

Proposed packaging material	
Code	ZOLADEX LA – PI-01.01
Regulatory Objective	<input type="checkbox"/> NDA <input checked="" type="checkbox"/> Renewal <input type="checkbox"/> Variation change detail no.: RO-Obligation Event-0011784
Code of previous version	N/A
Reference	<input type="checkbox"/> CDS version: <input type="checkbox"/> SmPC country/version/date: <input type="checkbox"/> CPIL version: <input type="checkbox"/> RAM approval:
Changes	Renewal
Name	ARH

ZOLADEX® LA
goserelin
Implant/depot 10.8 mg

Qualitative and quantitative composition

Goserelin acetate (equivalent to 10.8 mg goserelin)

Pharmaceutical form

ZOLADEX LA is presented as a sterile, white to cream coloured cylindrical depot in which goserelin acetate (equivalent to 10.8 mg of goserelin) is dispersed in a biodegradable matrix of lactide-glycolide co-polymer. It is supplied as a single dose SafeSystem™ syringe applicator with a protective sleeve in a sealed pouch which contains a desiccant.

Therapeutic indications

Prostate cancer : ZOLADEX LA is indicated in the management of prostate cancer suitable for hormonal manipulation.

Premenopausal Breast Cancer : ZOLADEX LA is indicated in the management of premenopausal breast cancer for hormone receptor positive.

Endometriosis : ZOLADEX LA is indicated in the management of endometriosis including alleviation of symptoms such as pain. Experience with Zoladex LA for the management of endometriosis has been limited to women 18 years of age and older treated for 6 months.

Posology and method of administration

Adult males (including the elderly)

Caution should be taken while inserting ZOLADEX into anterior abdominal wall due to the proximity of underlying inferior epigastric artery and its branches.

Use extra care when administering ZOLADEX to patients with a low body mass index (BMI) and/or who are receiving full anticoagulation medication (*see special warning and special precautions for use*).

For correct administration of ZOLADEX, see instructions on the instruction card.

One 10.8 mg depot of ZOLADEX LA injected subcutaneously into the anterior abdominal wall, every 12 weeks.

No dosage adjustment is necessary for patients with renal impairment. No dosage adjustment is necessary for patients with hepatic impairment.

Females

One 10.8 mg depot of ZOLADEX LA injected subcutaneously into the anterior abdominal wall, every 12 weeks.

Children

ZOLADEX LA is not indicated for use in children.

Contraindications

ZOLADEX LA should not be given to patients with a known hypersensitivity to the active substance, to other LHRH analogues, or to any of the excipients of this product.

ZOLADEX LA should not be used during pregnancy or lactation.

Special warnings and special precautions for use

ZOLADEX LA is not indicated for use in children, as safety and efficacy have not been established in this group of patients.

Injection site injury has been reported with ZOLADEX, including events of pain, haematoma, haemorrhage and vascular injury. Monitor affected patients for signs or symptoms of abdominal haemorrhage. In very rare cases, administration error resulted in vascular injury and haemorrhagic shock requiring blood transfusions and surgical intervention. Extra care should be taken when administering ZOLADEX to patients with a BMI and/or receiving full anticoagulation medications (*see posology and method of administration*).

The use of ZOLADEX LA in men at particular risk of developing ureteric obstruction or spinal cord compression should be considered carefully and the patients monitored closely during the first month of therapy. If spinal cord compression or renal impairment due to ureteric obstruction are present or develop, specific standard treatment of these complications should be instituted.

In women, ZOLADEX LA 10.8 mg is only indicated for use in endometriosis and breast cancer with hormone receptor positive in premenopausal women. For female patients requiring treatment with goserelin for other conditions, refer to the prescribing information for ZOLADEX 3.6 mg.

The use of LHRH agonists may cause a reduction in bone mineral density. In a women, current available data suggest that recovery of bone loss occurs on cessation of therapy in the majority. In patients receiving ZOLADEX 3.6 mg for the treatment of endometriosis, the addition of hormone replacement therapy (a daily oestrogenic agent and a progestogenic agent) has been shown to reduce bone mineral loss and vasomotor symptoms. There is no experience of the use of hormone replacement therapy in women receiving ZOLADEX LA 10.8 mg.

