ELIGARD 22.5 mg
ELIGARD 45 mg

1. NAME OF THE MEDICINAL PRODUCT

ELIGARD 22.5 mg powder and solvent for solution for injection

ELIGARD 45 mg powder and solvent for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ELIGARD 22.5 mg
One prefilled syringe with powder for solution for injection contains 22.5 mg leuprorelin acetate, equivalent to 20.87 mg leuprorelin.

ELIGARD 45 mg
One prefilled syringe with powder for solution for injection contains 45 mg leuprorelin acetate, equivalent to 41.7 mg leuprorelin.

For *a full list of* excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection**,**

Powder (Syringe B):
Pre-filled syringe with a white to off-white powder.

Solvent (Syringe A):
Pre-filled syringe with a clear, colourless to pale yellow solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ELIGARD is indicated for the treatment of hormone dependent advanced prostate cancer

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4.2 Posology and method of administration

Dosage for Adult Males

ELIGARD should be administered under the direction of a healthcare professional having available the appropriate expertise for monitoring the response to treatment.

ELIGARD 22.5 mg is administered as a single subcutaneous injection every three months. The injected solution forms a solid medicinal product delivery depot and provides continuous release of leuprorelin acetate over a three-month period.

ELIGARD 45 mg is administered as a single subcutaneous injection every six months. The injected solution forms a solid medicinal product delivery depot and provides continuous release of leuprorelin acetate over a six-month period.

As a rule, therapy of advanced prostate cancer with ELIGARD entails long-term treatment and therapy should not be discontinued when remission or improvement occurs.

Response to ELIGARD should be monitored by clinical parameters and by measuring prostate specific antigen (PSA) serum levels. Clinical studies have shown that testosterone levels increased during the first 3 days of treatment in the majority of non-orchiectomised patients and then decreased to below medical castration levels within 3 - 4 weeks. Once attained, castrate levels were maintained as long as medicinal product therapy continued (< 1% testosterone breakthroughs). In case the patient's response appears to be sub-optimal, it should be confirmed that serum testosterone levels have reached or are remaining at castrate levels.

Administration

The contents of the two pre-filled sterile syringes must be mixed immediately prior to administration of ELIGARD by subcutaneous injection.

Regarding the mixing procedure, see section 6.4. Lack of clinical efficacy may occur due to incorrect reconstitution of the product.

Based on data from animal experience, intra-arterial or intravenous injection, respectively, has to be strictly avoided.

As with other medicinal products administered by subcutaneous injection, the injection site should be varied periodically.

Children and adolescents

There is no experience in children (under the age of 18 years) (see also section 4.3)

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Dose Adjustment in Specific Patient Populations
No clinical studies were performed in patients with either liver or kidney impairment.

4.3 Contraindications

Hypersensitivity to leuprorelin acetate, to other GnRH agonists or to any of the excipients.

In patients who previously underwent orchiectomy (as with other GnRH agonists, ELIGARD does not result in further decrease of serum testosterone in case of surgical castration).

As sole treatment in prostate cancer patients with spinal cord compression or evidence of spinal metastases (see also section 4.4)

ELIGARD is contraindicated in women and in paediatric patients.

4.4 Special warnings and special precautions for use

Leuprorelin acetate, like other GnRH agonists, causes a transient increase in serum concentrations of testosterone, dihydrotestosterone and acid phosphatase during the first week of treatment. Patients may experience worsening of symptoms or onset of new symptoms, including bone pain, neuropathy, haematuria, or ureteral or bladder outlet obstruction (see section 4.8). These symptoms usually subside on continuation of therapy.

Additional administration of an appropriate antiandrogen should be considered beginning 3 days prior to leuprorelin therapy and continuing for the first two to three weeks of treatment. This has been reported to prevent the sequelae of an initial rise in serum testosterone.

Following surgical castration, ELIGARD does not lead to a further decrease in serum testosterone levels in male patients.

Cases of ureteral obstruction and spinal cord compression, which may contribute to paralysis with or without fatal complications, have been reported with GnRH agonists. If spinal cord compression or renal impairment develops, standard treatment of these complications should be instituted.

Patients with vertebral and/or brain metastases as well as patients with urinary tract obstruction should be closely monitored during the first few weeks of therapy.

A proportion of patients will have tumors which are not sensitive to hormone manipulation. Absence of clinical improvement despite adequate testosterone suppression is diagnostic of this condition, which will not benefit from further therapy with ELIGARD.

Decreased bone density has been reported in the medical literature in men who have had orchiectomy or who have been treated with a GnRH agonist (see section 4.8).
Antiandrogen therapy significantly increases the risk for fractures owing to osteoporosis. Only limited data is available on this issue. Fractures owing to osteoporosis were observed in 5% of patients following 22 months of pharmacological androgen deprivation therapy and in 4% of patients following 5 to 10 years of treatment. The risk for fractures owing to osteoporosis is generally higher than the risk for pathological fractures.

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Apart from long lasting testosterone deficiency, increased age, smoking and consumption of alcoholic beverages, obesity and insufficient exercise may have an influence on the development of osteoporosis.

During post-marketing surveillance, rare cases of pituitary apoplexy (a clinical syndrome secondary to infarction of the pituitary gland) have been reported after the administration of GnRH-agonists, with a majority occurring within 2 weeks of the first dose, and some within the first hour. In these cases, pituitary apoplexy was presented as sudden headache, vomiting, visual changes, ophthalmoplegia, altered mental status, and sometimes cardiovascular collapse. Immediate medical attention is required.

Androgen deprivation therapy may prolong the QT interval. Providers should consider whether the benefits of androgen deprivation therapy outweigh the potential risks in patients with congenital long QT syndrome, congestive heart failure, frequent electrolyte abnormalities, and in patients taking drugs known to prolong the QT interval. Electrolyte abnormalities should be corrected. Consider periodic monitoring of electrocardiograms and electrolytes.

Increased risk of developing myocardial infarction, sudden cardiac death and stroke has been reported in association with use of GnRH agonists in men. The risk appears low based on the reported odds ratios, and should be evaluated carefully along with cardiovascular risk factors when determining a treatment for patients with prostate cancer. Patients receiving a GnRH agonist should be monitored for symptoms and signs suggestive of development of cardiovascular disease and be managed according to current clinical practice.

Changes in glucose tolerance have been reported in some patients receiving GnRH agonist therapy. Hyperglycemia may represent development of diabetes mellitus or worsening of glycemic control in patients with diabetes. Monitor blood glucose and/or glycosylated hemoglobin (HbA1c) periodically in patients receiving a GnRH agonist and manage with current practice for treatment of hyperglycemia or diabetes.

Post marketing reports of convulsions have been observed in patients on leuprorelin acetate therapy with or without a history of predisposing factors. Convulsions are to be managed according to the current clinical practice.

There have been postmarketing reports of interstitial pneumonitis associated with leuprorelin use. Treatment should be discontinued immediately if the patient develops any signs or symptoms suggestive of interstitial lung disease.

4.5 Interaction with other medicinal products and other forms of interaction

No pharmacokinetic drug-drug interaction studies have been performed with ELIGARD. There have been no reports of any interactions of leuprorelin acetate with other medicinal products.

4.6 Pregnancy and lactation

Not applicable as ELIGARD is contraindicated in women.

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4.7 Effects on ability to drive and use machines

No studies on the effects of ELIGARD on the ability to drive and use machines have been performed.
The ability to drive and operate machines may be impaired due to fatigue, dizziness and visual disturbances being possible side effects of treatment or resulting from the underlying disease.

