

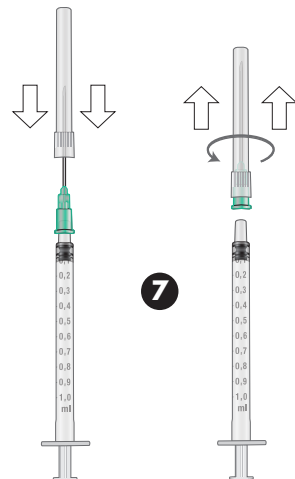
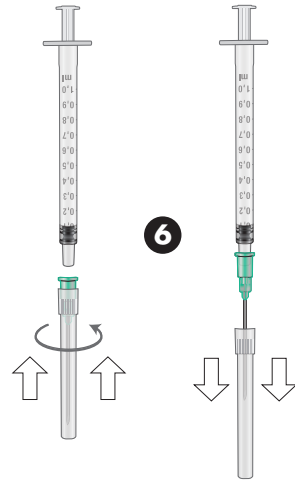


GUIDELINES FOR THE USE OF INVICORP INJECTION FOR MEN WITH ERECTILE DYSFUNCTION.

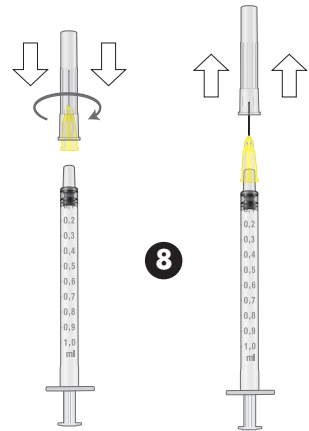
You should carry out the first Invicorp injection under a doctor's/nurse's supervision.

Preparation of Invicorp injection

1. Wash your hands and dry them with a clean towel.
2. Take one glass ampoule with two fingers and shake it firmly once 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.
5. Take the syringe out of the package and place on a clean surface.
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. Hold the ampoule in one hand and the syringe in the other. 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.

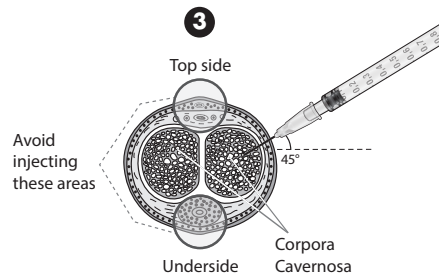
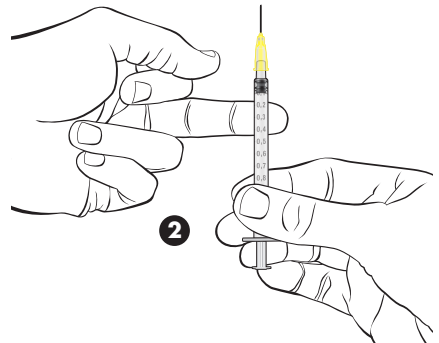


- Open the package containing the short needle (yellow colour intended for injection), and place on a clean surface. Hold the syringe at the top end and hold the short needle by the protective cap. Attach the needle to the syringe. Push and twist a half turn in one direction until it fits securely. Then remove protective cap.

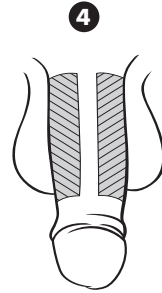


How to give yourself the injection

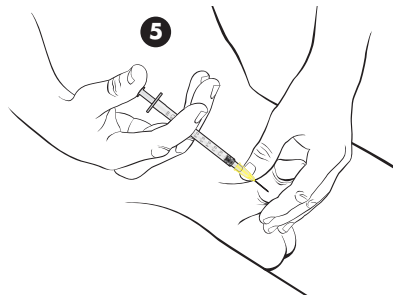
- Wash the injection site on your penis, with soap and water, rinse with water and dry with a clean towel.
- Take the syringe positioning the needle upwards, and carefully tap the barrel of the syringe until all trapped air bubbles move into the top of the syringe. Carefully push the plunger until a drop come out of the needle. Do this to prevent air in the needle. Note that the syringe contains only 0.35 ml fluid. Be careful not to accidentally eject the drug when removing the air bubbles!
- 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 in the picture below. Avoid injecting in top or underside of the penis.



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.



WHAT YOU SHOULD KNOW ABOUT INVICORP

Patient Information Leaflet

It is important that you read thoroughly the patient information leaflet provided in the Invicorp package. Once you have the leaflet, you can find further information in this folder about how Invicorp can help you to obtain an erection.

What is Invicorp?

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.

Effect

After self-injection of Invicorp it will take a little time for you to obtain an erection. The erection will normally not last longer than one hour.

Dose

The recommended dose is 25micrograms/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 entire content of the ampoule.

Side effects and precautions

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 must contact your doctor or go to your A&E (Accident & Emergency Unit).

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.

To avoid scarring at the injection site after several injections, it is important that you alternate the injection sites between the right and the left side of the penis. Always inject into the side of the penis as shown in the picture and not on the top or bottom. You may get a small amount of bleeding after the injection, so apply pressure to the injection site for a few minutes. It is important to remember to wash your hands thoroughly before injecting!

Proper instruction by medically trained personnel

Before using Invicorp for the first time, your doctor or nurse must train you in how to prepare and inject Invicorp properly. Often this includes you receiving a test-injection of Invicorp in the presence of medically trained personnel, in order to be shown the proper procedure for the injection.

Storage

Invicorp must be kept in the refrigerator (2-8°C). Just take out the ampule that you intend to use. 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. Do not freeze the ampoules.

Be aware of the expiration date on the carton containing the ampoules.

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

Reporting 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. Side effects could also be reported to Evolan Pharma on telephone number +46 8 544 960 30 or info@evolan.se

Approved by Evolan Pharma AB Medical Department October 2015

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