In men preliminary data suggest the use of a bisphosphonate in combination with a LHRH agonist may reduce mineral loss.

A reduction in glucose tolerance has been observed in males receiving LHRH agonists. This may manifest as diabetes or loss of glycaemic control in those with pre-existing diabetes mellitus. Consideration should therefore be given to monitoring blood glucose.

Cardiovascular Disease:

Increased risk of myocardial infarction and sudden cardiac death has been reported in association with use of GnRH analogs in men. Monitor for cardiovascular disease and manage according to current clinical practice.

Time to return of menses after cessation of therapy with ZOLADEX LA 10.8 mg may be prolonged in some patients.

The use of ZOLADEX LA may cause an increase in cervical resistance and care should be taken when dilating the cervix.

There are no clinical data on the effects of treating benign gynaecological conditions with ZOLADEX LA for periods in excess of six months.

Androgen deprivation therapy may prolong the QT interval, although a causal association has not been established with ZOLADEX. In patients with a history of or who have risk factors for QT prolongation and in patients receiving concomitant medicinal products that may prolong the QT interval (see *Interactions with other medicinal products and other forms of interaction*) physicians should assess the benefit risk ratio including the potential for Torsade de Pointes prior to initiating ZOLADEX.

Interactions with other medicinal products and other forms of interaction

None known.

Since androgen deprivation treatment may prolong the QT interval, the concomitant use of ZOLADEX with medicinal products known to prolong the QT interval or medicinal products able to induce Torsade de Pointes should be carefully evaluated (see *Special warnings and special precautions for use*).

Pregnancy and Lactation

Pregnancy: ZOLADEX LA should not be used in pregnancy as there is a theoretical risk of abortion or foetal abnormality if LHRH agonists are used during pregnancy. Potentially fertile women should be examined carefully before treatment to exclude pregnancy. Non-hormonal methods of contraception should be employed during therapy until menses resume. (Also see the warning re. time to return of menses in Section Special warnings and precautions for use)

Lactation: The use of ZOLADEX LA during breast feeding is not recommended

Effect on ability to drive or operate machinery

There is no evidence that ZOLADEX LA results in impairment of ability to drive or operate machinery.

Undesirable effects

The following frequency categories for adverse drug reactions (ADRs) were calculated based on reports from ZOLADEX clinical trials and post-marketing sources.

Table 1. ZOLADEX 10.8 mg adverse drug reactions by frequency and System Organ Class (SOC)

Frequency Descriptor	SOC	Males
Very Common (≥10%)	Psychiatric disorders	Libido decreased ^a
	Vascular disorders	Hot flush ^a

	Skin and subcutaneous tissue disorders	Hyperhidrosis ^a
	Reproductive system and breast disorders	Erectile dysfunction
		N/A
Common (≥1% and <10%)	Metabolism and nutrition disorders	Glucose tolerance impaired ^b
	Psychiatric disorders	Mood swings
	Nervous system disorders	Paraesthesia
		Spinal cord compression
		N/A
	Cardiac disorders	Cardiac failure ^f myocardial infarction ^f
	Vascular disorders	Blood pressure abnormal ^c
	Skin and subcutaneous tissue disorders	Rash ^d
	Musculoskeletal, connective tissue and bone disorders	Bone pain ^e
		(see Uncommon)
	Reproductive system and breast disorders	Gynaecomastia
General disorders and administration site conditions	Injection site reaction	
	N/A	
Investigations	Bone density decreased, weight increased	
Uncommon (≥0.1% and <1%)	Immune system disorders	Drug hypersensitivity
	Musculoskeletal, connective tissue and bone disorders	Arthralgia
	Renal and urinary disorders	Ureteric obstruction
	Reproductive system and breast disorders	Breast tenderness
Rare (≥0.01% and <0.1%)	Immune system disorders	Anaphylactic reaction
Very rare (<0.01%)	Neoplasms benign, malignant and unspecified (including cysts and polyps)	Pituitary tumour
	Endocrine disorders	Pituitary haemorrhage
	Psychiatric disorders	Psychotic disorder
Unknown	Skin and subcutaneous tissue disorders	Alopecia ^g
	Cardiac disorders	QT Prolongation

