

AN APPROVED SOLUTION FOR TREATMENT OF ERECTILE DYSFUNCTION!

- Innovative combination of Phentolamine and aviptadil (VIP)
- Post injection penile pain rarely occurs³
- Single dose only
- Ready to use solution
- Proven efficacy^{1,2,3}



Invicorp 25 micrograms / 2 mg solution for injection
Abbreviated Prescribing Information (UK)
Please refer to SmPC before prescribing Invicorp

Presentation: Invicorp 25 micrograms / 2 mg, solution for injection. One dose (ampoule 0.35 ml) contains 25 micrograms of aviptadil and 2 mg of Phentolamine mesilate. **Indication:** Invicorp is indicated for the symptomatic treatment of erectile dysfunction in adult males due to neurogenic, vasculogenic, psychogenic, or mixed aetiology. **Dosage:** 25 micrograms / 2 mg. Injection frequency should not exceed once daily or 3 times weekly. **Administration:** The initial injections of Invicorp must be administered by medically trained personnel, and after proper training, Invicorp may be injected at home. Invicorp should be administered by direct intracavernous injection using the 1½ -inch 21 gauge needle. The usual site of injection is along the dorsolateral aspect of the proximal third of the penis. Visible veins should be avoided. Both the side of the penis and the site of injection must be altered between injections. **Contraindications:** Hypersensitivity to any of the active substances of the product. Men for whom sexual activity is not advisable or is contraindicated due to organic disease. Men on treatment with anticoagulant agents, such as heparins and warfarin, including oral anticoagulants, such as dabigatran, rivaroxaban, or apixaban. Men with conditions that might predispose to priapism, such as sickle cell anaemia or trait, multiple myeloma, or leukemia. Men with anatomical deformation of the penis, such as angulation, cavernosal fibrosis, or Peyronie's disease and men with penile implants. **Special Warnings and Precautions etc:** Prolonged erection and/or priapism may occur following intracavernosal administration of Invicorp. Patients should be instructed to immediately report to a physician any erection lasting for a prolonged period, such as 4 hours or longer. Treatment of priapism should not be delayed more than 6 hours. Penile fibrosis, including angulation, cavernosal fibrosis, fibrotic nodules and Peyronie's disease may occur following the intracavernosal administration of Invicorp. The occurrence of fibrosis may increase with increased duration of use. Mild transient flushing of the face or trunk occurs commonly. Invicorp must be used with caution in patients with severe cardiovascular or cerebrovascular conditions. Sexual stimulation and intercourse can lead to cardiac and pulmonary events in patients with coronary heart disease, congestive heart failure and pulmonary disease. Invicorp is not suitable for concomitant use with other treatments of erectile dysfunction. The potential for abuse of Invicorp should be considered in patients with a history of psychiatric disorder or addiction. Correct injection technique is important and Invicorp should not be prescribed without adequate instruction and training in its use.

Drug Interactions: No clinical interaction has been observed in the use of Invicorp with concomitant intake of anti-hypertensive or other cardiovascular medication. **Undesirable Effects:** Flushing, headache, dizziness, tachycardia, palpitations, myocardial infarction, angina pectoris, priapism, prolonged erection, penile nodules/fibrosis following multiple injections, bruising, haematoma, pain post injection. **Package Quantities and Basic NHS Cost:** 25 micrograms / 2 mg solution for injection, 1 pack containing 2 ampoules: £19.00. 25 micrograms / 2 mg solution for injection, 1 pack containing 5 ampoules: £47.50.

Marketing Authorisation Number and Holder: Invicorp 25 micrograms / 2 mg: PL44616/0001. Evolan Pharma AB, Box 120, SE-182 12 Danderyd, Sweden. **Legal Category:** Prescription Only Medicin, POM.

Adverse Event Reporting

Adverse events should be reported.

