

Proposed packaging material	
Code	DECDAI01-I-ID-03.01
Size	N/A
Submission	<input type="checkbox"/> NDA <input type="checkbox"/> Renewal <input checked="" type="checkbox"/> Variation change detail no.: 258831
Code of previous version	DECDAI01-I-ID-02.02
Changes	Add Zuellig Pharma as secondary packaging and releasing activities site of DECAPEPTYL
Reference	<input type="checkbox"/> CCDS version: <input type="checkbox"/> SPC country/version/date: <input type="checkbox"/> Core PIL version: <input type="checkbox"/> LAC no.:
Name & Date	HINI, 01 Sep 2025

DECAPEPTYL® 0.1 mg/ml Triptorelin acetate Solution for injection

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pre-filled syringe of 1 ml solution for injection contains 100 micrograms triptorelin acetate equivalent to 95.6 micrograms triptorelin free base.

Excipients: Sodium chloride, Acetic acid, glacial (for pH adjustment), Water for injections

PHARMACEUTICAL FORM

Solution for injection

Clear colourless solution.

THERAPEUTIC INDICATIONS

DECAPEPTYL® 0.1 mg/ml is indicated for downregulation and prevention of premature luteinizing hormone (LH) surges in women undergoing controlled ovarian hyperstimulation for assisted reproductive technologies (ART).

In clinical trials DECAPEPTYL® 0.1 mg/ml has been used in cycles where urinary and recombinant human follicle stimulating hormone (FSH) as well as human menopausal gonadotrophin (HMG) were used for stimulation.

POSOLOGY AND METHOD OF ADMINISTRATION

Treatment with DECAPEPTYL® 0.1 mg/ml should be initiated under the supervision of a physician experienced in the treatment of infertility. DECAPEPTYL® is intended for subcutaneous injection once daily into the lower abdominal wall. Following the first administration, it is advised that the patient be kept under medical supervision for 30 minutes to ensure there is no allergic/pseudo-allergic reaction to the injection. Facilities for the treatment for such reactions should be immediately available. The following injections may be self-administered as long as the patient is made aware of the signs and symptoms that may indicate hypersensitivity, the consequences of such a reaction and the need for immediate medical intervention. The injection site should be varied to prevent lipoatrophy.

Treatment can be started in the early follicular phase (day 2 or 3 of the menstrual cycle) or in the mid-luteal phase (day 21-23 of the menstrual cycle or 5-7 days before expected start of menses). Controlled ovarian hyperstimulation with gonadotrophins should be started after approximately 2-4 weeks of DECAPEPTYL® treatment. Ovarian response should be monitored clinically (including ovarian ultrasound alone or preferably in combination with measurement of oestradiol levels) and the dose of gonadotrophins adjusted accordingly.

When a suitable number of follicles have reached an appropriate size, treatment with DECAPEPTYL® and gonadotrophin is stopped and a single injection of hCG is administered to induce the final follicular maturation. If downregulation is not confirmed after 4 weeks (determined by ultrasound documentation of a shedded endometrium alone or preferably in combination with measurement of oestradiol levels), discontinuation of DECAPEPTYL® should be considered. The total duration of treatment is usually 4-7 weeks. When using DECAPEPTYL®, luteal phase support should be provided according to the reproductive medical centre's practice.

No specific dose recommendations are given for subjects with renal or hepatic impairment. A clinical

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study indicated that the risk of accumulation of triptorelin in patients with severe liver and renal impairment is small (see section Pharmacokinetic properties).

Paediatric population

There is no relevant use of DECAPEPTYL in the paediatric population.

CONTRAINDICATIONS

DECAPEPTYL® 0.1 mg/ml is contraindicated in cases of:

- Hypersensitivity to the active substance or to any of the excipients
- Hypersensitivity to gonadotrophin-releasing hormone (GnRH) or any other GnRH analogue
- Pregnancy and Lactation period

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

The use of GnRH agonists may cause reduction in bone mineral density. In men, preliminary data suggest that the use of a bisphosphonate in combination with an GnRH agonist may reduce bone mineral loss.