- a These are pharmacological effects which seldom require withdrawal of therapy.
- b A reduction in glucose tolerance has been observed in males receiving LHRH agonists. This may manifest as diabetes or loss of glycaemic control in those with pre-existing diabetes mellitus.
- c These may manifest as hypotension or hypertension, have been occasionally observed in patients administered ZOLADEX. The changes are usually transient, resolving either during continued therapy or after cessation of therapy with ZOLADEX. Rarely, such changes have been sufficient to require medical intervention, including withdrawal of treatment from ZOLADEX.
- d These are generally mild, often regressing without discontinuation of therapy.
- e Initially, prostate cancer patients may experience a temporary increase in bone pain, which can be managed symptomatically.
- f Observed in a pharmacoepidemiology study of LHRH agonists used in the treatment of prostate cancer. The risk appears to be increased when used in combination with anti-androgens.
- g Loss of head hair has been reported in females, including younger patients treated for benign conditions. This is usually mild but occasionally can be severe.
- h Particularly loss of body hair, an expected effect of lowered androgen levels.
- i In most cases acne was reported within one month after the start of ZOLADEX.

Pharmaceutical effects of Zoladex treatment in women include hot flushes and sweating, and a change in libido, seldom requiring withdrawal of therapy. Headaches, mood changes including depression, vaginal dryness and change in breast size have been noted infrequently.

As with other LHRH agonists, there have been reports of ovarian cyst formation.

Overdose

There is limited experience of overdosage in humans. In cases where ZOLADEX has unintentionally been readministered early, or given at a higher dose, no clinically relevant adverse effects have been seen. Animal tests suggest that no effect other than the intended therapeutic effects on sex hormone concentrations and on the reproductive tract will be evident with higher doses of ZOLADEX. If overdosage occurs, this should be managed symptomatically.

Pharmacological properties

Pharmacodynamic properties

ZOLADEX (D-Ser(Bu)^t₆ Azgly¹⁰ LHRH) is a synthetic analogue of naturally occurring luteinising hormone releasing hormone (LHRH). On chronic administration ZOLADEX LA results in inhibition of pituitary LH secretion leading to a fall in serum testosterone concentrations in males. Initially, ZOLADEX LA, like other LHRH agonists, transiently increases serum testosterone concentration.

In men by around 21 days after the first depot injection testosterone concentrations have fallen to within the castrate range and remain suppressed with treatment every 12 weeks. If in exceptional circumstances repeat dosing does not occur at 3 months, data indicate that castrate levels of testosterone are maintained for up to 16 weeks in the majority of patients.

In women, serum oestradiol concentrations are suppressed by around 4 weeks after the first depot injection and remain suppressed until the end of the treatment period. In patients with oestradiol already suppressed by an LHRH analogue, suppression is maintained on the change of therapy of ZOLADEX LA. Suppression of oestradiol is associated with a response in endometriosis will result in amenorrhoea in the majority of patients.

During early treatment with ZOLADEX some women may experience vaginal bleeding of variable duration and intensity. Such bleeding probably represents oestrogen withdrawal bleeding and is expected to stop spontaneously.

Rarely, some woman may enter the menopause during treatment with LHRH analogues and do not resume menses on cessation of therapy.

Japanese Phase II study

Disease free survival following subcutaneous administration of Zoladex 10.8 mg depot once every 12 weeks as adjuvant therapy to premenopausal women with ER positive breast cancer who underwent radical surgery was assessed in comparison with Zoladex 3.6 mg depot, both in combination with tamoxifen citrate (the duration of treatment was 96 weeks). Four (4.7%) and 1 (1.2%) events were observed in the Zoladex 10.8 mg depot group and Zoladex 3.6 mg depot group, respectively, with median (min, max) disease free survival of 675.0 days (142 days, 687 days) and 675.5 days (160 days, 685 days) in the Zoladex 10.8 mg depot group and Zoladex 3.6 mg depot group, respectively.