4.8 Undesirable effects

Adverse reactions seen with ELIGARD are mainly subject to the specific pharmacological action of leuprorelin acetate, namely increases and decreases in certain hormone levels. The most commonly reported adverse reactions are hot flashes, malaise, nausea and fatigue and transient local irritation at the site of injection. Mild or moderate hot flashes occur in approximately 58% of patients.

The following adverse events were reported during clinical trials with ELIGARD in patients with advanced prostate carcinoma. Adverse events are classified, by frequency, as very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1,000), and very rare (<1/10,000), not known (cannot be estimated from the available data).

Table 1: ***Undesirable effects in clinical studies with Eligard***

Infections and infestations	
common	nasopharyngitis
uncommon	urinary tract infection, local skin infection
Metabolism and nutrition disorders	
uncommon	aggravated diabetes mellitus
Psychiatric disorders	
uncommon	abnormal dreams, depression, decreased libido
Nervous system disorders	
uncommon	dizziness, headache, hypoaesthesia, insomnia, taste disturbance, smell disturbance, vertigo
rare	abnormal involuntary movements
Vascular disorders	
very common	hot flashes
uncommon	hypertension, hypotension
rare	syncope, collapse
Respiratory, thoracic and mediastinal disorders	
uncommon	rhinorrhoea, dyspnoea
not known	interstitial lung disease
Gastrointestinal disorders	
common	nausea, diarrhea, gastroenteritis/colitis
uncommon	constipation, dry mouth, dyspepsia, vomiting
rare	flatulence, eructation,
Skin and subcutaneous tissue disorders	

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very common	ecchymoses, erythema
common	pruritus, night sweats
uncommon	clamminess, increased sweating
rare	alopecia, skin eruption
Musculoskeletal, connective tissues and bone disorders	
common	arthralgia, limb pain, myalgia
uncommon	back pain, muscle cramps
Renal and urinary disorders	
common	urinary infrequency, difficulty in micturation, dysuria, nocturia, oliguria
uncommon	bladder spasm, haematuria, aggravated urinary frequency, urinary retention
Reproductive system and breast disorders	
common	breast tenderness, testicular atrophy, testicular pain infertility, breast hypertrophy, erectile dysfunction, reduced penis size
uncommon	gynaecomastia, impotence, testicular disorder
rare	breast pain
General disorders and administration site reactions	
very common	fatigue, injection site burning, injection site paraesthesia
common	malaise, injection site pain, injection site bruising, injection site stinging , rigors, weakness
uncommon	injection site pruritus, injection site induration, lethargy, pain, pyrexia
rare	injection site ulceration
very rare	injection site necrosis
Blood and lymphatic system disorders	
Common	hematology changes, anaemia
Investigations	
common	increased blood creatinine phosphokinase, prolonged coagulation time
uncommon	increased alanine aminotransferase, increased blood triglycerides, prolonged prothrombin time, increased weight

Other adverse events which have been reported in general to occur with leuprorelin acetate treatment include peripheral oedema, pulmonary embolism, palpitations, myalgia, muscle weakness, an alteration in the skin sensation, chills, peripheral vertigo, rash, amnesia and visual disturbances. Muscular atrophy has been observed with long term use of products in this class. Infarction of pre-existing pituitary apoplexy has been reported rarely after administration of both short and long acting GnRH agonists. There have been rare reports of thrombocytopenia and leucopenia. Changes in glucose tolerance have been reported.

Convulsions have been reported after GnRH agonist analogue administration (see section 4.4).

Local adverse events reported after injection of ELIGARD are similar to the local adverse events associated with similar subcutaneously injected products.

Generally, these localised adverse events following subcutaneous injection are mild and described as being of brief duration.

Anaphylactic/anaphylactoid reactions have been reported rarely after GnRH agonist analogue administration.

Changes in Bone Density
Decreased bone density has been reported in the medical literature in men who have had orchiectomy or who have been treated with a GnRH analogues. It can be anticipated that long periods of treatment with leuprorelin may show increasing signs of osteoporosis. Regarding the increased risk for fractures owing to osteoporosis (see section 4.4).

Exacerbation of signs and symptoms of the disease
Treatment with leuprorelin acetate can cause exacerbations of signs and symptoms of the disease during the first few weeks. If conditions such as vertebral metastases and/or urinary obstruction or haematuria are aggravated, neurological problems, such as weakness and/or paraesthesia of the lower limbs or worsening of urinary symptoms may occur.

4.9 Overdose

ELIGARD does not have the potential for abuse, and deliberate overdose is unlikely. There are no reports of abuse or overdose having occurred in clinical practice with leuprorelin acetate, but in the event that excessive exposure becomes a reality, observation and symptomatic supportive treatment are recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Gonadotropin releasing hormone analogues
ATC code: L02A E02

Leuprorelin acetate is a synthetic nonapeptide agonist of naturally occurring gonadotropin releasing hormone (GnRH) that, when given continuously, inhibits pituitary gonadotropin secretion and suppresses testicular steroidogenesis in males. This effect is reversible upon discontinuation of medicinal product therapy. However, the agonist possesses greater potency than the natural hormone and the time to recovery of testosterone levels may vary between patients.

Administration of leuprorelin acetate results in an initial increase in circulating levels of luteinising hormone (LH) and follicle stimulating hormone (FSH), leading to a transient increase in levels of the gonadal steroids, testosterone and dihydrotestosterone in males.

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Continuous administration of leuprorelin acetate results in decreased levels of LH and FSH. In males, testosterone is reduced to below castrate threshold (≤ 50 ng/dL).

ELIGARD 22.5 mg : These decreases occur within three to five weeks after initiation of treatment. Mean testosterone levels at six months are 10.1 (± 0.7) ng/dL, comparable to levels following bilateral orchiectomy. All patients who received the full dose of 22.5 mg leuprorelin in the pivotal clinical study reached castrate levels at 5 weeks; 99 % had reached this by day 28. In the vast majority of patients the testosterone levels seen were below 20 ng/dL although the full benefit of these low levels has not yet been established. PSA levels decreased by 98% over six months.

ELIGARD 45 mg : These decrease occur within three to four weeks after initiation of treatment. Mean testosterone levels at six months are 104 (± 0.53) ng/dL, comparable to levels following bilateral orchiectomy. All but one patient who received the full dose of 45 mg leuprorelin in the pivotal clinical study reached castrate levels at 4 weeks. In the vast majority of patients the testosterone levels seen were below 20 ng/dL although the full benefit of these low levels has not yet been established. PSA levels decreased by 97% over six months

Long-term studies have shown that continuation of therapy maintains testosterone below the castrate level for up to seven years, and presumably indefinitely.

Tumour size was not measured directly during the clinical trial programme, but there was an indirect beneficial tumour response as shown by a 94% reduction in mean PSA for ELIGARD 7.5 mg, 98% reduction for ELIGARD 22.5 mg and 97% reduction for ELIGARD 45 mg.

5.2 Pharmacokinetic properties

Absorption:
ELIGARD 22.5 mg:
In patients with advanced carcinoma of the prostate, mean serum leuprorelin concentrations following the initial injection rise to 127ng/ml at 4.6 hr (Cmax) after injection. After the initial increase following each injection (the plateau phase from 3 - 84 days after each dose), serum concentrations remained relatively constant (0.2 – 2 ng/ml). There is no evidence of accumulation during repeated dosing.

