

Invicorp

Aviptadil / Phentolamine mesylate

25 microgram / 1 mg and 25 microgram / 2 mg
solution for injection
aviptadil / phentolamine mesylate

Red all of this leaflet carefully before you start using this medicine.

- 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 symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET:

1. What Invicorp is and what it is used for
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1. WHAT INVICORP IS AND WHAT IT IS USED FOR

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

Invicorp is used to treat a condition called erectile dysfunction of the penis. This may involve weak erections and impotence.

Your doctor could have prescribed this medicine for another use. Always use Invicorp as your doctor has told you.

2. BEFORE YOU USE INVICORP

Do not use Invicorp if you:

- are allergic to aviptadil, phentolamine mesylate, or any of the other ingredients of Invicorp.
- have or have had leukaemia, bone cancer or have sickle cell anaemia, since it may cause a painful, long lasting erection.
- are being treated with anticoagulants (blood thinning drugs) such as warfarin or heparin, including low-molecular-weight heparin (dalteparin, enoxaparin, tinzaparin).
- your doctor has told you not to have sex because of your state of health.

Take special care with Invicorp:

Tell your doctor, if:

- you suffer from heart problems or have had a stroke.
- you have a penis that is not straight, or which has a tight foreskin or other deviations.
- you suffer from kidney or liver problems.
- you are older than 75 years.

Stop using Invicorp if you experience palpitations or a rapid pulse.

If your erection is uncomfortable and painful or has lasted for more than 4 hours, contact your doctor or a hospital.

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

Taking other medicines

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

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without prescription, at the pharmacy or over the counter, before you start using Invicorp.

Pregnancy and breast-feeding

Not relevant. Invicorp is only to be used by men.

Important information about some of the ingredients of Invicorp

Invicorp contains less than 1 mmole (23 mg) sodium per dose.

3. HOW TO USE INVICORP

Invicorp is intended for direct injection into the spongy tissue on either side of the shaft of the penis (intracavernous injection). A doctor or nurse will show you how you carry out the first injection.

Do not attempt to inject yourself, if:

- you were not shown how to give the injection.
- you had any problems with the first injection.
- you didn't understand the instructions.

Please also see the instructions at the end of this leaflet for information on preparing for the injection. If you cannot remember how you should administer the injection, you should consult your doctor. You must not try to use the injection if you are not sure what you should do.

Dosage

The start dose is 25 microgram / 1 mg Invicorp. If this does not work sufficiently well, your doctor may increase the dose to 25 microgram / 2 mg Invicorp.

You must not administer more than one ampoule per day, and not exceed 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 each time the product is administered.

Always use Invicorp as your doctor has told you. For treatment of erectile dysfunction, different men will need different treatment.

You should only change dose or stop treatment by appointment with your doctor.

How you should use Invicorp

The product should be brought to room temperature before use. Unless your doctor has instructed otherwise, you should follow the dose guidelines that are given in this leaflet, as otherwise Invicorp cannot work properly.

The first Invicorp injection should be carried out under a doctor's or nurse's supervision.

After administration of Invicorp

It will take a little time for you to obtain an erection after self-injection of Invicorp. The Invicorp injection should ensure that your erection will be adequate to enjoy sex. The erection will normally not last longer than an hour.

Contact your doctor or a hospital if your erection has lasted for more than 4 hours.

If you use more Invicorp than you should

Contact a doctor, hospital or pharmacy, if you have used more of Invicorp than stated in this leaflet or more than your doctor has prescribed for you, and you feel uncomfortable.

4. POSSIBLE SIDE EFFECTS

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

Serious side effects

Rare side effects (expected in 1 to 10 out of 10 000 patients)

- Long lasting painful erection. Contact your doctor or a hospital if your erection has lasted for more than 4 hours.

Very rare side effects (expected in less than 1 out of 10 000 patients)

- Heart Cramps (angina), chest pain. Contact your doctor or a hospital.
- Heart thrombus with shortness of breath, anxiety, possible severe pain radiating into left arm and chest pain. Call 999 .

Non serious side effects

Common side effects (expected in 1 to 10 out of 100 patients)

- Flushing of the face and upper part of the body.
- Bruising around the injection site. You can lower the risk of bruising by avoiding injecting Invicorp in a visible vein.