Particular caution is necessary in patients with additional risk factors for osteoporosis (e.g. chronic alcohol abuse, smokers, long-term therapy with drugs that reduce bone mineral density, e.g. anticonvulsants or corticoids, family history of osteoporosis, malnutrition).

Loss of bone mineral density

The use of GnRH agonists is likely to cause reduction in bone mineral density averaging 1% per month during a six month treatment period. Every 10% reduction in bone mineral density is linked with about a two to three times increased fracture risk.

In the majority of women, currently available data suggest that recovery of bone loss occurs after cessation of therapy.

No specific data is available for patients with established osteoporosis or with risk factors for osteoporosis (e.g. chronic alcohol abuse, smokers, long-term therapy with drugs that reduce bone mineral density, e.g. anticonvulsants or corticoids, family history of osteoporosis, malnutrition, e.g. anorexia nervosa). Since reduction in bone mineral density is likely to be more detrimental in these patients, treatment with triptorelin should be considered on an individual basis and only be initiated if the benefits of treatment outweigh the risk following a very careful appraisal. Consideration should be given to additional measures in order to counteract loss of bone mineral density.

It should be confirmed that the patient is not pregnant before prescription of triptorelin.

Rarely, treatment with GnRH agonists may reveal the presence of a previously unknown gonadotroph cell pituitary adenoma. These patients may present with a pituitary apoplexy characterised by sudden headache, vomiting, visual impairment and ophthalmoplegia.

There is an increased risk of incident depression (which may be severe) in patients undergoing treatment with GnRH agonists, such as triptorelin. Patients should be informed accordingly and treated as appropriate if symptoms occur.

Mood changes have been reported. Patients with known depression should be monitored closely during therapy.

Ovarian stimulation should be done under strict medical supervision.

In patients with renal or hepatic impairment, triptorelin has a mean terminal half life of 7-8 hours compared to 3-5 hours in healthy subjects. Despite this prolonged exposure, triptorelin is not expected

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to be present in circulation at the time of embryo transfer.

Special care should be taken in women with signs and symptoms of active allergic conditions or known history of allergic predisposition. Treatment with DECAPEPTYL® is not advised in women with severe allergic conditions. Women of childbearing potential should be examined carefully before treatment to exclude pregnancy.

ART is associated with an increased risk of multiple pregnancies, pregnancy wastage, ectopic pregnancies and congenital malformations. These risks are also valid with usage of DECAPEPTYL® 0.1 mg/ml as adjunct therapy in controlled ovarian hyperstimulation. The use of DECAPEPTYL® in controlled ovarian hyperstimulation may increase the risk of ovarian hyperstimulation syndrome (OHSS) and ovarian cysts.

Follicular recruitment, induced by the use of GnRH analogues and gonadotrophins, may be markedly increased in a minority of predisposed patients, particularly in case of Polycystic Ovarian Syndrome. As with other GnRH analogues there have been reports of OHSS associated with the use of triptorelin in combination with gonadotrophins.

Ovarian Hyperstimulation Syndrome (OHSS):

OHSS is a medical event distinct from uncomplicated ovarian enlargement. OHSS is a syndrome that can manifest itself with increasing degrees of severity. It comprises marked ovarian enlargement, high serum sex steroids, and an increase in vascular permeability which can result in an accumulation of fluid in the peritoneal, pleural and, rarely, in the pericardial cavities.

The following symptoms may be observed in severe cases of OHSS: abdominal pain, abdominal distension, severe ovarian enlargement, weight gain, dyspnoea, oliguria and gastrointestinal symptoms including nausea, vomiting and diarrhoea. Clinical evaluation may reveal hypovolaemia, haemoconcentration, electrolyte imbalances, ascites, haemoperitoneum, pleural effusions, hydrothorax, acute pulmonary distress, and thromboembolic events.

Excessive ovarian response to gonadotrophin treatment seldom gives rise to OHSS unless hCG is administered to trigger ovulation. Therefore in cases of OHSS it is prudent to withhold hCG and advise the patient to refrain from coitus or to use barrier methods for at least 4 days. OHSS may progress rapidly (within 24 hours to several days) to become a serious medical event, therefore patients should be followed for at least two weeks after the hCG administration.