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ELIGARD 45 mg:
In patients with advanced carcinoma of the prostate, mean serum leuprorelin concentrations following the initial injection rise to 82 ng/ml at 4.4 hr (Cmax) after injection. After the initial increase following each injection (the plateau phase from 3 - 168 days after each dose), serum concentrations remained relatively constant (0.2 – 2 ng/ml). There is no evidence of accumulation during repeated dosing.

Distribution: The mean steady-state volume of distribution of leuprorelin following intravenous bolus administration to healthy male volunteers was 27 liters. In vitro binding to human plasma proteins ranged from 43% to 49%.

Elimination: In healthy male volunteers, a 1 mg bolus of leuprorelin acetate administered intravenously revealed that the mean systemic clearance was 8.34 l/h, with a terminal elimination half-life of approximately 3 hours based on a two compartment model.

No excretion studies have been conducted with ELIGARD.

No drug metabolism study was conducted with ELIGARD.

5.3 Preclinical safety data

Preclinical studies with leuprorelin acetate, revealed in both sexes effects on the reproductive system, which were expected from the known pharmacological properties. These effects were shown to be reversible after discontinuation of the treatment and an appropriate period of regeneration. Leuprorelin acetate did not show teratogenicity. Embryotoxicity/lethality was observed in rabbits, in line with the pharmacological effects of leuprorelin acetate on the reproductive system.

Carcinogenicity studies were performed in rats and mice over 24 months. In rats, a dose- related increase in pituitary apoplexy was observed after subcutaneous administration at doses of 0.6 to 4 mg/kg/day. No such effect was observed in mice.

Leuprorelin acetate and related one-month product ELIGARD 7.5 mg were not mutagenic in a set of in vitro and in vivo assays.

Reporting side effects

If there are complaints of side effects or uncomfortable conditions during and after using the drug, consult a doctor, pharmacist, or nurse. You can also report complaints of side effects or uncomfortable conditions directly to the Pharmaceutical Industry through the following contacts:
PT. Meprofarm Pharmaceutical Industries
Jl. Soekarno Hatta 789
Bandung 40294
Jawa Barat, Indonesia
Phone Contact 022-7805588 ext. 2176 or ext. 1155 (8:00 AM - 5:00 PM WIB) every weekday
Report via the link www.epv.meprofarm.com or BPOM Pharmacovigilance Center via email at pv-center@pom.go.id

By reporting side effects, you can help provide more information about the safety of this drug

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

ELIGARD 22.5 mg
Solvent (syringe A): Poly (DL-lactic-co-glycolic-acid) (75:25) N-Methylpyrrolidone
ELIGARD 45 mg
Solvent (syringe A): Poly(DL-lactic-co-glycolic-acid) (85:15) N-Methylpyrrolidone

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Powder (syringe B): None

6.2 Incompatibilities

The leuprorelin present in syringe B must only be mixed with the solvent in syringe A and must not be mixed with other medicinal products.

6.3 Nature and contents of container

Two pre-filled syringes, one containing powder (Syringe B), and one containing solvent (Syringe A). Together the two syringes comprise a mixing system.

Syringe A has a plunger tip of thermoplastic rubber and is capped with a polyethylene or polypropylene Luer Lock cover. The syringe tip cap is composed of bromobutyl rubber and the two plunger tips of Syringe B are composed of chlorobutyl rubber.

The following pack sizes are available:
ELIGARD ELIGARD 22.5 mg:

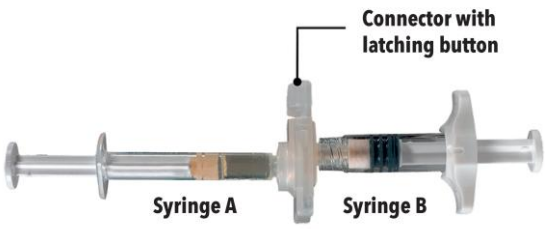
- A kit consisting of two thermoformed trays in a cardboard carton. One tray contains one pre-filled syringe A, a large plunger rod and a desiccant pouch. The other tray contains pre-filled syringe B, a 20-gauge sterile needle and a silicone desiccant pouch.

ELIGARD 45 mg
A kit consisting of two thermoformed trays in a cardboard carton. One tray contains pre-filled syringe A, a large plunger rod for syringe B and a desiccant pouch. The other tray contains pre-filled syringe B, a sterile 18-gauge needle and a desiccant pouch.

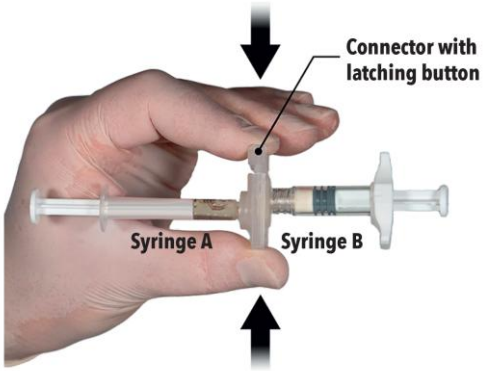
6.4 Special precautions for disposal and other handling

Please proceed as follows:
Allow the product to come to room temperature by removing from the refrigerator prior to use.
Please prepare the patient for injection first, followed by the preparation of the product, using the instructions below.

Step 1:
On a clean field, open the tray by tearing off the foil from the corners to remove the contents. Discard the desiccant pouch. Remove the pre-connected syringe system (Figure 1.1) from the tray. Open the safety needle package (Figure 1.2) by peeling back the paper tab. Note: Syringe A and Syringe B should not be lined-up yet.

Tray Contents: pre-connected syringe system	Under the Tray: safety needle and cap
	 Safety needle and cap

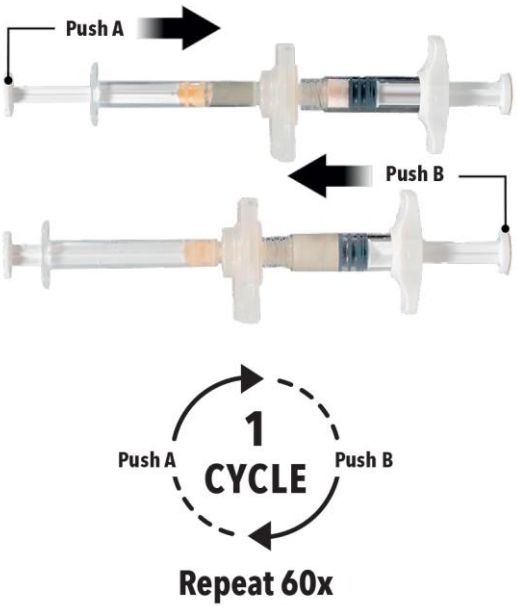
Step 2:
Grasp the latching button on the connector with your finger and thumb and press (Figure 2) until you hear a snapping sound. The two syringes will be lined up. No particular orientation of the syringe system is required to activate the connector. Do not bend the syringe system (please note that this may cause leakage as you may partially unscrew the syringes).