Uncommon side effects (expected in 1 to 10 out of 1000 patients)

- Headache, dizziness.
- Increased heart rate or palpitations.
Stop using Invicorp if you get some of these side effects.
- Accumulation of blood under the skin at the injection site.

Rare side effects (expected in 1 to 10 out of 10 000 patients)

- Small lumps on the penis by repeated injections.
- Pain at the injection site.

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

5. HOW TO STORE INVICORP

Keep out of the reach and sight of children.

Do not use Invicorp after the expiry date which is stated on the carton/label.

Store in a refrigerator (2°C – 8°C). Do not freeze.

The ampoule should be at room temperature before use. Inject Invicorp within 24 hours of taking the ampoule out of the refrigerator.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

Ampoules supplied in cardboard carton: After use, the injection needle should be clipped off with the aid of needle clippers such as “BD Safe-clip”. The ampoule and needle should then be disposed of in a needle holder suitable for this purpose.

Ampoules supplied in plastic box: After use, the protective cap should be carefully replaced on the needles, which should then be returned to the plastic box, together with used ampoules and syringes. The box should be securely closed before disposal.

6. FURTHER INFORMATION

Invicorp injection contains

The active ingredients are aviptadil and phentolamine mesylate.

Each ampoule of Invicorp 25 micrograms/ 1 mg contains 25 micrograms of aviptadil and 1 mg of phentolamine mesylate. Each ampoule of Invicorp 25 micrograms/2 mg contains 25 micrograms of aviptadil and 2 mg of phentolamine mesylate.

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

What Invicorp looks like and contents of the pack

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

Invicorp is available in packs of

- 5 or 10 ampoules in a cardboard carton.
- 2 ampoules in a plastic box, also containing two large needles, two small needles and two syringes.

Not all pack sizes may be marketed

Marketing authorisation holder in Denmark

Evolan Pharma AB
P.O. Box 120
SE-18212 Danderyd
Sweden

Manufacturer

Hameln Pharmaceuticals GmbH
P.O. Box 100863
31758 Hameln
Germany

HB-Medical ApS
Kanalholmen 25-29 bygn. 6
DK-2650 Hvidovre
Denmark

The Specials Laboratory
Units 1 & 2, Regents DriveLow
Prudhoe Industrial Estate Prudhoe
Northumberland NE42 6PX
United Kingdom

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Instructions for ampoules in cardboard boxes **INSTRUCTIONS FOR USE FOR INVICORP INJECTION**

1. Wash your hands and dry them with a clean towel.
2. Take one ampoule (glass bottle) with two fingers and swing it gently in order to ensure that the liquid is located in the bottom of the ampoule.
3. Crack the top of the ampoule and place the ampoule gently on a flat surface.
4. Open the package containing the large needle. The large needle is used to draw up medicine from the ampoule. **DO NOT USE IT FOR THE INJECTION.** Put the needle on a clean surface for example a clean paper towel.
5. Remove the syringe from its packaging and place it on the paper towel.
6. Hold the end of the syringe and grasp the needle protective cap. Place the syringe in the needle end that is open. Push and turn the needle half a turn until it is fixed. Remove the protective cap from the needle.
7. Insert the needle into the ampoule and pull out the plunger to draw liquid from the ampoule into the syringe. Replace the protective cap on the large needle and remove the needle from the syringe.
8. Open the package containing the small needle (for injection), and place it on a clean surface for example a paper towel.
9. Hold the end of the syringe and grasp the short needle protective cap. Assemble the syringe and needle. Push and turn one half turn until the needle is fixed. Remove the protective cap from the needle.

HOW YOU GIVE YOURSELF AN INJECTION

1. Wash the area on your penis, where you will place the injection, with water and soap, rinse with water and dry with a clean towel.
2. Take the syringe with the needle pointing upwards and gently hit the side of the syringe until all air bubbles have risen up in the syringe tip. Gently press the plunger until a few drops of liquid are coming out of the needle. This is to avoid air in the needle.
3. Hold the needle perpendicular to the side of the penis. Be sure that you do not inject into the urethra or visible veins. Then stick the needle in the penis until approximately half of the needle is inside. Gently press the plunger and inject all liquid.
4. Pull the needle out and put the protection cap back on the needle. Put the rest of the ampoule, the used syringe and needle in a needle container.