Asian multinational Phase III study

The efficacy and safety of subcutaneous administration of Zoladex 10.8 mg depot once every 12 weeks to premenopausal women with ER positive advanced/recurrent breast cancer were assessed in comparison with Zoladex 3.6 mg depot, both in combination with tamoxifen citrate (the duration of treatment was 24 weeks). The progression free survival (%PFS) at Week 24, the primary endpoint, were 67/109 (61.5%) in the Zoladex 10.8 mg depot and 68/113 (60.2%) in the Zoladex 3.6 mg depot with the difference [95% CI] of 1.29% [-11.40 - 13.90], which met the pre-specified non-inferiority criterion.

Pharmacokinetic Properties

Administration of ZOLADEX LA every 12 weeks ensures that exposure to goserelin is maintained with no clinically significant accumulation. ZOLADEX is poorly protein bound and has a serum elimination half-life of two to four hours in subjects with normal renal function. The half-life is increased in patients with impaired renal function. For the compound given in a 10.8mg depot formulation every 12 weeks, this change will not lead to any accumulation. Hence, no change in dosing is necessary in these patients. There is no significant change in pharmacokinetics in patients with hepatic failure.

Following subcutaneous administration of this drug to premenopausal patients with breast cancer, plasma goserelin concentrations reached C_{max} 2 hours at-post dose (mean value of 4.5 ng/mL). Subsequently, plasma goserelin levels decreased promptly until 48 hours postdose, and thereafter it eliminated gradually and maintained around the lower limit of quantitation (0.1 ng/mL) at Week 10 and 12.

Preclinical safety data

Following long-term repeated dosing with ZOLADEX, an increased incidence of benign pituitary tumours has been observed in male rats. Whilst this finding is similar to that previously noted in this species following surgical castration, any relevance to humans has not been established.

In mice, long term repeated dosing with multiples of the human dose produced histological changes in some regions of the digestive system. This is manifested by pancreatic islet cell hyperplasia and a benign proliferative condition in the pyloric region of the stomach, also reported as a spontaneous lesion in this species. The clinical relevance of these findings is unknown.

Precautions for storage

Do not store above 25°C.

Instructions for use, handling and disposal

For correct administration of ZOLADEX, see instructions on the instruction card. Use as directed by the prescriber. Use extra care when administering ZOLADEX to patients with low body mass index (BMI) and/or who are receiving full anticoagulation medication (*see special warnings and special precautions for use*).

Use only if pouch is undamaged. Use immediately after opening pouch. Dispose of the syringe in an approved sharps collector.

Shelf life

Please refer to expiry date on the outer carton.

Pack size

Box, 1 syringe @ 10.8 mg (Reg. No.: DK19859600643B1)

HARUS DENGAN RESEP DOKTER

Manufactured by:

AstraZeneca UK Limited

Macclesfield, Cheshire – United Kingdom

Imported by:

PT AstraZeneca Indonesia

Cikarang, Bekasi – Indonesia

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Leaflet Informasi Pasien ZOLADEX LA 10.8 mg Implant Goserelin

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.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakanlah dokter, apoteker, atau perawat Anda.
- Obat ini diresepkan khusus hanya untuk Anda. Jangan berikan pada orang lain. Obat ini dapat membahayakan mereka walaupun tanda-tanda penyakit yang mereka miliki sama dengan anda.
- Jika Anda mengalami efek samping, beritahu dokter, apoteker, ataupun perawat Anda. Hal ini termasuk efek samping yang mungkin terjadi terdapat pada leaflet ini. Lihat bagian 4.

Leaflet ini berisi informasi mengenai:

1. ZOLADEX LA dan kegunaannya
2. Hal yang perlu diketahui sebelum menggunakan ZOLADEX LA
3. Cara pemakaian ZOLADEX LA
4. Efek samping yang mungkin terjadi
5. Cara penyimpanan ZOLADEX LA
6. Isi kemasan dan informasi lainnya

1. ZOLADEX LA dan kegunaannya

Zoladex LA mengandung obat yang disebut Goserelin. Zoladex LA merupakan Kelompok obat yang disebut 'Analog LHRH'.

