Proposed packaging material		
Code	DECDAI01-I-ID-03.01	
Size	N/A	
Submission	☐NDA ☐Renewal ☒Variation change detail no.:	
Code of previous version	DECDAI01-I-ID-02.02	
Changes	Transfer Zuellig to FICSA	
Reference	■CCDS version: 6.0 ☐Core PIL version:	☐SPC country/version/date: ☐LAC no.:
Name & Date	HINI, 03 November 2025	

DECAPEPTYL® 0.1 mg/ml

Triptorelin acetate

Solution for injection

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pre-filled syringe with 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.

Proposed packaging material		
Code	DECDAI01-I-ID-03.01	
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Code of previous version	DECDAI01-I-ID-02.02	
Changes	Transfer Zuellig to FICSA	
Reference	☒CCDS version: 6.0 ☐Core PIL version:	☐SPC country/version/date: ☐LAC no.:
Name & Date	HINI, 03 November 2025	

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

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, smoking, long-term therapy with drugs that reduce bone mineral density, e.g. anticonvulsants or corticoids, family history of osteoporosis, malnutrition).

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 depression in patients undergoing treatment with GnRH agonists, such as triptorelin. Patients should be informed accordingly and treated as appropriate if symptoms occur.

Patients with known depression should be monitored closely during therapy.

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. For this reason, treatment without add-back therapy should not exceed duration of 6 months. 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.

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

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Code	DECDAI01-I-ID-03.01	
Size	N/A	
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Code of previous version	DECDAI01-I-ID-02.02	
Changes	Transfer Zuellig to FICSA	
Reference	■CCDS version: 6.0 ☐Core PIL version:	☐SPC country/version/date: ☐LAC no.:
Name & Date	HINI, 03 November 2025	

exclude pregnancy.

Assisted reproduction techniques are associated with an increased risk of multiple pregnancies, pregnancy loss, 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 gonadotrophins following treatment with GnRH analogues, 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.

Special populations
Despite prolonged exposure in patients with renal and hepatic impairment, triptorelin is not expected to

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Code	DECDAI01-I-ID-03.01	
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Code of previous version	DECDAI01-I-ID-02.02	
Changes	Transfer Zuellig to FICSA	
Reference	☒CCDS version: 6.0 ☐Core PIL version:	☐SPC country/version/date: ☐LAC no.:
Name & Date	HINI, 03 November 2025	

be present in circulation at the time of embryo transfer (see section Pharmacokinetic Properties).

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
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 monitored.

No formal drug-drug interaction studies have been performed. The possibility of interactions with commonly used medicinal products, including histamine liberating products, cannot be excluded.

PREGNANCY AND LACTATION
Women of childbearing potential/contraception in males and females
With the exception of when triptorelin is used for infertility treatment, non-hormonal methods of contraception should be employed during therapy until menses resume.

Pregnancy
Prior to treatment, potentially fertile women should be examined carefully to exclude pregnancy.

Triptorelin should not be used during pregnancy since concurrent use of GnRH agonists is associated with a theoretical risk of abortion or foetal abnormality. Very limited data on the use of triptorelin during pregnancy do not indicate an increased risk of congenital malformations. However, long-term follow-up studies on development are too limited. Animal data do not indicate direct or indirect harmful effects with respect to pregnancies or postnatal developments, but there are indications for delayed fetal development and parturition (see section Preclinical Safety Data). Based on the pharmacological effects disadvantageous influence on the pregnancy and the offspring cannot be excluded and DECAPEPTYL should not be used during pregnancy.

When triptorelin is used for infertility treatment, there is no clinical evidence to suggest a causal connection between triptorelin and any subsequent abnormalities of oocyte development or pregnancy outcome.

Lactation
It is not known whether triptorelin is excreted in human milk. Because of the potential for adverse reactions from triptorelin in nursing infants, breastfeeding should be discontinued prior to and throughout administration.