Reporting forms and information can be found at <http://www.mhra.gov.uk/yellowcard>

Adverse events should also be reported to Evolan Pharma on telephone number +46 8 544 960 30 or info@evolan.se

References:

- 1- VP 004, D. Sanhdu et al, 1999
- 2- VP 005, W.V. Dinsmore et al, 1999
- 3- SmPC, May 2015

Approved by Evolan Pharma AB Medical Department October 2015

Evolan Pharma AB

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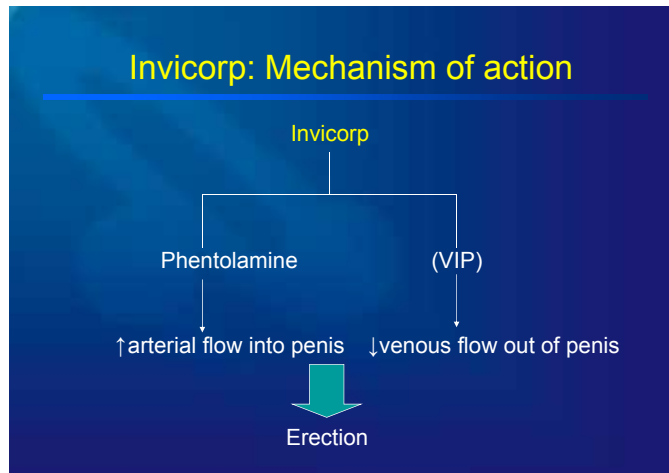
Invicorp

(Phentolamine Mesilate / Aviptadil, solution for injection)

Intracavernous injection with proven efficacy and tolerability^{1,2}

Intracavernous injection for treatment of erectile dysfunction

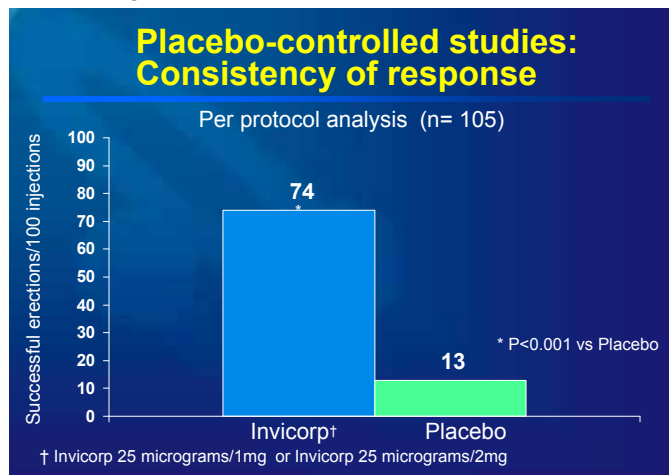
- Innovative combination of 2 mg Phentolamine Mesilate and 25 µg aviptadil (VIP)^{1,2,3}
- Single dose only
- Ready to use solution
- Post injection penile pain rarely occurs^{1,2,3}



Junemann et al 1987; Junemann et al 1986

Good efficacy

- 74 % of patients achieve a grade 3-4 erection due to treatment with Invicorp³



Dinsmore et al 1999

Good tolerability

- Post injection penile pain rarely occurs³
- Priapism occurs very rarely and appears only in 5 of 10 000 injections^{1,2}
- Compared to placebo, only flushing and tachycardia occur significantly more frequently with Invicorp^{1,2}

Placebo-controlled studies: Invicorp tolerability

Treatment-related adverse events in placebo-controlled phase

Adverse event	% of Injektions		
	VIP/P-1*	VIP/P-2**	Placebo†
<i>Local</i>			
Bruising	5.3	4.1	5.3
Bleeding at injection site	3.0	1.6	2.0
Pain on injection	0.5	0.4	3.6
Pain post injection	0	0	0
Urethral bleeding	1.5	1.1	1.0
Priapism	0.05	0.0	0.0
<i>Systemic</i>			
Flushing	33.8	33.9	6.9
Dizziness	0.7	0	0
Headache	0.6	1.0	0.6
Palpitation	1.3	1.7	0
Tachycardia	0.7	1.6	0.2

* 152 patients received 2061 injections; ** 43 patients received 699 injections; † 195 patients received 507 injections; VIP/P-1 = Invicorp 25 microgram/1mg; VIP/P-2 = Invicorp 25 microgram/2mg

Adapted from Sandhu et al 1999