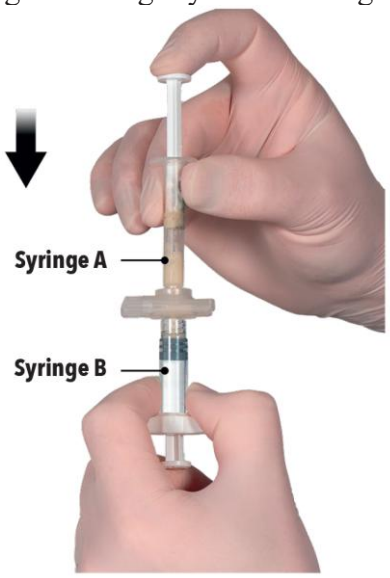
Step 3:
Holding the syringes in a horizontal position, transfer the liquid contents of Syringe A into the leuprorelin acetate powder contained in Syringe B. Thoroughly mix the product for 60 cycles by gently pushing the contents of both syringes back and forth between both syringes (a cycle is one push of the plunger for Syringe A and one push of the plunger for Syringe B) in a horizontal position to obtain a homogenous, viscous solution (Figure 3). Do not bend the syringe system (please note that this may cause leakage as you may partially unscrew the syringes).

When thoroughly mixed, the viscous solution will appear with a colour in the range of colourless to white to pale brown (which could include shades of white to pale yellow). Important: After mixing proceed with the next step immediately as the product gets more viscous over time. Do not refrigerate the mixed product.

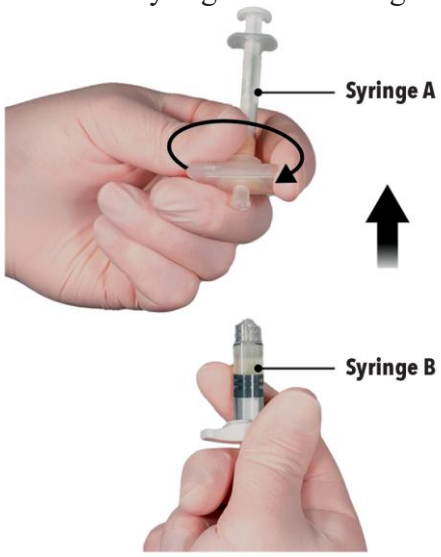
Please note: Product must be mixed as described; shaking WILL NOT provide adequate mixing of the product.



Step 4:
After mixing, hold the syringes vertically with Syringe B on the bottom. The syringes should remain securely coupled. Draw the entire mixed product into Syringe B (short, wide syringe) by pushing down the Syringe A plunger and slightly withdrawing the Syringe B plunger (Figure 4).



Step 5:
While ensuring Syringe A plunger is fully pushed down, hold the connector and unscrew it from Syringe B. Syringe A will remain attached to the connector (Figure 5). Ensure that no product leaks out as the needle will then not secure properly when attached.
Please note: one large or a few small air bubbles may remain in the formulation - this is acceptable.
Please do not purge the air bubbles from Syringe B at this stage as product may be lost!

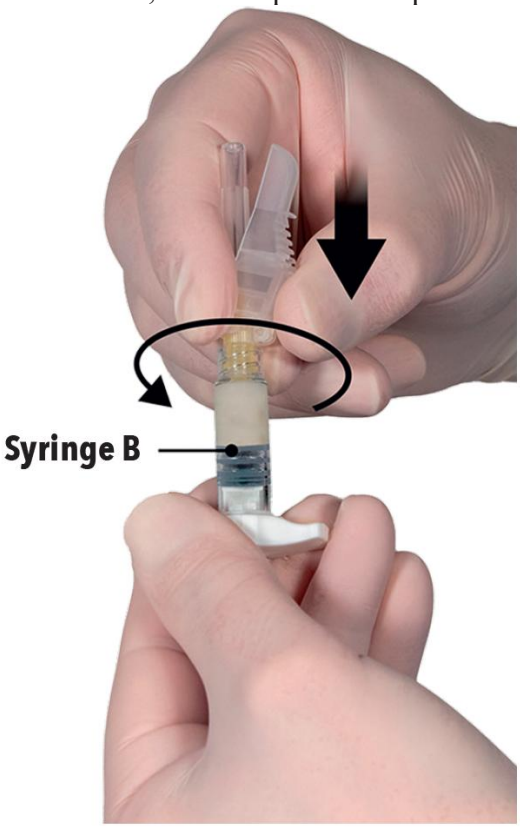


Step 6:
• Hold Syringe B upright and hold back the white plunger to prevent loss of the product.
• Secure the safety needle to Syringe B by holding the syringe and gently turning the needle clockwise with approximately a three-quarter turn until the needle is secure (Figure 6).

Do not over tighten as this may cause cracking of the needle hub resulting in leakage of the product during injection. The safety shield may also be damaged if the needle is screwed with too much force.

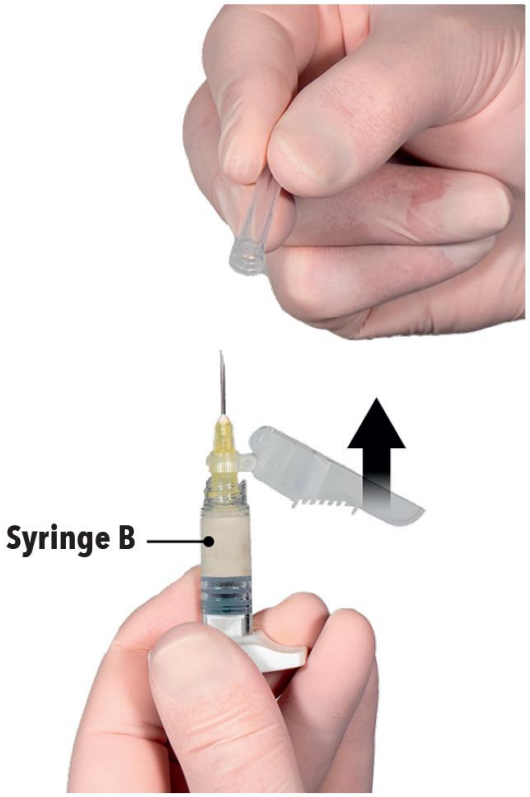
Should the needle hub crack, appear to be damaged, or have any leakage, the product should not be used. The damaged
needle should not be substituted/replaced and the product should not be injected. The entire product should be disposed of securely.

In the event of damage to the needle hub, a new replacement product should be used.



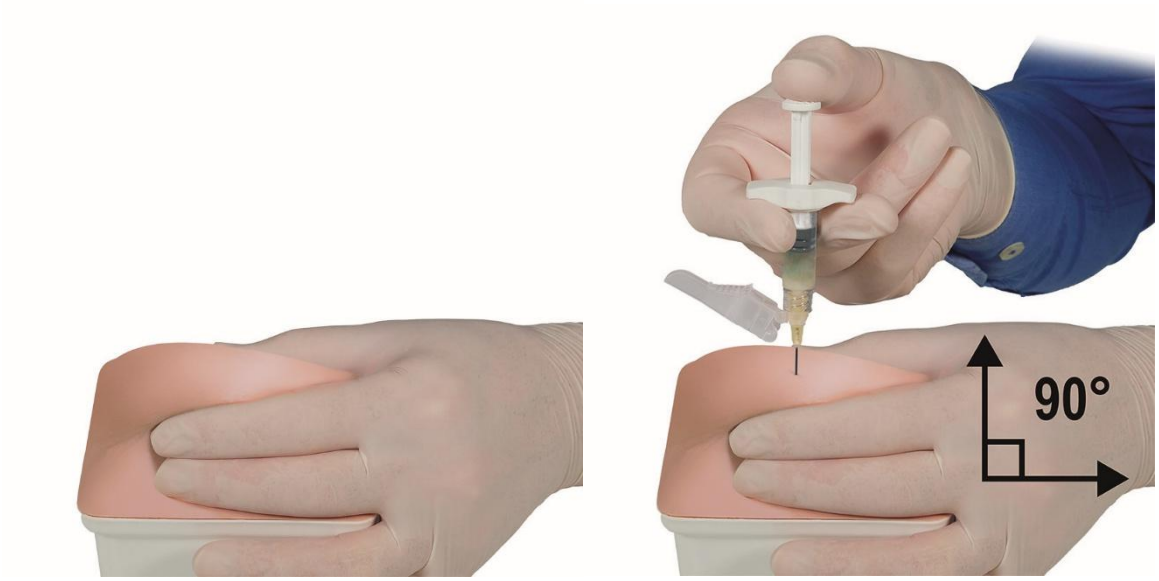
Step 7:
Move the safety shield away from the needle and pull off the protective needle cover immediately prior to administration.