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
The most frequent adverse events are headache (27%), vaginal bleeding/spotting (24%), abdominal pain (15%), injection site inflammation (12%) and nausea (10%). Ovarian cysts have been reported to occur commonly (1%) during the initial phase of treatment with DECAPEPTYL®.

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.

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®. No anaphylactic reactions have been seen in clinical trials.

Tabulated summary of adverse reactions

Based on the frequency of adverse drug reactions reported in clinical trials with DECAPEPTYL in females for downregulation and prevention of premature LH surges (N=2,095).

MedDRA System Organ Class	**Very common (≥1/10)**	**Common (≥1/100 to < 1/10)**	**Uncommon (≥1/1,000 to < 1/100)**	**Rare (≥1/10,000 to < 1/1,000)**	**Frequency Not known***
Infections and infestations	-	Upper respiratory tract infection, pharyngitis	-		-
Immune system disorders	-	-	Hypersensitivity		
Psychiatric disorders	-	-	Mood altered**, depression**	Fear	Sleep disorder, libido decreased
Nervous system disorders	Headache	Dizziness	-		-
Eye disorders	-	-	-		Vision blurred, Visual impairment,
Vascular disorders	-	Hot flush	-		-
Respiratory, thoracic and mediastinal disorders	-	-	-	Dyspnoea	
Gastrointestinal disorders	Abdominal pain, nausea	Abdominal distension, vomiting	-		Abdominal discomfort
Skin and subcutaneous tissue disorders	-	-	Hyperhidrosis, Rash	Pruritus, Blister	Urticaria, angioedema
Musculoskeletal and connective tissue and bone disorders	-	Back pain	Musculoskeletal pain		Muscle spasms, arthralgia
Pregnancy, puerperium and perinatal conditions	-	Abortion	-		-
Reproductive system and breast disorders	Vaginal haemorrhage	Pelvic pain, ovarian hyperstimulation syndrome, dysmenorrhea, ovarian cyst***	Breast pain	Vaginal discharge	Ovarian enlargement, menorrhagia, metrorrhagia, vulvovaginal

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Code of previous version	DECDAI01-I-ID-02.02	
Changes	Transfer Zuellig to FICSA	
Reference	☒CCDS version: 6.0 ☐Core PIL version:	☐SPC country/version/date: ☐LAC no.:
Name & Date	HINI, 03 November 2025	

MedDRA System Organ Class	Very common (≥1/10)	Common (≥1/100 to < 1/10)	Uncommon (≥1/1,000 to < 1/100)	Rare (≥1/10,000 to < 1/1,000)	Frequency Not known*
					dryness, dyspareunia
General disorders and administration site conditions	Injection site inflammation	Injection site erythema, Injection site pain, injection site reactions (HLT)[I], fatigue, influenza like illness	-	Injection site discolouration, Injection site irritation, cyst	Asthenia
Investigations	-	-	-		Weight increased

* Frequencies of these adverse events cannot be estimated from the available data.
** This frequency is based on class-effect frequencies common for all GnRH agonists.
*** Ovarian cysts may occur during the initial phase of treatment with GnRH agonist. They are usually asymptomatic and non-functional.
[I] The injection site reactions High Level Term (HLT) includes several injection site reaction terms that have been reported in post-marketing experience with triptorelin acetate.

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: SafetyMaliboxIndonesia@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/

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. Tripiorelin 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 DECAPEPLYL®, 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 downregulaltion with GnRH agonist reduces the cycle cancellation rate and improves the pregnancy rate in ART cycles.

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Code of previous version	DECDAI01-I-ID-02.02	
Changes	Transfer Zuellig to FICSA	
Reference	■CCDS version: 6.0 ☐Core PIL version:	☐SPC country/version/date: ☐LAC no.:
Name & Date	HINI, 03 November 2025	

PHARMACOKINETIC PROPERTIES
The pharmacokinetic data suggest that after subcutaneous administration of DECAPEPLYL® 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.

Special Populations:
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. The clinical studies indicated that the risk of accumulation of triptorelin in patients with severe liver and renal impairment is small.