OHSS may be more severe and more protracted if pregnancy occurs. Most often, OHSS occurs after hormonal treatment has been discontinued and reaches its maximum severity at about seven to ten days following treatment. Usually, OHSS resolves spontaneously with the onset of menses.

If severe OHSS occurs, gonadotrophin treatment should be stopped if still ongoing, the patient hospitalised and specific therapy for OHSS started e.g. with rest, intravenous infusion of electrolyte solutions or colloids and heparin.

This syndrome occurs with higher incidence in patients with polycystic ovarian disease.

The risk of OHSS might be higher with use of GnRH agonists in combination with gonadotrophins than with use of gonadotrophins alone.

Ovarian cysts:

Ovarian cysts may occur during the initial phase of treatment with GnRH agonist. They are usually asymptomatic and non-functional.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Interactions of DECAPEPTYL® 0.1 mg/ml with other medicines have not been investigated for this indication. The possibility of interactions with commonly used medicinal products, including histamine liberating products, cannot be excluded.

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When triptorelin is co-administered with drugs affecting pituitary secretion of gonadotrophins caution should be given and it is recommended that the patient's hormonal status should be supervised.

PREGNANCY AND LACTATION

Pregnancy

DECAPEPTYL® 0.1 mg/ml is not indicated during pregnancy. Pregnancy must be excluded before initiation of fertilisation treatment. Non-hormonal methods of contraception should be employed during therapy until menses resume. If a patient becomes pregnant while receiving triptorelin, therapy should be discontinued.

When triptorelin is used for fertilisation treatment, there is no clinical evidence to suggest a causal connection between triptorelin and any subsequent abnormalities of oocyte development or pregnancy or outcome. Very limited data on the use of triptorelin during pregnancy do not indicate an increased risk of congenital malformations. Studies in animals have shown reproductive toxicity (see section Preclinical safety data). Based on the pharmacological effects disadvantageous influence on the pregnancy and the offspring cannot be excluded.

Lactation

DECAPEPTYL® is not indicated for use during lactation.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No studies on the effects of the ability to drive and use machines have been performed. However, due to its pharmacological profile DECAPEPTYL® 0.1 mg/ml is likely to have no or negligible influence on the patient's ability to drive and use machines.

UNDESIRABLE EFFECTS

Frequently ($\geq 2\%$) reported adverse events during treatment with DECAPEPTYL® 0.1 mg/ml in clinical trials, either before or during co-administration with gonadotrophins, are listed in the table below. The most frequent adverse events are headache (27%), vaginal bleeding/spotting (24%), abdominal pain (15%), injection site inflammation (12%) and nausea (10%).

Mild to severe hot flushes and hyperhidrosis may occur which do not usually require discontinuation of therapy.

At the beginning of treatment with DECAPEPTYL® 0.1 mg/ml, the combination with gonadotrophins may result in ovarian hyperstimulation syndrome. Ovarian enlargement, dyspnoea, pelvic and/or abdominal pain may be observed (refer to section Special warnings and precautions for use). Genital haemorrhage including menorrhagia and metrorrhagia may occur at the beginning of treatment with DECAPEPTYL® 0.1 mg/ml.

Ovarian cysts have been reported to occur commonly (1%) during the initial phase of treatment with DECAPEPTYL®.

During treatment with triptorelin some adverse reactions showed a general pattern of hypo-oestrogenic events related to pituitary-ovarian blockade such as sleep disorder, headache, mood altered, vulvovaginal dryness, dyspareunia and libido decreased.

Breast pain, muscle spasms, arthralgia, weight increased, nausea, abdominal pain, abdominal discomfort, asthenia and episodes of blurred vision and visual disturbances may occur during treatment with DECAPEPTYL® 0.1 mg/ml.

Single cases of allergic reactions, localized or generalized, have been reported after injection of DECAPEPTYL®.