Zoladex LA digunakan untuk mengobati kanker prostat yang bekerja dengan mengatur jumlah hormon yang diproduksi oleh tubuh Anda.

Zoladex LA digunakan untuk mengobati kanker payudara premenopausal dengan reseptor hormon positif.

Zoladex LA digunakan untuk mengobati endometriosis dan mengurangi gejala yang menyertainya seperti rasa nyeri. Penggunaan Zoladex LA untuk mengobati endometriosis terbatas untuk wanita usia 18 tahun keatas selama 6 bulan.

2. Hal yang perlu diketahui sebelum menggunakan ZOLADEX LA.

Jangan gunakan ZOLADEX LA, jika:

- Anda alergi (hipersensitif) terhadap goserelin, analog LHRH (hormone stimulator bagi sekresi hormone FSH dan LH) lainnya atau bahan lain yang terkandung dalam obat ini (baca bagian 6).

- Anda sedang hamil atau menyusui.

Jika Anda tidak yakin, beritahu dokter, apoteker ataupun perawat Anda sebelum menggunakan ZOLADEX LA.

Peringatan dan perhatian

Beritahu dokter, apoteker ataupun perawat Anda sebelum menggunakan Zoladex LA, Jika:

- Jika Anda memiliki masalah buang air kecil (air) atau masalah dengan punggung Anda.
- Jika Anda menderita diabetes.
- Anda memiliki tekanan darah tinggi.
- Jika Anda memiliki kondisi apa pun yang mempengaruhi kekuatan tulang Anda, terutama jika Anda seorang peminum berat, perokok, memiliki riwayat keluarga osteoporosis (suatu kondisi yang mempengaruhi kekuatan tulang Anda) atau minum antikonvulsan (obat untuk epilepsi atau cocok) atau kortikosteroid (steroid). Obat-obatan jenis ini dapat menyebabkan pengurangan kalsium tulang (penipisan tulang).
- Anda memiliki kondisi jantung atau pembuluh darah, termasuk masalah irama jantung (Aritmia), atau sedang dirawat dengan obat-obatan untuk kondisi ini. Resiko masalah irama jantung dapat meningkat saat menggunakan Zoladex LA.
- Ada laporan depresi yang mungkin parah pada pasien yang memakai Zoladex LA. Jika Anda menggunakan Zoladex LA dan mengalami perasaan depresi, beri tahu dokter Anda.

Jika Anda mengalami salah satu hal di atas (atau jika Anda tidak yakin), beritahu dokter, apoteker, ataupun perawat Anda sebelum menggunakan obat ini.

Anak-anak dan remaja

Belum dilakukan studi ZOLADEX LA untuk penggunaan pada anak-anak dan remaja. Jangan berikan obat ini pada anak-anak atau remaja di bawah usia 18 tahun.

Obat-obatan lain dan ZOLADEX LA

Beritahu dokter Anda jika Anda sedang menggunakan atau mungkin menggunakan obat-obatan lain termasuk obat herbal, dan obat yang Anda beli tanpa resep dokter. Hal ini karena ZOLADEX LA dapat mempengaruhi kerja beberapa obat lainnya dan obat lain juga dapat mempengaruhi cara kerja ZOLADEX LA.

Zoladex LA mungkin mengganggu beberapa obat yang digunakan untuk mengobati masalah irama jantung (misalnya quinidine, procainamide, amiodarone dan sotalol) atau dapat meningkatkan risiko masalah irama jantung ketika digunakan dengan beberapa obat lain (misal metadon (digunakan untuk menghilangkan rasa sakit dan bagian dari detoksifikasi kecanduan obat), moxifloxacin (antibiotik), antipsikotik yang digunakan untuk penyakit mental yang serius).

Jika Anda menggunakan salah satu obat di atas, beritahu dokter anda sebelum menggunakan ZOLADEX LA.

Dokter Anda akan mendiskusikan pengobatan yang sesuai untuk Anda.