PRECLINICAL SAFETY DATA
Short- and long-term nonclinical studies reveal no special hazards for humans. Changes in organ weights and lowering of plasma hormone concentrations were related to the pharmacological effect of triptorelin.

Life-long exposure to triptorelin had no carcinogenic effect on mice but caused species specific pituitary adenomas in rats. The rat finding was considered to be related to a rodent specific pharmacological effect of triptorelin and of no relevance to humans; no signs of mutagenicity, clastogenicity or carcinogenicity were recorded for triptorelin.

Reproductive toxicity studies in rats, rabbits and monkeys showed no toxic effects of treatment with triptorelin on fertility, embryo-fetal and pre- and postnatal development. Triptorelin is not teratogenic but there are indications for delayed fetal development and parturition in rats.

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 in order to protect from light.

NATURE AND CONTENTS OF CONTAINER
DECAPEPTYL® 0.1 mg/ml solution for injection is packaged in single use pre-filled disposable 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 XXXXXXXXXXXX)

HARUS DENGAN RESEP DOKTER

Manufacturer:
Ferring GmbH
Kiel, Germany

Proposed packaging material		
Code	DECDAI01-I-ID-03.01	
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Code of previous version	DECDAI01-I-ID-02.02	
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Name & Date	HINI, 03 November 2025	

Secondary packager and batch releaser:
Ferring International Center SA
St. Prex, Switzerland

Imported by:
PT Ferring Pharmaceuticals Industry
BSD–Indonesia

Date of revision : 03 June 2025

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Changes	Transfer Back Zuellig to FICSA	
Reference	☒CCDS version: 6.0 ☐Core PIL version:	☐SPC country/version/date: ☐LAC no.:
Name & Date	HINI, 15 November 2025	

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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Name & Date	HINI, 15 November 2025	

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.

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 analagoue 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
- 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
- Pembengkakan pada perut
- Mual
- Muntah
- Diare
- Peningkatan berat badan
- Kesulitan bernapas
- 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.
Jangan menggunakan obat ini apabila Anda kemungkinan hamil. Kehamilan harus dikesampingkan/dicegah dahulu oleh dokter Anda.

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Changes	Transfer Back Zuellig to FICSA	
Reference	☒CCDS version: 6.0 ☐Core PIL version:	☐SPC country/version/date: ☐LAC no.:
Name & Date	HINI, 15 November 2025	

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

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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 (**≥1/100 to < 1/10**) :

- Pilek
- Sakit tenggorokan
- Kemerahan pada muka
- Gejala flu
- Pusing
- Muntah
- Perut kembung
- Aborsi
- Eritema ditempat suntikan
- 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 (**≥1/1000 to < 1/100**) :

- Gangguan suasana hati, depresi, hipersensitivitas, ruam, hiperhidrosis, nyeri muskuloskeletal, nyeri payudara

Rare (≥1/10.000 to < 1/1.000) :
frekuensi tidak dapat diperkirakan dari data yang ada:

- Takut
- Dispnea
- Pruritus
- Iritasi pada saat penyuntikan
- Keputihan
- Cystitis

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Frekuensi Tidak Diketahui :

- Gangguan Tidur
- Penurunan Libido
- Penglihatan Kabur
- Gangguan Penglihatan
- Nyeri Sendi
- Pembesaran Ovarium
- Kekeringan vulva dan vagina
- Nyeri saat berhubungan seksual
- Ketidaknyamanan Pada Daerah Perut
- Biduran
- Angiodema
- Kejang Otot
- Haid yang berlebihan atau berlangsung lama
- Pendarahan rahim diluar jadwal haid
- Kelemahan fisik atau kelelahan ekstrim

Pelaporan Efek Samping

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
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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

Decapeptyl mengandung:

- Bahan aktif berupa triptorelin acetate. Setiap suntikan berisi 1 ml cairan untuk injeksi yang

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mengandung 100 mikrogram triptorelin acetate setara dengan 95.6 mikrogram triptorelin.

- Kandungan yang lain adalah natrium klorida, asam asetet 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.

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