MedDRA System Organ Class	Very common ($\geq 1/10$)	Common ($\geq 1/100$ to $< 1/10$)	Uncommon ($\geq 1/1000$ to $< 1/100$)	Not known
Infections and	-	Upper respiratory tract	-	-

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infestations		infection, pharyngitis		
Immune system disorders	-	-	-	Hypersensitivity
Psychiatric disorders	-	-	Mood changes, depression	Sleep disorder, libido decreased
Nervous system disorders	Headache	Dizziness	-	-
Eye disorders	-	-	-	Visual impairment, vision blurred
Vascular disorders	-	Hot flushes	-	-
Respiratory, thoracic and mediastinal disorders	-	-	-	Dyspnoea
Gastrointestinal disorders	Abdominal pain, nausea	Abdominal distension, vomiting	-	Abdominal discomfort
Skin and subcutaneous tissue disorders	-	-	-	Hyperhidrosis, pruritus, rash, angioedema, urticaria
Musculoskeletal and connective tissue and bone disorders	-	Back pain	-	Muscle spasms, arthralgia
Pregnancy, puerperium and perinatal conditions	-	Abortion	-	-
Reproductive system and breast disorders	Vaginal haemorrhage	Pelvic pain, ovarian hyperstimulation syndrome, dysmenorrhoea, ovarian cyst	-	Ovarian enlargement, menorrhagia, metrorrhagia, vulvovaginal dryness, dyspareunia, breast pain
General disorders and administration site conditions	Injection site inflammation	Injection site pain, injection site reaction, fatigue, influenza like illness	-	Asthenia, injection site erythema
Investigations	-	-	-	Weight increased

Adverse Event Reporting

If you notice any of the adverse events reactions mentioned above, or any adverse reactions not listed in this leaflet, please contact your doctor or nurse. You can also report these side effects to Ferring or the national reporting system provided below. Reporting side effects helps to gather more information about the safety of this medication.

PT Ferring Pharmaceuticals Industry
 Safety Mailbox Indonesia
 No Telp: (021) 50868801
 Email: SafetyMailboxIndonesia@ferring.com

Pusat MESO/Farmakovigilans Nasional
 Direktorat Pengawasan Keamanan, Mutu dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif
 Badan POM RI
 Jl. Percetakan Negara 23 Jakarta Pusat, 10560
 No Telp: 021 – 4244691 Ext.1079
 Email: pv-center@pom.go.id
 Web : <http://e-meso.pom.go.id/>

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OVERDOSE

Overdose in humans may result in a prolonged duration of action. In case of overdose, DECAPEPTYL® 0.1 mg/ml treatment should be (temporarily) discontinued. No adverse reaction has been reported as a consequence of overdose.

PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Gonadotropin releasing hormone analogues, ATC code: L02AE04
 Triptorelin (acetate) is a synthetic decapeptide and an analog of the natural hypothalamus hormone GnRH. Triptorelin has a longer duration of action than the natural GnRH and has a biphasic effect at the pituitary level. After an initial large sudden increase in LH and FSH levels (flare-up), circulating LH and FSH levels decrease due to the pituitary GnRH-receptor desensitization, with a consequent marked reduction in the gonadal production. The exact duration of action of DECAPEPTYL® 0.1 mg/ml has not been established, but pituitary suppression is maintained for at least 6 days after stopping administration. After discontinuation of DECAPEPTYL®, a further drop in circulating LH levels should be expected, with LH levels returning to baseline after approximately 2 weeks. The DECAPEPTYL®-induced downregulation of the pituitary can prevent the LH surge and thereby premature ovulation and/or follicular luteinization. The use of downregulation with GnRH agonist reduces the cycle cancellation rate and improves the pregnancy rate in ART cycles.

PHARMACOKINETIC PROPERTIES

The pharmacokinetic data suggest that after subcutaneous administration of DECAPEPTYL® the systemic bioavailability of triptorelin is close to 100%. The elimination half-life of triptorelin is approximately 3-5 hours, indicating that triptorelin is eliminated within 24 hours and therefore will not be present in circulation at the time of embryo transfer.. Metabolism to smaller peptides and amino acids primarily occurs in the liver and kidneys. Triptorelin is predominantly excreted in the urine. The clinical studies indicated that the risk of accumulation of triptorelin in patients with severe liver and renal impairment is small (i.e. half-life of approximately 8 hours in these patients).

PRECLINICAL SAFETY DATA

In rats treated over a long period of time with triptorelin, an increase in pituitary tumors has been detected. LHRH analogues are known to induce pituitary tumours in rodents due to the rodent specific regulation of the endocrine system which is different from the regulation in humans. The influence of triptorelin on pituitary abnormalities in humans is unknown and the observation in rats is considered not to be relevant to humans.

