

Product Information

DECAPEPTYL®

Directions for use.
Please read carefully!

DECAPEPTYL® 0.1 mg
Active Ingredient: Triptorelin

Presentation and Composition

1 disposable syringe with 1 ml injectable solution contains:
DECAPEPTYL® 0.1 mg:
100 µg triptorelin acetate (95.6 µg triptorelin) in an pH adjusted aqueous sodium chloride solution.

Pharmacology

DECAPEPTYL® is a synthetic analogue of gonadorelin (GnRH). As a result of the substitution of the 6th amino acid residue in the native molecule, the agonistic effect is more pronounced and the plasma half-life prolonged.

Daily injection of DECAPEPTYL® initially results in a stimulation of the pituitary release of LH and FSH. After prolonged stimulation the pituitary becomes refractory, the gonadotropin release declines, resulting in a decrease of the sex steroids (testosterone or estrogen) to castrate levels. The effects are reversible.

Indications

DECAPEPTYL® is indicated in situations where lowering of sex steroid serum levels to castrate level is desired. For example:

Men

Therapy: Symptomatic treatment of an advanced hormone-dependent prostate carcinoma. As a diagnostic agent: To clarify through differential diagnosis the hormonal dependence of a prostate carcinoma.

Women

Endometriosis, Uterine Myoma, IVF

Contra-Indications

DECAPEPTYL® should not be used in prostate carcinoma when this is hormone insensitive or after prostatectomy.
DECAPEPTYL® should be discontinued if the patient becomes pregnant.

Pregnancy, Lactation

In animal tests, no teratogenic effects have been detected. In humans, there is insufficient experience.
There are insufficient data relating to the use of DECAPEPTYL® during lactation.

Precautions

Monitoring of the therapy should be performed according to the sex steroid serum levels.
Assisted Reproduction
To prevent hyperstimulation, careful monitoring of follicular growth and luteal phase especially in patients with polycystic ovaries.

Men: The initial transient increase of serum testosterone has, in a few patients, been associated with a temporary aggravation of secondary symptoms of the disease, e.g. urinary obstructions, skeletal pain due to metastasis. Close monitoring during the first weeks of treatment should, in these cases, be carried out. The temporary increase of serum testosterone levels can be avoided by treatment with an antiandrogen during the first treatment period. Symptomatic treatment can also be used in relevant cases.

Women: Prior to treatment, non-pregnancy should be confirmed. During the first month of treatment, patients should use non-hormonal contraceptives. Women should not use preparations containing estrogens during the DECAPEPTYL® therapy. During treatment of uterine myoma, uterus and myoma size should be measured regularly by means of, for example, ultrasonography. Unproportionally rapid reduction of uterus volume in comparison with myoma tissue has, in a few cases, caused bleeding and sepsis.

Side effects

The pharmacological side effects owing to the suppression of hormone production include in men: hot flushes, impotence and loss of libido, gynecomastia; in women: hot flushes, vaginal dryness and/or dyspareunia, spotting and as a result of the decrease of estrogen levels to post-menopausal values, slight trabecular bone loss may occur. However, this is recovered completely within 6–9 months after treatment has been discontinued. Less frequent side effects reported include: in rare cases allergic reactions (fever, itching, exanthema, anaphylaxia), headache, tiredness and sleep disturbances. In general, the side effects are mild and disappear after treatment has been stopped.

Interactions

Not yet known.

Dosage and Administration

Usual dose 0.5 mg s.c. daily for 7 days, after that 0.1 mg daily as maintenance dose.
IVF: 7 to 10 days with 0.5 mg s.c.; followed by 0.1 mg s.c. daily.

Stability and storage

3 years. Store in a refrigerator (2 - 8 °C). Do not freeze. Store in the original package.

The disposable syringes should be stored in package, protected from light.

Remarks

Prescription only

Packaging

DECAPEPTYL® 0.1 mg:
7 disposable syringes à 1 ml solution
28 disposable syringes à 1 ml solution

Manufacturer

Ferring GmbH
Wittland 11, 24109 Kiel, Germany

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