile dysfunction, you can use Invicorp to help you to obtain an erection more easily.

2. What you need to know before you use Invicorp

Do not use Invicorp:

- if you are allergic to aviptadil or phentolamine mesilate or any of the other ingredients of this medicine (listed in section 6)
- if you have or have had leukaemia (cancer of the blood), multiple myeloma (bone cancer) or sickle cell anaemia or trait (a blood disease), as you may experience a painful, long lasting erection
- if you are taking blood thinning medicines such as warfarin or heparin, including oral blood thinning medicines such as dabigatran, rivaroxaban, apixaban
- if your doctor has advised you not to have sex because of your health condition
- if you have a penis which is scarred or not straight which may sometimes be referred to as Peyronie's disease or if you have abnormal fibrous tissue in the erectile tissue of the penis (cavernosal fibrosis)
- if you have an implant in your penis.

Warnings and precautions

If your erection is uncomfortable or painful or lasts for more than 4 hours, you must contact your doctor or emergency room immediately, since the treatment of this must be initiated within 6 hours.

Talk to your doctor, pharmacist or nurse before using Invicorp if:

- you suffer from heart or lung problems or have had a stroke (in these cases you should engage in sexual activity with caution)
- you have a history of mental illness or addiction.

Mild transient flushing of the face or trunk occurs commonly. In rare cases this is associated with discomfort and abnormal heart beat or rapid pulse. If you experience an abnormal heart beat or a rapid pulse, you should stop taking Invicorp.

It is important that you learn how to administer Invicorp correctly.

Other medicines and Invicorp

Do not take other medicines for erectile dysfunction at the same time as Invicorp.

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

Pregnancy, breast-feeding and fertility

Not relevant. Invicorp is only intended for men.

Invicorp contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium free".

3. How to use Invicorp

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

Invicorp is intended for injection into the spongy tissue on either side of the shaft of the penis (intracavernous injection). A doctor or nurse will show you how to carry out at least the first injection. Hereafter your doctor will monitor you regularly (e.g. every 3 months) particularly in the beginning of the self-injection therapy.

Do not attempt to inject yourself with Invicorp if:

- you have not been shown how to inject yourself
- you had any problems with the first injection
- you did not understand the instructions.

If you cannot remember how to administer the injections, you should contact your doctor. You must not try to use the injection if you are not sure what you should do.

Use in children and adolescents:

Invicorp should not be used in children and adolescents.

Dose

The recommended dose is 25 micrograms / 2 mg. Do not administer more than one injection per day, and not more than 3 injections per week. Each ampoule contains the correct amount for a single injection. You must inject the whole of the contents of the ampoule.

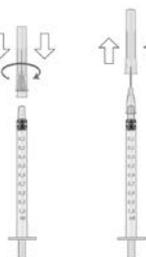
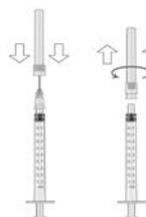
How you should use Invicorp

Invicorp can be brought to room temperature before use, or it can be used directly from the refrigerator. Unless your doctor has instructed otherwise, you should follow the dose guidelines that are given in this leaflet, as otherwise Invicorp cannot work properly.

You should carry out the first Invicorp injection under a doctor's or nurse's supervision.

Preparation of Invicorp injection

1. Wash your hands and dry them with a clean towel.
2. Take one glass ampoule with two fingers and turn it gently to ensure that all of the fluid is in the lowest part of the ampoule.
3. Break off the top of the ampoule and carefully place the ampoule on an even surface.
4. Open the package containing the long needle. You need the long needle to fill the syringe with the solution for injection from the ampoule. **DO NOT USE THIS NEEDLE FOR INJECTION.** Place the needle on a clean surface such as a clean paper tissue.
5. Take the syringe out of the package and place on the paper tissue.
6. Hold the syringe at the top end and hold the needle by the protective cap. Attach the syringe to the open end of the needle. Push and twist a half turn in one direction, until it fits securely. Remove the protective cap from the needle.
7. Insert the needle into the ampoule drawing back all the fluid from the ampoule into the syringe by pulling the plunger of the syringe. Replace the protective cap on the long needle and remove the needle from the syringe.
8. Open the package containing the short needle (for injection), and place on a clean surface such as a clean paper tissue.
9. Hold the syringe at the top end and hold the short needle by the protective cap. Attach the needle to the syringe. Push and twist a half turn in one direction until it fits securely. Then remove protective cap.