Triptorelin is not teratogenic but there are indications for delayed fetal development and parturition in rats. Preclinical data reveal no special hazard to humans based on repeat dose toxicity and genotoxicity studies.

INCOMPATIBILITIES

In the absence of incompatibility studies, the medicinal product must not be mixed with other medicinal products.

SHELF LIFE

3 years

SPECIAL PRECAUTIONS FOR STORAGE

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

NATURE AND CONTENTS OF CONTAINER

DECAPEPTYL® 0.1 mg/ml solution for injection is packaged in single use pre-filled disposable

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borosilicate type 1 glass syringes with integrated needle and rigid needle shield. The syringe is closed with a chlorobutyl rubber stopper with a polystyrene plunger rod.

Pack sizes:

7 x 1 ml pre-filled syringes 0.1 mg/ml (Reg. No.: DKI XXXXXXXXXXXXX)

HARUS DENGAN RESEP DOKTER

Manufacturer:

Ferring GmbH
Kiel, Germany

Secondary packager and batch releaser:

Zuellig Pharma Specialty Solutions Group Pte. Ltd
Singapore

Imported by:

PT Ferring Pharmaceuticals Industry
BSD-Indonesia

Date of revision : 01-Sep-2025

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Informasi untuk pasien
Decapeptyl 0.1 mg/mL, cairan untuk injeksi
triptorelin-acetate

Bacalah seluruh isi leaflet ini dengan seksama sebelum Anda mulai menggunakan obat ini karena leaflet ini berisi hal-hal penting untuk Anda.

- Simpanlah leaflet ini. Anda mungkin perlu membacanya di kemudian hari
- Apabila Anda memiliki pertanyaan lebih lanjut, tanyakanlah dokter, apoteker, atau perawat Anda
- Obat ini telah diresepkan khusus untuk Anda. Dilarang memberikan obat ini untuk orang lain karena hal ini dapat membahayakan mereka, meskipun tanda dan gejala penyakit mereka sama dengan yang Anda alami.
- Apabila Anda mengalami efek samping, komunikasikanlah pada dokter atau apoteker Anda. Perhatikan pula kemungkinan efek samping yang tidak terdaftar dalam leaflet ini.

Informasi yang terkandung dalam leaflet ini:

1. Apa itu Decapeptyl dan apa saja kegunaannya
2. Apa yang perlu Anda ketahui sebelum menggunakan Decapeptyl
3. Bagaimana cara pakai Decapeptyl
4. Efek samping yang dapat timbul
5. Bagaimana cara penyimpanan Decapeptyl
6. Isi dari kemasan dan informasi lain

1. Apa itu Decapeptyl dan apa saja kegunaannya

Obat ini diberikan dalam bentuk cairan injeksi sebagai suntikan sekali pakai. Penyuntikan obat ini dilakukan di area bawah kulit pada perut bagian bawah.

Obat ini mengandung triptorelin yang merupakan analog sintesis dari *gonadotrophin releasing hormone* (GnRH) alami. GnRH merupakan hormon yang mengatur pelepasan *gonadotrophins* (termasuk hormon seks : *luteinising hormone* (LH) dan *follicle-stimulating hormone* (FSH)). Decapeptyl menghambat kerja GnRH sehingga menurunkan kadar LH dan FSH (disebut juga *down regulation*) dan mencegah terjadinya ovulasi dini (pelepasan sel telur).

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Obat ini digunakan pada wanita pada yang menjalani terapi *Assisted Reproduction Techniques* (ART). Pada kondisi ART ovulasi sering terjadi terlalu dini sehingga mengurangi kesempatan hamil. Decapeptyl digunakan untuk *downregulation* dan pencegahan lonjakan LH terlalu awal yang dapat menyebabkan ovulasi dini.

Populasi Pediatrik

Tidak ada penggunaan yang relevan dari DECAPEPTYL pada anak-anak.