Important: Do not operate the safety needle mechanism before administration. Should the needle hub appear to be damaged, or leak, the product should NOT be used. The damaged needle should NOT be replaced and the product should NOT be injected. In the event of damage to the needle hub, use another ELIGARD kit.

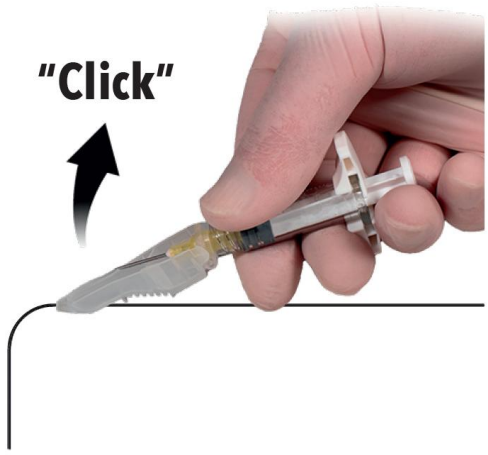


Step 8:
Prior to administration, purge any large air bubbles from Syringe B. Administer the product subcutaneously whilst
keeping the safety shield away from the needle.

Administration Procedure:
• Select an injection site on the abdomen, upper buttocks, or another location with adequate amounts of subcutaneous
tissue that does not have excessive pigment, nodules, lesions, or hair and has not recently been used.
• Cleanse the injection-site area with an alcohol swab (not enclosed).
• Using the thumb and forefinger, grab and bunch the area of skin around the injection site.
• Using your dominant hand, insert the needle quickly at a 90° angle to the skin surface. The depth of penetration will depend on the amount and fullness of the subcutaneous tissue and the length of the needle. After the needle is
inserted, release the skin.
• Inject the drug using a slow, steady push and press down on the plunger until the syringe is empty. Please ensure that the full amount of the product in Syringe B is injected before removing the needle.
• Withdraw the needle quickly at the same 90° angle used for insertion while maintaining pressure on the plunger..



Step 9:
After injection, lock the safety shield using any of the activation methods listed below.

1. Closure on a flat surface	2. Closure with your thumb
Press the safety shield, lever side down, onto a flat surface (Figure 9a) to cover the needle and lock the shield. Verify locked position through audible and tactile "click". Locked position will completely cover needle tip.	Placing your thumb on the safety shield (Figure 9b), cover the needle tip and lock the shield. Verify locked position through audible and tactile "click". Locked position will completely cover needle tip.
	OR
	

Once safety shield is locked, immediately dispose of the needle and syringe in an approved sharps container.

PACKAGING :

ELIGARD 22.5 mg and 45 mg: 1 Box of Syringe A (solvent) + Syringe B (Leuprorelin acetate)

SHELF LIFE

2 years
Once the product has been removed from the refrigerator, it may be stored in the original packaging at room temperature (below 25°C) for up to eight weeks.
After first opening of the tray or the large outer aluminium pouch, the powder and solvent for solution for injection are to be immediately reconstituted and administered to the patient.

Once reconstituted: use immediately, as the viscosity of the solution increases with time

STORAGE :
Store in a refrigerator (2°C – 8°C); in the original package in order to protect from moisture. This product must be at room temperature prior to injection. Remove from the refrigerator approximately 30 minutes before use. Once outside the refrigerator this product may be stored in its original packaging at room temperature (below 25°C) for up to eight weeks.

NATURE AND CONTENTS OF CONTAINER
A pre-connected syringe system consisting of:
• one pre-filled cyclic olefin copolymer syringe containing powder (Syringe B)
• one pre-filled polypropylene syringe containing solvent (Syringe A)
• a connector with latching button for Syringe A and B.

Syringe A has a plunger tip of thermoplastic rubber. The plunger tip of Syringe B is composed of chlorobutyl rubber.

The following pack sizes are available:

ELIGARD 22.5mg:
• A kit consisting of a thermoformed tray and a 20-gauge sterile needle in a cardboard carton. The tray contains one pre-connected syringe system and a desiccant pouch.
• A bundle pack containing kits of 3 pre-connected syringe system

ELIGARD 45 mg:
• A kit consisting of a thermoformed tray and a 18-gauge sterile needle in a cardboard carton. The tray contains one pre-connected syringe(s) system and a desiccant pouch.
• A bundle pack containing kits of 2 pre-connected syringe system

Not all pack sizes may be marketed.

"HARUS DENGAN RESEP DOKTER"

DISETUJUI OLEH BPOM: 22/01/2026
ID: EREG100255VR12500252 EREG100255VR12400024
EREG100255VR12500253 EREG100255VR12400023

REG NO:
ELIGARD 22,5 mg powder and solvent for solution for injection :

DKI XXXXXXXX (Tolmar Inc., Fort Collins, USA)

DKI XXXXXXXX (Tolmar Inc., Windsor, USA)

ELIGARD 45 mg powder and solvent for solution for injection :

DKI XXXXXXXX (Tolmar Inc., Fort Collins, USA)

DKI XXXXXXXX (Tolmar Inc., Windsor, USA)

MANUFACTURED BY
Tolmar Inc.
701 Centre Avenue, Fort Collins, CO 80526, USA.

Tolmar, Inc., 1201 Cornerstone Drive,
Windsor, CO 80550, USA

IMPORTED AND MARKETED BY:
PT. DCH Auriga Indonesia, Jakarta-Indonesia

MARKETING AUTHORISATION HOLDER
PT. Meprofarm Pharmaceutical Industries, Bandung-Indonesia

DISETUJUI OLEH BPOM: 22/01/2026 ID: EREG100255VR12500252 EREG100255VR12400024
EREG100255VR12500253 EREG100255VR12400023

Informasi untuk Pasien
ELIGARD
***Leuproline acetate* untuk injeksi**

Bacalah leaflet ini dengan seksama sebelum anda mengkonsumsi ELIGARD karena leaflet ini mengandung informasi yang penting untuk anda.
- Simpanlah leaflet ini untuk dibaca kembali.
- Hubungi dokter atau apoteker anda apabila ada pertanyaan lebih lanjut.
- Obat ini diresepkan khusus kepada anda. Dilarang memberikan obat ini kepada orang lain, karena dapat membahayakan bagi orang lain, walaupun gejala dan penyakitnya sama seperti anda.
- Jika anda mengalami efek samping, bicarakan dengan dokter atau apoteker anda. Hal ini termasuk efek samping yang tidak tercantum dalam leaflet ini.

TENTANG ELIGARD

Apa kegunaan dari ELIGARD?
ELIGARD digunakan sebagai pengobatan untuk kanker prostat.
ELIGARD harus diberikan oleh tenaga kesehatan profesional.