Kehamilan—Informasi untuk pasien wanita

- Jika Anda hamil, atau Anda merasa Anda hamil, atau berencana untuk hamil, mintalah saran dari dokter Anda sebelum menggunakan obat ini. Jika Anda hamil selama pengobatan, segera beritahu dengan dokter Anda. Dokter Anda akan memutuskan apakah pengobatan yang Anda lakukan dengan ZOLADEX LA akan dilanjutkan atau tidak.
- Anda sebaiknya tidak hamil selama menggunakan obat ini, pakailah kontrasepsi yang efektif.
- Jika Anda berencana hamil setelah menggunakan dosis terakhir obat ini, mintalah saran pada dokter Anda, karena sedikit obat masih dapat tertinggal didalam tubuh Anda.

Menyusui

Jangan menyusui selama menggunakan obat ini karena belum diketahui apakah obat ini berisiko terhadap bayi Anda.

Mengemudi dan menjalankan mesin

Tidak ada studi tentang efek pada kemampuan untuk mengemudi ataupun menjalankan mesin yang telah dilakukan. Jika pasien mengalami gejala yang mempengaruhi kemampuan Anda untuk berkonsentrasi dan bereaksi, disarankan Anda untuk tidak mengemudi atau menjalankan mesin sampai efek mereda.

3. Cara penggunaan ZOLADEX LA

Selalu gunakan obat ini sesuai dengan petunjuk dari dokter Anda. Periksa kembali dengan dokter atau apoteker Anda jika Anda tidak yakin.

Bagaimana cara menggunakannya

- Zoladex LA Implan akan disuntikkan di bawah kulit pada perut Anda setiap 12 minggu. Ini akan dilakukan oleh dokter atau perawat Anda.
- Penting bahwa Anda tetap menjalani pengobatan Zoladex LA, bahkan jika Anda merasa sehat.
- Tetap menjalani perawatan ini sampai dokter Anda memutuskan bahwa sudah saatnya bagi Anda untuk berhenti.

Buat Janji Anda selanjutnya:

- Anda harus diberikan suntikan Zoladex LA setiap 12 minggu.
- Selalu ingatkan dokter atau perawat untuk membuat janji temu untuk injeksi Anda berikutnya.
- Jika Anda diberi janji untuk injeksi berikutnya yang lebih awal atau lebih dari 12 minggu dari suntikan terakhir Anda, beri tahu dokter atau perawat Anda.
- Jika sudah lebih dari 12 minggu sejak injeksi terakhir Anda, hubungi dokter atau perawat Anda.
- Anda dapat menerima suntikan Anda sesegera mungkin.

Jika Anda memiliki pertanyaan lebih lanjut mengenai pemakaian obat ini, tanyakanlah pada dokter, apoteker, ataupun perawat Anda.

4. Efek samping yang mungkin terjadi

Seperti obat lainnya, Obat ini dapat menimbulkan efek samping, walaupun tidak setiap orang dapat mengalaminya.

Efek samping berikut dapat terjadi pada pria atau wanita:

Reaksi alergi:

Ini jarang terjadi. Gejala-gejalanya dapat termasuk onset mendadak:

- Ruam, gatal atau gatal-gatal pada kulit.
- Pembengkakan pada wajah, bibir atau lidah atau bagian tubuh lainnya.
- Napas pendek, mengi atau kesulitan bernapas.

Jika ini terjadi pada Anda, segera temui dokter.

Cedera di tempat suntikan (termasuk kerusakan pembuluh darah di perut) telah dilaporkan setelah injeksi Zoladex LA. Dalam kasus yang sangat jarang, ini menyebabkan pendarahan hebat. Kontak dokter Anda segera jika Anda mengalami salah satu dari gejala berikut:

- Nyeri perut.

- Distensi perut.
- Napas pendek.
- Pusing.
- Tekanan darah rendah dan / atau tingkat kesadaran yang berubah.

Kemungkinan efek samping lainnya:

Sangat umum (dapat mempengaruhi lebih dari 1 dalam 10 orang)

- *Hot flushes* dan berkeringat. Kadang-kadang efek samping ini dapat berlanjut untuk beberapa waktu (mungkin berbulan-bulan) setelah menghentikan Zoladex LA.
- Penurunan gairah seks.