2. Apa yang perlu Anda ketahui sebelum menggunakan Decapeptyl

Jangan menggunakan Decapeptyl apabila:

- Anda memiliki alergi terhadap triptorelin acetate atau bahan-bahan lain yang terkandung dalam obat ini.
- Anda memiliki alergi terhadap GnRH atau analogue GnRH (obat yang memiliki kerja yang mirip dengan Decapeptyl).
- Apabila Anda sedang hamil atau menyusui, lihat bagian Kehamilan dan Menyusui .

Peringatan dan perhatian

- Bicarakan dengan dokter atau perawat Anda sebelum menggunakan Decapeptyl.
- Terdapat laporan tentang kejadian depresi pada pasien yang menggunakan Decapeptyl. Beritahukan dokter Anda apabila Anda mengalami gangguan suasana hati. Dokter Anda akan mengawasi secara hati-hati apabila Anda mengalami depresi.
- Penggunaan obat ini dapat menyebabkan perdarahan otak namun kejadian ini sangat jarang (*pituitary apoplexia*). Segera hubungi dokter Anda apabila Anda mengalami sakit kepala secara tiba-tiba, muntah, atau mengalami gangguan penglihatan.
- Penggunaan obat ini dapat menyebabkan pengeroposan tulang yang memicu cedera tulang. Beritahukan dokter Anda apabila Anda memiliki resiko pengeroposan tulang (*osteoporosis*), sebelum menggunakan obat ini. Faktor resiko seperti :
 - Apabila Anda atau keluarga Anda memiliki riwayat pengeroposan tulang (*osteoporosis*).
 - Apabila Anda minum minuman beralkohol tinggi, pola makan tidak sehat, dan/atau perokok berat.
 - Anda juga sedang dalam pengobatan yang berdampak pada kekuatan tulang.

Hubungi dokter Anda apabila mengalami atau pernah mengalami kejadian dibawah ini:

- Apabila Anda memiliki riwayat gangguan hati ringan hingga sedang

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- Apabila Anda memiliki riwayat alergi atau mudah mengalami alergi
- Apabila Anda menyuntikkan obat ini sendiri. Anda harus memahami kemungkinan terjadinya reaksi alergi (gatal, kulit kemerahan, demam). Lihat bagian 4 “Efek samping yang mungkin terjadi”

Segera hubungi dokter Anda apabila Anda mengalami reaksi setelah disuntik Decapeptyl.

Jika Anda mengalami:

- | | |
|---------------------------|---------------------------|
| - Nyeri pada perut | - Diare |
| - Pembengkakan pada perut | - Peningkatan berat badan |
| - Mual | - Kesulitan bernapas |
| - Muntah | - Penurunan berkemih |

Segera hubungi dokter Anda meskipun gejala tersebut hanya dirasakan beberapa hari setelah Anda menerima suntikan terakhir. Hal ini merupakan pertanda terjadi peningkatan aktivitas pada ovarium yang mungkin menjadi parah (lihat Bagian 4 “Efek samping yang mungkin terjadi”). Apabila gejala tersebut menjadi semakin parah, hentikan penggunaan terapi kesuburan dan Anda harus segera mendapat pengobatan di rumah sakit.

Selama dalam masa pengobatan dengan obat ini, dokter Anda umumnya akan melakukan *ultrasound scan* (USG) dan pemeriksaan darah untuk memonitor reaksi tubuh Anda.

Dalam menjalani terapi kesuburan dengan hormon seperti obat ini, dapat meningkatkan resiko:

- Kehamilan ektopik (kehamilan yang berkembang diluar rahim), apabila ada riwayat penyakit pada tuba falopi
- Keguguran
- Kehamilan multipel (kembar dua, tiga, dst)
- Kelainan bawaan (Cacat fisik bawaan sejak dalam kandungan)

Obat lain dengan Decapeptyl

Beritahukan dokter atau Apoteker apabila Anda telah menggunakan, mungkin menggunakan, atau sedang menggunakan obat lain termasuk obat tanpa resep dokter dan obat tradisional.

Kehamilan, menyusui dan kesuburan

Jangan menggunakan obat ini apabila sedang hamil atau menyusui.