Apa itu ELIGARD?
ELIGARD termasuk dalam golongan obat analog *leutinizing hormone-releasing hormone* (analog LH-RH).
ELIGARD bekerja dengan menekan produksi hormon testosteron, hormon alami pria yang dihasilkan oleh testis. Sel-sel pada kanker prostat membutuhkan hormon testosteron untuk pertumbuhannya. Jika jumlah hormon testosteron dalam tubuh menurun, pada umumnya kanker prostat akan mengecil atau berhenti tumbuh, sehingga dapat menurunkan gejala yang berkaitan dengan penyakit tersebut.

Kapan tidak boleh menggunakan ELIGARD?
- Jika alergi terhadap salah satu dari komponen ELIGARD (lihat bagian zat aktif dan zat tambahan di bawah ini) atau jika pernah mengalami reaksi alergi dengan penggunaan ELIGARD atau obat seperti ELIGARD.
- Jika anda wanita.

Zat aktif Eligard : Leuproline acetate

Zat tambahan Eligard **:** N-methyl-2-pyrrolidone
Poly (DL-lactide-co-glycolide)

Seperti apa kemasan ELIGARD?
Kemasan ELIGARD terdiri dari 2 (dua) suntikan. Satu suntikan mengandung zat aktif dalam bentuk serbuk. Suntikan yang lain digunakan untuk melarutkan serbuk. Isi dari kedua suntikan ini dicampur sesaat sebelum digunakan.

ELIGARD 22.5mg (3 bulan): Injeksi 1 (satu) kali tiap 3 (tiga) bulan
ELIGARD 45mg (6 bulan): Injeksi 1 (satu) kali tiap 6 (enam) bulan

ELIGARD bekerja terus menerus dan konsisten di antara waktu injeksi.

PERINGATAN DAN PERHATIAN

PERINGATAN DAN PERHATIAN SERIUS
ELIGARD harus diresepkan oleh dokter yang sudah berpengalaman dengan jenis obat seperti ini.

ELIGARD dapat menyebabkan:
- Memburuknya gejala dari kanker prostat di awal pengobatan

- Pengeroposan tulang

ELIGARD tidak boleh digunakan untuk wanita dan anak – anak dibawah 18 tahun.

Sebelum menggunakan ELIGARD bicarakan dengan dokter atau apoteker anda jika anda:
- Alergi terhadap *leuproline acetate*.
- Menggunakan obat-obatan lainnya yang diresepkan dokter.
- Mempunyai riwayat gangguan saluran kemih.
- Mengalami kanker yang telah menyebar ke tulang belakang atau mempunyai riwayat kompresi/penekanan tulang belakang.
- Memiliki penyakit anemia.
- Keluarga anda mempunyai riwayat osteoporosis yang berat. ELIGARD dapat meningkatkan risiko osteoporosis dan patah tulang.
- Memiliki penyakit diabetes (kadar gula di dalam darah tinggi)
- Memiliki riwayat penyakit jantung

EFEK SAMPING YANG DAPAT TERJADI

Efek samping yang biasanya terjadi:
- Rasa terbakar pada wajah
- Warna kemerahan pada kulit
- Rasa kelelahan
- Rasa terbakar pada tempat yang disuntikkan

Efek samping yang dapat terjadi:
- Gangguan tekanan darah
- Mual dan diare
- Berkeringat di malam hari
- Nyeri otot
- Rasa tidak nyaman pada tempat yang disuntikkan

Jika terdapat efek samping, bicarakan dengan dokter atau apoteker anda. Termasuk efek samping yang tidak tercantum di dalam leafet ini.

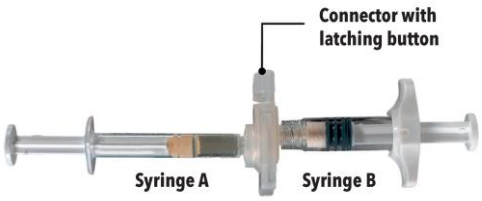
CARA PENGGUNAAN

Gunakan seperti cara yang tertulis dibawah ini:

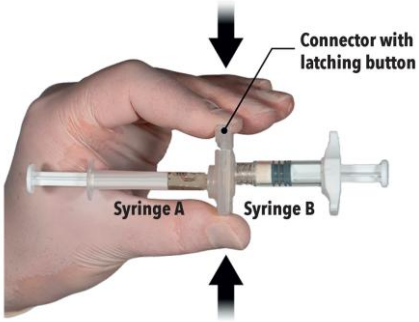
Tempatkan obat pada suhu ruangan dengan memindahkannya dari kulkas sebelum digunakan.

Siapkan pasien terlebih dahulu, diikuti dengan persiapan produk dengan menggunakan instruksi dibawah ini:

Langkah 1:
Pada tempat yang bersih, buka baki dengan merobek lapisan foil dari sudut-sudutnya untuk mengeluarkan isinya. Buang kantong pengering. Lepaskan sistem jarum suntik yang telah terhubung sebelumnya (Gambar 1.1) dari baki. Buka kemasan jarum pengaman (Gambar 1.2) dengan mengupas tab kertas.
Catatan: Jarum suntik A dan jarum suntik B belum boleh sejajar.

Isi Wadah : sistem jarum suntik yang sudah terhubung sebelumnya	Di Bawah Baki: jarum pengaman dan tutup
	

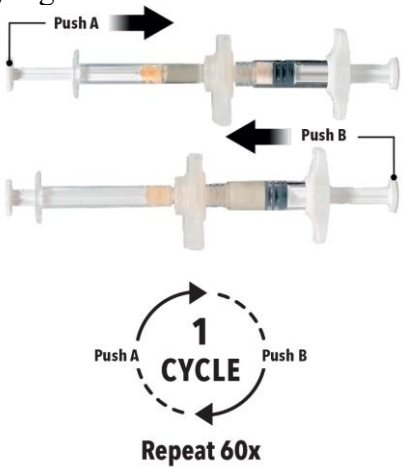
Langkah 2:
Pegang tombol pengunci pada konektor dengan jari dan ibu jari Anda, lalu tekan (Gambar 2) hingga terdengar bunyi klik. Kedua spuit akan sejajar. Tidak diperlukan orientasi khusus sistem spuit untuk mengaktifkan konektor. Jangan menekuk sistem spuit (perhatikan bahwa hal ini dapat menyebabkan kebocoran karena Anda mungkin membuka sebagian spuit).



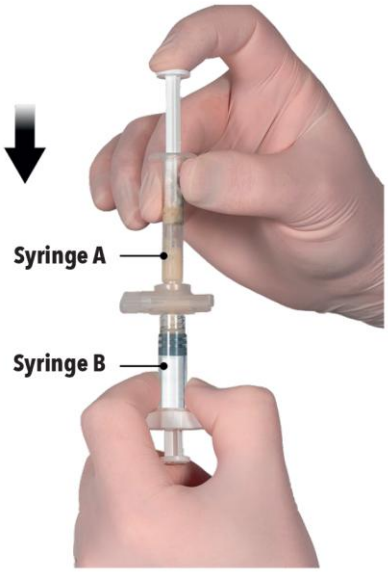
Langkah 3:
Dengan memegang spuit dalam posisi horizontal, pindahkan isi cairan dari Spuit A ke dalam bubuk leuprorelin asetat yang terdapat dalam Spuit B. Aduk produk secara menyeluruh selama 60 siklus dengan mendorong isi kedua spuit secara perlahan bolak-balik di antara kedua spuit (satu siklus adalah satu dorongan pendorong untuk Spuit A dan satu dorongan pendorong untuk Spuit B) dalam posisi horizontal untuk mendapatkan larutan yang homogen dan kental (Gambar 3). Jangan membengkokkan sistem spuit (perlu diketahui bahwa hal ini dapat menyebabkan kebocoran karena Anda dapat membuka sebagian spuit).