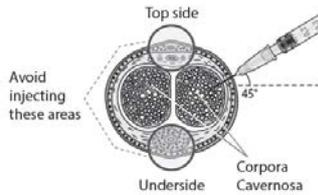
How to give yourself the injection

1. Wash the injection site on your penis, with soap and water, rinse with water and dry with a clean towel.

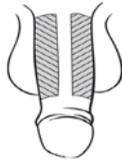
2. Take the syringe positioning the needle upwards, and carefully tap the barrel of the syringe until all trapped air bubbles move into the top of the syringe. Carefully push the plunger until a few drops come out of the needle. Do this to prevent air in the needle.



3. Hold the syringe with the needle at right angles to the side of the penis.



4. Make sure you do not inject into the urinary tract or into visible blood vessels. Inject into the grey shaded areas shown.



5. Push the needle into the penis until about half of the needle is in. Carefully push the plunger of the syringe and inject all the fluid.



6. Take the needle out and replace the protective cap on the needle.

7. Carefully place the parts of the ampoule, the used syringe and needle in a needle container for disposal of needles.

After injection of Invicorp

After self-injection of Invicorp it will take a little time for you to obtain an erection. The injection should ensure a sufficient erection to enable you to have sexual intercourse.

The erection will normally not last longer than one hour.

Please contact your doctor or emergency room immediately if you have an erection which lasts longer than 4 hours after injecting Invicorp.

If you use more Invicorp than you should

Contact your doctor, emergency room or pharmacist if you have taken more Invicorp than stated in this leaflet or more than your doctor has prescribed.

4. Possible side effects

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

Serious side effects

Rare: may affect up to 1 in 1,000 people

– Long lasting and painful erection. Contact your doctor or emergency room immediately if your erection lasts more than 4 hours.

Very rare: may affect up to 1 in 10,000 people

– Angina, chest pain. Contact your doctor or emergency room.
– Heart attack and difficulty breathing, anxiety, possibly radiation of strong pains to the left arm and chest pain. Stop using the medicine and seek urgent medical advice immediately if you experience these side effects.

Other side effects

Common: may affect up to 1 in 10 people

– Flushing of the face and upper part of the body.
– Bruises around the injection site. To reduce the risk of bruising you should avoid visible blood vessels (veins) during self-injection.

Uncommon: may affect up to 1 in 100 people

– Headache, dizziness.
– Increased heart rate (pulse). Abnormal heart beats. Stop using the medicine if you experience these side effects.
– Accumulation of blood under the skin around the injection site.

Rare: may affect up to 1 in 1,000 people

– Small nodules on the penis may occur with repeated injections.
– Pain at the site of injection.

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 internet at www.mhra.gov.uk/yellowcard alternatively you can call Freephone 0800 100 3352 (available between 10am-2pm Monday-Friday) or fill in a paper form available from your local pharmacy. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Invicorp

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton.

Store in a refrigerator (2 - 8°C).

Do not freeze.

The ampoule can be brought to room temperature before use. You should use the injection within 24 hours of taking the ampoule out of the refrigerator.

The ampoule and needle should be disposed in a container suitable for this purpose.

Do not throw away any 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 Invicorp contains

– The active substances are aviptadil and phentolamine mesilate.

Each ampoule of Invicorp 25 micrograms / 2 mg contains 25 micrograms of aviptadil and 2 mg phentolamine mesilate.

– The other ingredients are: Sodium chloride, disodium edetate, phosphoric acid, hydrochloric acid, sodium hydroxide and water for injections.

What Invicorp looks like and contents of the pack

Invicorp is a sterile solution for injection (0.35ml), contained in a light brown glass ampoule.

The ampoule(s) is(are) packed into cardboard box(es). The ampoule(s) is(are) co-packed with a separate box containing syringe(s) and needles.

Pack sizes:

Glass ampoule 1 x 0.35 ml with 1 syringe, 1 30G needle and 1 21G needle
Glass ampoules 2 x 0.35 ml with 2 syringes, 2 30G needles and 2 21G needles
Glass ampoules 3 x 0.35 ml with 3 syringes, 3 30G needles and 3 21G needles
Glass ampoules 4 x 0.35 ml with 4 syringes, 4 30G needles and 4 21G needles
Glass ampoules 5 x 0.35 ml with 5 syringes, 5 30G needles and 5 21G needles
Glass ampoules 10 x 0.35 ml with 10 syringes, 10 30G needles and 10 21G needles

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Evolan Pharma AB
Box 120
SE-182 12 Danderyd
Sweden

Manufacturer

HB-Medical ApS
Dr. Neergaardsvej 17
DK- 2970 Hørsholm
Denmark

Rechon Life Science AB
Soldattorpsvägen 5
Limhamn
Sweden

This leaflet was last revised in 07/2015