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Code of previous version	DECDAI01-I(PIL)-ID-02.01.
Changes	Add Zuellig Pharma as secondary packaging and releasing activities site of DECAPEPTYL
Reference	<input type="checkbox"/> CCDS version: <input checked="" type="checkbox"/> SPC country/version/date: EU MRP PIL <input type="checkbox"/> Core PIL version: Version 3.1,06/2015 <input type="checkbox"/> LAC no.:
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Jangan menggunakan obat ini apabila Anda kemungkinan hamil. Kehamilan harus dikesampingkan/dicegah dahulu oleh dokter Anda.

Apabila Anda baru mengetahui terjadi kehamilan selama pengobatan, hentikan penggunaan Decapeptyl dan segera hubungi dokter Anda.

Kontrasepsi non-hormonal seperti kondom atau diafragma dapat digunakan selama pengobatan dengan Decapeptyl.

Mengendarai kendaraan bermotor dan menjalankan mesin

Obat ini tidak mempengaruhi kemampuan mengendarai kendaraan bermotor maupun menjalankan mesin.

Decapeptyl mengandung natrium

Obat ini mengandung natrium kurang dari 1mmol (23 mg) per dosis, sehingga dapat dianggap bebas natrium.

3. Bagaimana cara pakai Decapeptyl

Biasakan meminum obat sesuai anjuran dokter Anda. Periksalah kepada dokter bila Anda tidak yakin. Dosis yang direkomendasikan adalah satu suntikan dibawah kulit bagian perut bawah Anda. Pengobatan dapat dimulai pada hari ke-2 atau ke-3 atau ke-21 hingga ke-23 pada siklus menstruasi (atau 5-7 hari sebelum perkiraan menstruasi). Setelah 2 sampai 4 minggu, hormon lain akan diberikan untuk menstimulasi pertumbuhan folikel (seperti pertumbuhan kantung kehamilan). Secara umum, pengobatan dengan Decapeptyl akan diteruskan hingga dicapai ukuran folikel yang cukup. Durasi pengobatan ini umumnya berkisar 4 hingga 7 minggu.

Apabila kantung kehamilan sudah terbentuk, Anda akan diberikan suntikan tunggal yang dinamakan *human chorionic gonadotrophin* (hCG) untuk menginduksi terjadinya ovulasi (pelepasan sel telur).

Dokter akan mengawasi kemajuan pengobatan Anda selama kurang lebih 2 minggu setelah menerima suntikan hCG.

PETUNJUK PENGGUNAAN

Apabila klinik meminta Anda untuk menyuntikkan sendiri obat ini, Anda harus mengikuti petunjuk yang mereka berikan.

Suntikkan pertama obat ini harus diberikan dibawah pengawasan dokter.

- Lepaskan foil pelindung lalu keluarkan suntikan dari kemasan blister. Tegakkan suntikan lurus keatas dengan posisi penutup berwarna abu-abu di ujung atas. Tekan perlahan bagian atas suntikan (*plunger*) hingga tetesan obat pertama keluar dari suntikan.

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- Lipat kulit bagian perut menggunakan ibu jari dan jari telunjuk. Suntikan perlahan dengan cara menekan *plunger*.

Apabila Anda menggunakan Decapeptyl dalam jumlah yang lebih banyak
 Segera hubungi dokter atau perawat Anda.

Apabila Anda lupa menggunakan Decapeptyl
 Segera hubungi dokter atau perawat Anda.

Apabila Anda berhenti menggunakan Decapeptyl

Jangan berhenti menggunakan Decapeptyl sebelum menghubungi dokter Anda. Bila Anda berhenti secara tiba-tiba maka akan mengurangi kemungkinan untuk hamil.
 Jika Anda memiliki pertanyaan lebih lanjut mengenai obat ini, hubungi dokter, perawat, atau apoteker Anda.

4. Efek samping yang mungkin terjadi

Sama seperti obat pada umumnya, obat ini dapat menimbulkan efek samping walaupun tidak semua orang akan mengalaminya.