Setelah tercampur rata, larutan kental akan muncul dengan warna berkisar antara tidak berwarna, putih, hingga cokelat pucat (yang dapat mencakup nuansa putih hingga kuning pucat). Penting: Setelah pencampuran, segera lanjutkan ke langkah berikutnya karena produk akan semakin kental seiring waktu. Jangan simpan produk yang telah dicampur di lemari es.

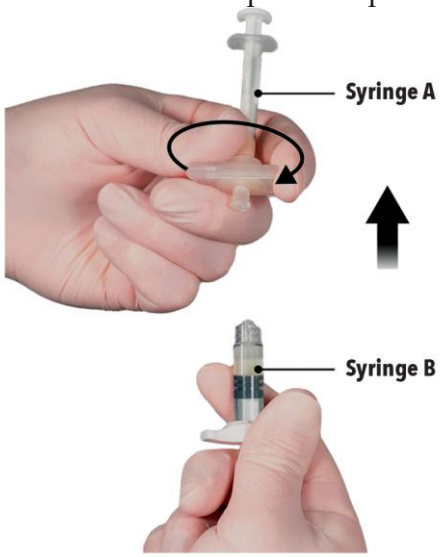
Harap diperhatikan: Produk harus dicampur sesuai petunjuk; pengocokan TIDAK AKAN memastikan pencampuran produk yang memadai.



Langkah 4:
Setelah pencampuran, pegang spuit secara vertikal dengan Spuit B di bawah. Spuit harus tetap terpasang erat. Tarik seluruh produk yang telah tercampur ke dalam Spuit B (semprit pendek dan lebar) dengan menekan plunger Spuit A ke bawah dan sedikit menarik plunger Spuit B (Gambar 4).



Langkah 5:
Sambil memastikan plunger Jarum Suntik A terdorong sepenuhnya ke bawah, pegang konektor dan lepaskan dari Jarum Suntik B. Jarum Suntik A akan tetap terpasang pada konektor (Gambar 5). Pastikan tidak ada produk yang bocor karena jarum tidak akan terpasang dengan benar.
Harap diperhatikan: satu gelembung udara besar atau beberapa gelembung udara kecil mungkin masih tersisa di dalam formulasi - hal ini dapat diterima.
Jangan buang gelembung udara dari Jarum Suntik B pada tahap ini karena produk mungkin hilang!

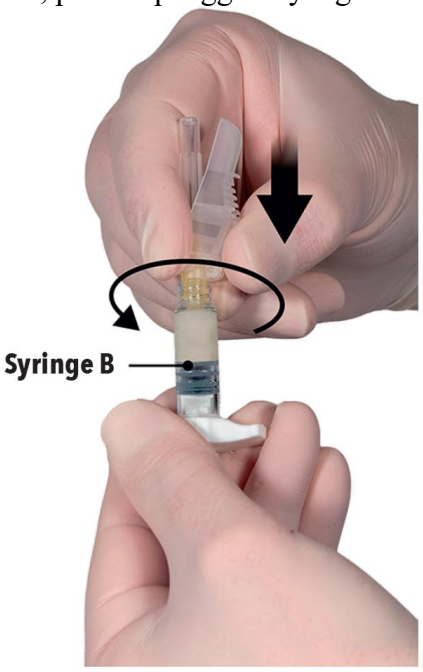


Langkah 6:
• Pegang Spuit B tegak lurus dan tahan plunger putih untuk mencegah produk tumpah.
• Pasangkan jarum pengaman ke Spuit B dengan memegang spuit dan memutar jarum searah jarum jam secara perlahan sekitar tiga perempat putaran hingga jarum terpasang dengan aman (Gambar 6).

Jangan memutar terlalu kencang karena dapat menyebabkan retak pada hub jarum yang mengakibatkan kebocoran produk selama penyuntikan. Pelindung pengaman juga dapat rusak jika jarum disekrup terlalu kuat.

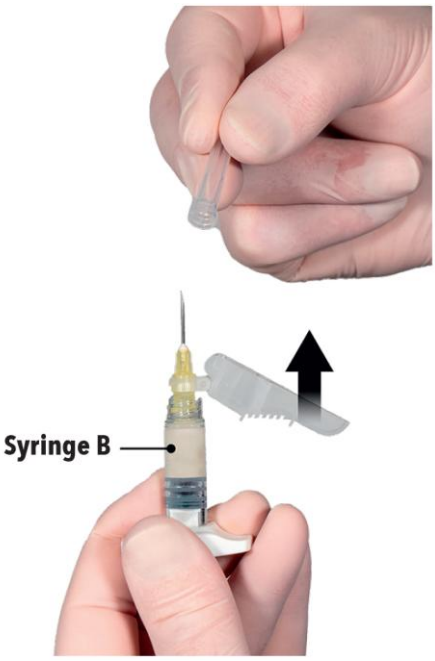
Jika hub jarum retak, tampak rusak, atau bocor, produk tersebut tidak boleh digunakan. Jarum yang rusak tidak boleh diganti dan produk tidak boleh disuntikkan. Seluruh produk harus dibuang dengan aman.

Jika terjadi kerusakan pada hub jarum, produk pengganti yang baru harus digunakan.



Langkah 7:
Jauhkan pelindung jarum dari jarum dan lepaskan penutup jarum pelindung segera sebelum penyuntikan.

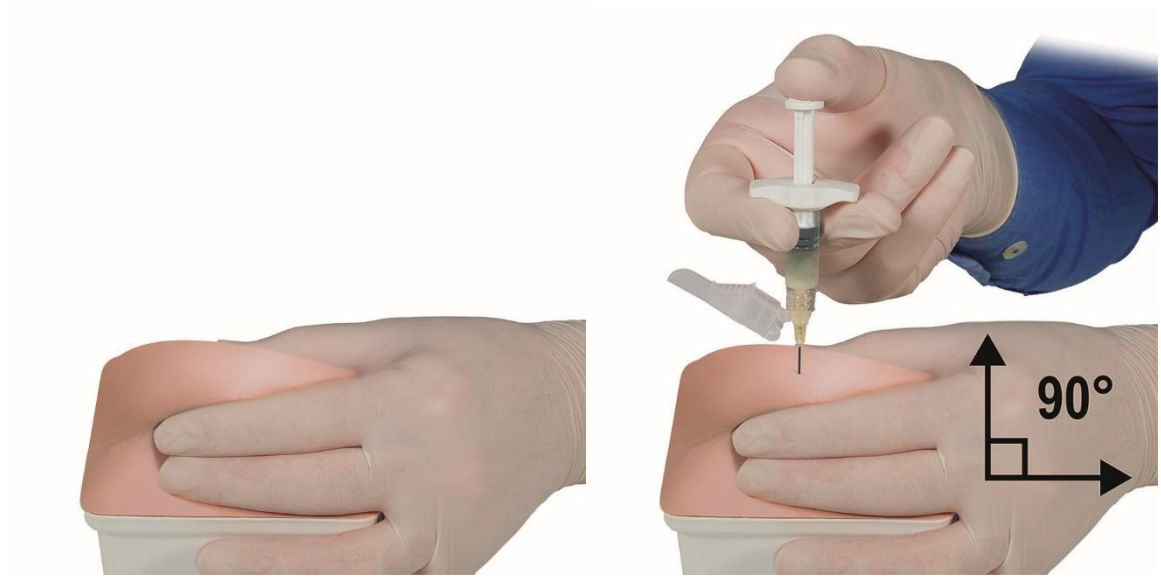
Penting: Jangan mengoperasikan mekanisme jarum pengaman sebelum penyuntikan. Jika hub jarum tampak rusak, atau bocor, produk TIDAK BOLEH digunakan. Jarum yang rusak TIDAK BOLEH diganti dan produk TIDAK BOLEH disuntikkan. Jika terjadi kerusakan pada hub jarum, gunakan kit ELIGARD lain.