Umum (dapat menyerang hingga 1 dari 10 orang)

- Nyeri pada punggung bagian bawah atau masalah buang air kecil. Jika hal ini terjadi hubungi dokter anda.
- Nyeri tulang pada saat awal pengobatan. Jika hal ini terjadi, hubungi dokter anda.
- Penipisan tulang Anda.
- Peningkatan kadar gula darah.
- Kesemutan di jari tangan atau kaki Anda.
- Ruam kulit.
- Penambahan berat badan.
- Nyeri, ruam, pendarahan, kemerahan, atau bengkak pada tempat penyuntikan Zoladex LA.
- Perubahan tekanan darah.
- Pembengkakan atau nyeri pada payudara.
- Perubahan suasana hati Anda (termasuk depresi).
- Mengurangi fungsi jantung atau serangan jantung.

Jarang (dapat mempengaruhi 1 dari 100 orang)

- Nyeri pada persendian

Sangat jarang (dapat mempengaruhi hingga 1 dari 10.000 orang)

- Masalah kejiwaan yang disebut gangguan psikotik yang mungkin termasuk halusinasi (melihat, merasakan atau mendengar hal-hal yang tidak ada di sana), pikiran yang kacau dan perubahan kepribadian.
- Perkembangan tumor kelenjar hipofisis di kepala Anda atau, jika Anda sudah memiliki tumor di kelenjar pituitari Anda, Zoladex LA dapat membuat tumor berdarah atau runtuh. Ini efeknya sangat jarang. Tumor hipofisis dapat menyebabkan sakit kepala parah, merasa atau sakit, kehilangan penglihatan dan menjadi tidak sadar.

Tidak diketahui (frekuensi tidak dapat diperkirakan dari data yang tersedia)

- Kerontokan rambut
- Perubahan dalam darah Anda.
- Masalah hati.
- Gumpalan darah di paru-paru Anda menyebabkan nyeri dada atau sesak napas.
- Peradangan paru-paru. Gejala-gejalanya mungkin seperti pneumonia (seperti merasa kekurangan napas dan batuk).
- Perubahan EKG (perpanjangan QT).

Jangan khawatir dengan daftar efek samping di atas. Anda mungkin tidak akan mengalami efek samping tersebut.

5. Cara Penyimpanan ZOLADEX LA

Dokter Anda mungkin memberi Anda resep sehingga Anda bisa mendapatkan obat dari apotek dan berikan kepada dokter Anda ketika Anda melihatnya lagi.

- Jauhkan obat ini dari pandangan dan jangkauan anak-anak.
- Simpan dalam paket aslinya dan jangan merusak segelnya.
- Jangan menyimpannya di atas 25°C.
- Jangan menggunakan obat ini setelah tanggal kedaluwarsa yang tercantum pada karton. Tanggal kedaluwarsa mengacu pada hari terakhir bulan itu.
- Jangan membuang obat apa pun melalui air limbah atau limbah rumah tangga. Tanyakan apoteker Anda cara membuang obat yang tidak lagi Anda gunakan. Langkah-langkah ini akan membantu melindungi lingkungan hidup.

6. Isi kemasan dan informasi lainnya

ZOLADEX LA mengandung:

- Zat aktif goserelin asetat (setara dengan 10.8 mg goserelin).
- Bahan lainnya adalah lactide/glycolide 95/5 co-polymer, asam asetat.

Isi kemasan

ZOLADEX LA 10.8 mg: Depot silinder berwarna putih hingga krem dimana goserelin asetat (setara dengan 10.8 mg goserelin) didispersikan dalam matriks biodegradable lactide/glycolide 95/5 co-polymer.

HARUS DENGAN RESEP DOKTER

Diproduksi oleh:

AstraZeneca UK Limited
Macclesfield, Cheshire
United Kingdom

Diimpor oleh:

PT AstraZeneca Indonesia
Cikarang, Bekasi – Indonesia

Informasi lebih lanjut dapat menghubungi:

PT AstraZeneca Indonesia
Perkantoran Hijau Arkadia Tower G, 16th floor
Jl. T.B. Simatupang Kav. 88, Jakarta – 12520
Tel: +62 21 299 79 000

Nomor izin edar : DKI9859600643B1

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