Sangat sering terjadi (dialami lebih dari 1 pada 10 orang):

- Sakit kepala
- Perdarahan/bercak pada vagina
- Peradangan pada lokasi suntikan
- Sakit pada bagian perut
- Mual

Sering terjadi (dialami kurang dari 1 pada 10 orang) :

- Pilek
- Sakit tenggorokan
- Kemerahan pada muka
- Gejala flu
- Pusing
- Muntah
- Perut kembung
- Aborsi
- Stimulasi berlebih pada ovarium (lihat bagian “Peringatan dan Perhatian”)
- Sakit saat menstruasi
- Kelelahan
- Sakit punggung
- Kista ovarium (pada permulaan terapi)
- Sakit pada tempat suntikkan

Jarang terjadi (dialami kurang dari 1 pada 100 orang) :

- Gangguan suasana hati, depresi

Tidak diketahui: frekuensi tidak dapat diperkirakan dari data yang ada:

- Rasa tidak nyaman pada perut
- Keringat berlebih

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- Reaksi alergi (lihat bagian “Peringatan dan Perhatian”)
- Gangguan tidur
- Peningkatan berat badan
- Mata buram
- Gatal
- Kemerahan
- Angioedema (bengkak pada bagian bawah kulit)
- Kelelahan
- Kejang otot
- Pembesaran pada ovarium
- Bercak darah diantara periode menstruasi
- Kemerahan pada lokasi suntikan
- Penurunan libido
- Napas pendek
- Gangguan penglihatan
- Periode menstruasi yang tidak teratur / lebih lama/ lebih banyak
- Rasa kering pada vagina
- Rasa sakit saat senggama
- Sakit pada payudara
- Sakit pada sendi

Pelaporan Kejadian yang Tidak Diinginkan (Adverse Event Reporting)

Jika Anda mengalami salah satu reaksi yang tidak diinginkan seperti yang disebutkan di atas, atau reaksi yang tidak tercantum dalam leaflet ini, harap segera hubungi dokter atau perawat Anda. Anda juga dapat melaporkan efek samping tersebut kepada Ferring atau sistem pelaporan nasional yang tercantum di bawah ini. Pelaporan efek samping membantu mengumpulkan lebih banyak informasi mengenai keamanan obat ini.

PT Ferring Pharmaceuticals Industry
Safety Mailbox Indonesia
No. Telp: (021) 50868801
Email: SafetyMaliboxIndonesia@ferring.com

5. Bagaimana cara penyimpanan Decapeptyl

Simpanlah di lemari es (2°C – 8°C). Jangan dibekukan. Simpan obat ini dalam kemasan asli untuk menghindari paparan cahaya.
Simpan obat ini pada tempat yang tidak dapat dijangkau anak-anak.

Jangan gunakan obat ini setelah lewat tanggal kadaluwarsa yang dapat dilihat pada karton setelah tanda ‘EXP’. Tanggal kadaluwarsa disini mengacu pada tanggal terakhir bulan yang tercantum.

Jangan membuang obat ini pada saluran pembuangan air atau tempat sampah rumah tangga. Mintalah petunjuk dari apoteker tentang tata cara pembuangan sisa obat yang sudah tidak digunakan. Hal ini dapat membantu melindungi lingkungan hidup.

6. Isi dari paket obat dan informasi lain

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Decapeptyl mengandung:

- Bahan aktif berupa triptorelin acetate. Setiap suntikan berisi 1 ml cairan untuk injeksi yang mengandung 100 mikrogram triptorelin acetate setara dengan 95.6 mikrogram triptorelin.
- Kandungan yang lain adalah natrium klorida, asam asetat glasial, dan cairan untuk injeksi.

Tampilan Decapeptyl dan isi dari paket obat:

Obat ini berupa cairan bening dalam suntikan kaca 1 ml dengan jarum yang sudah terpasang. Alat suntik dan jarum suntik ditutup dengan karet pengaman dan penutup jarum. Semua dikemas pada dus obat yang berisi 7 suntikan.

Pack sizes:

7 x 1 ml pre-filled syringes 0.1 mg/ml (Reg. No.: DKI XXXXXXXXXXXXX)

HARUS DENGAN RESEP DOKTER

Pemegang Hak Pemasaran dan Produsen

Diproduksi oleh:

Ferring GmbH

Kiel, Germany

Dikemas sekunder dan dirilis oleh:

Zuellig Pharma Specialty Solutions Group Pte. Ltd

Singapore

Diimpor oleh:

PT Ferring Pharmaceuticals Industry

BSD–Indonesia

Leaflet ini terakhir diperbaharui pada tanggal 01 September 2025