Langkah 8:
Sebelum pemberian, bersihkan gelembung udara yang besar dari Spuit B. Berikan produk secara subkutan sambil menjauhkan pelindung pengaman dari jarum.

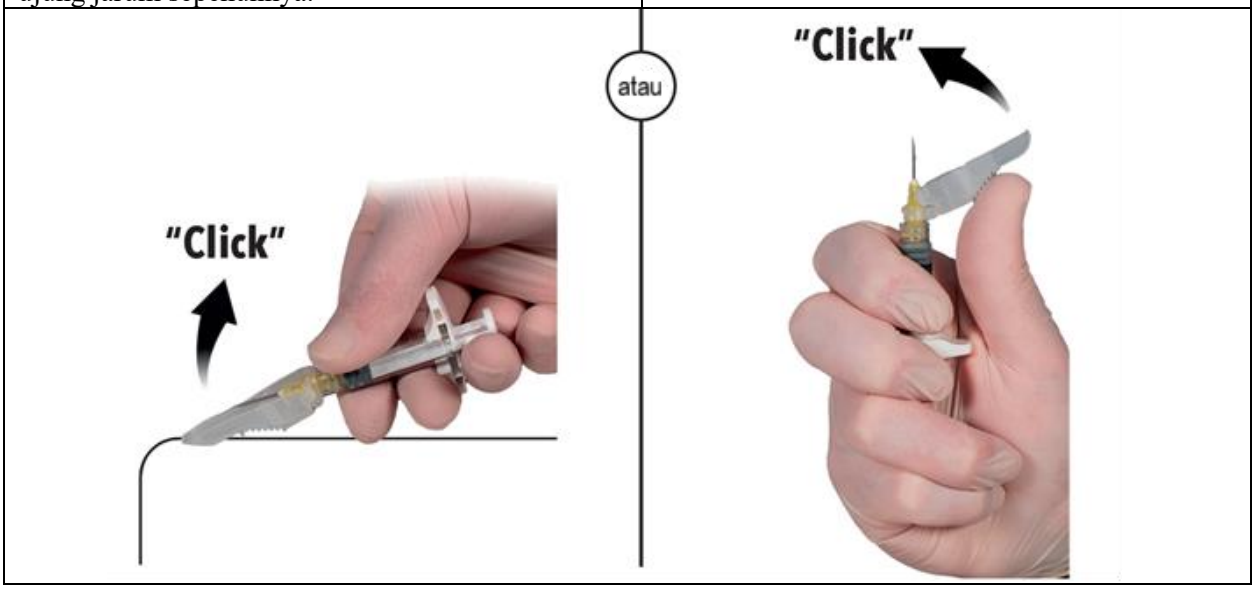
Prosedur Pemberian:

- Pilih lokasi suntikan di perut, bokong atas, atau lokasi lain dengan jumlah jaringan subkutan yang memadai
- yang tidak memiliki pigmen, nodul, lesi, atau rambut berlebih dan belum pernah digunakan baru-baru ini.
- Bersihkan area lokasi suntikan dengan kapas alkohol (tidak disertakan).
- Dengan menggunakan ibu jari dan jari telunjuk, pegang dan tekan area kulit di sekitar lokasi suntikan.
- Dengan menggunakan tangan dominan Anda, masukkan jarum dengan cepat pada sudut 90° terhadap permukaan kulit. Kedalaman penetrasi akan bergantung pada jumlah dan kepenuhan jaringan subkutan serta panjang jarum. Setelah jarum
- dimasukkan, lepaskan kulit.
- Suntikkan obat dengan dorongan perlahan dan stabil, lalu tekan plunger hingga spuit kosong. Pastikan seluruh jumlah produk dalam Alat Suntik B telah disuntikkan sebelum mencabut jarum.
- Tarik jarum dengan cepat pada sudut 90° yang sama dengan sudut penyisipan, sambil tetap menekan plunger.



Langkah 9:
Setelah penyuntikan, kunci pelindung pengaman menggunakan salah satu metode aktivasi yang tercantum di bawah ini.

1. Tutup pada permukaan datar	2. Tutup dengan ibu jari Anda
Tekan pelindung pengaman dengan sisi tuas menghadap ke bawah pada permukaan datar (Gambar 9a) untuk menutup jarum dan mengunci pelindung. Pastikan posisi terkunci melalui bunyi "klik" yang terdengar dan taktil. Posisi terkunci akan menutup ujung jarum sepenuhnya.	Letakkan ibu jari Anda pada pelindung pengaman (Gambar 9b), tutup ujung jarum dan kunci pelindung. Pastikan posisi terkunci melalui bunyi "klik" yang terdengar dan taktil. Posisi terkunci akan menutup ujung jarum sepenuhnya.



Setelah pelindung pengaman terkunci, segera buang jarum dan alat suntik ke dalam wadah benda tajam yang disetujui.

CARA PENYIMPANAN
Simpan dalam lemari es (2°C – 8°C); dalam kemasan aslinya agar terlindung dari kelembapan.
Produk ini harus berada pada suhu ruangan sebelum disuntikkan. Keluarkan dari lemari es sekitar 30 menit sebelum digunakan. Setelah dikeluarkan dari lemari es, produk ini dapat disimpan dalam kemasan aslinya pada suhu ruangan (di bawah 25°C) hingga delapan minggu.

Apabila ada keluhan efek samping atau kondisi tidak nyaman selama dan setelah penggunaan obat, konsultasikan ke dokter, apoteker, atau perawat. Anda dapat juga melaporkan keluhan efek samping atau konsisi tidak nyaman tersebut secara langsung ke Industri Farmasi melalui kontak berikut:
PT. Meprofarm Pharmaceutical Industries
Jl. Soekarno Hatta 789
Bandung 40294
Jawa Barat, Indonesia
Telp. 022-7805588 ext 2176 atau ext. 1155 (jam 08.00-17.00 WIB) setiap hari kerja atau melaporkan melalui link www.epv.meprofarm.com.

Dengan melaporkan efek samping, Anda dapat membantu memberikan informasi lebih lanjut mengenai keamanan obat ini.

“HARUS DENGAN RESEP DOKTER”

REG NO:
ELIGARD 22,5 mg powder and solvent for solution for injection :
DKI XXXXXXXX (Tolmar Inc., Fort Collins, USA)
DKI XXXXXXXX (Tolmar Inc., Windsor, USA)

ELIGARD 45 mg powder and solvent for solution for injection :
DKI XXXXXXXX (Tolmar Inc., Fort Collins, USA)
DKI XXXXXXXX (Tolmar Inc., Windsor, USA)

PEMEGANG IJIN EDAR, PRODUSEN DAN PENGEMAS

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Bandung 40294
Jawa Barat, Indonesia

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Tolmar, Inc.,
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Diimpor dan didistribusikan oleh
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Jakarta-Indonesia