For the use of Registered Medical Practitioner or a Hospital only

MEGAPTH

TERIPARATIDE (r- Human Parathyroid Hormone) (1-34) Injection

750 mcg/3 ml

WARNING

POTENTIAL RISK OF OSTEOSARCOMA

In male and female rats, teriparatide caused an increase in the incidence of osteosarcoma (a malignant bone tumor) that was dependent on dose and treatment duration. The effect was observed at systemic exposures to teriparatide ranging from 3 to 60 times the exposure in humans given a 20-mcg dose. Because of the uncertain relevance of the rat osteosarcoma finding to humans, prescribe teriparatide (rDNA origin) injection only for patients for whom the potential benefits are considered to outweigh the potential risk. Teriparatide (rDNA origin) injection should not be prescribed for patients who are at increased baseline risk for osteosarcoma including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton.

COMPOSITION

Each ml of TERIPARATIDE (r- Human Parathyroid Hormone) (1-34)

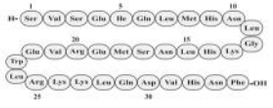
Injection contains:

Recombinant human Parathyroid Hormone (1-34) IHS	250 mcg
Succinic acid USP	0.29 mg
Sodium Hydroxide USP	0.05 mg
Glycerol USP	50 mg
M-Cresol USP	3 mg
Water for Injection USP	q.s.

DRUG DESCRIPTION

Teriparatide (rDNA origin) contains recombinant human parathyroid hormone (1-34), and is also called rhPTH (1-34). It has an identical sequence to the 34 N-terminal amino acids (the biologically active region) of the 84-amino acid human parathyroid hormone.

Teriparatide has a molecular weight of 4117.8 daltons and its amino acid sequence is shown below:



Teriparatide (rDNA origin) is manufactured using a strain of Escherichia coli modified by recombinant DNA technology. Teriparatide injection is available as a clear and colorless solution.

Inactive Ingredients- Succinic acid USP/NF, Sodium hydroxide USP/NF, Glycerol USP/NF, m-cresol USP/NF, Water for injection USP/NF, Hydrochloric acid.

INDICATIONS

MEGAPTH is indicated for the treatment of patients with severe osteoporosis.

Efficacy can be demonstrated up to 14 months of therapy (see clinical studies).

CONTRAINDICATIONS

rh PTH(1-34)(Teriparatide for Injection) is contraindicated in the following patients.

- Hypersensitivity to teriparatide or to any of the excipients of this product.
- Pre-existing hypercalcaemia.
- Severe renal impairment.
- Metabolic bone diseases other than primary osteoporosis (including Hyper Parathyroidism and Paget's disease of bone.)
- Unexplained elevations of alkaline phosphatase.
- Prior external beam or implant radiation therapy to the skeleton.
- Patients with skeletal malignancies or bone metastases should be excluded from treatment with teriparatide.

Posology

DOSAGE AND ADMINISTRATION

Posology and method of administration

Route/Way of administration: Subcutaneous

The recommended dose of formulated rhPTH (1-34) injection is 80 mcl containing 20 mcg teriparatide to be administrated once daily by subcutaneous injection in the thigh or abdomen. rhPTH(1-34) (teriparatide for injection) should be administered initially in an environment in which the patient can assume a supine or sitting position if orthostatic hypotension should occur.

Patients should receive supplemental calcium and vitamin D supplements if dietarry intake is inadequate.

Following cessation of rhPTH (1-34) (teriparatide for injection) therapy, patients may be continued on other osteoporosis therapies.

Use in renal impairment: rhPTH (1-34) (teriparatide for injection) should not be used in patients with severe renal impairment. In patients with moderate renal impairment, rhPTH (1-34) (teriparatide for injection) should be used with cautions.

Use in hepatic impairment: No data are available in patients with impaired hepatic function.

Pediatric: There is no experience in children. rhPTH (1-34) (teriparatide for injection) should be not used in pediatric patients or young adults with open epihyses.

Geriatric: Dosage adjusment based on age is not required

MISSED DOSE: If you missa dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

CLINICAL PHARMACOLOGY

Mechanism of Action

Endogenous 84-amino acid parathyroid hormone (PTH) is the primary regulator of calcium and phosphate metabolism in bone and kidney. Teriparatide is the active fragment (1-34) of endogenous human parathyroid hormone. Physiological actions of PTH include stimulation of bone formation by direct effects on bone forming cells (osteoblasts), indirectly increasing the intestinal absorption of calcium and increasing the tubular re-absorption of calcium and excretion of phosphate by the kidney.

Pharmacodynamic Effects

Teriparatide is a bone formation agent to treat osteoporosis. The skeletal effects of Teriparatide depend upon the pattern of systemic exposure. Once daily administration of Teriparatide increases apposition of new bone on trabecular and cortical bone surfaces by preferential stimulation of osteoblastic activity over osteoclastic activity.

PHARMACOKINETICS

Teriparatide is extensively absorbed after subcutaneous injection; peak plasma concentrations are reached after about 30 minutes. Absolute bioavailability is reported to be about 95%. Teriparatide is eliminated through hepatic and extra hepatic clearance (approximately 62 L/hr in women and 94 L/hr in men). The volume of distribution is approximately 1.7 L/kg. The half-life of teriparatide is approximately 1 hr. when administered subcutaneously, which reflects the time required for absorption from the injection site. No metabolism or excretion studies with teriparatide have been reported but the peripheral metabolism of parathyroid hormone is believed to occur predominantly in liver and kidney.

Pharmacokinetics in special population:

Teriparatide is extensively absorbed after subcutaneous injection; the absolute bioavailability is approximately 95% based on pooled data from 20, 40, and 80-mcg doses. The rates of absorption and elimination are rapid. The peptide reaches peak serum concentrations about 30 minutes after subcutaneous injection of a 20-mcg dose and declines to non-quantifiable concentrations within 3 hours.

Systemic clearance of teriparatide (approximately 62 L/hr in women and 94 L/hr in men) exceeds the rate of normal liver plasma flow, consistent with both hepatic and extra-hepatic clearance. Volume of distribution, following intravenous injection, is approximately 0.12 L/kg. Intersubject variability in systemic clearance and volume of distribution is 25% to 50%. The half-life of teriparatide in serum is 5 minutes when administered by intravenous injection and approximately 1 hour when administered by subcutaneous injection. The longer half-life following subcutaneous administration reflects the time required for absorption from the injection site.

No metabolism or excretion studies have been performed with teriparatide. Peripheral metabolism of PTH is believed to occur by non-specific enzymatic mechanisms in the liver followed by excretion via the kidneys.

Special Populations

Pediatric - Pharmacokinetic data in pediatric patients are not available.

Geriatric - No age-related differences in teriparatide pharmacokinetics were detected (range 31 to 85 years).

Gender - Although systemic exposure to teriparatide was approximately 20% to 30% lower in men than women, the recommended dose for both genders is 20 mcg/day.

Race - The populations included in the pharmacokinetic analyses were 98.5% Caucasian. The influence of race has not been determined.

Renal insufficiency - No pharmacokinetic differences were identified in 11 patients with mild or moderate renal insufficiency [creatinine clearance (CrCl) 30 to 72 mL/min] administered a single dose of teriparatide. In 5 patients with severe renal insufficiency (CrCl < 30 mL/min), the AUC and $t_{1/2}$ of teriparatide were increased by 73% and 77%, respectively. Maximum serum concentration of teriparatide was not increased. No studies have been performed in patients undergoing dialysis for chronic renal failure.

Heart failure - No clinically relevant pharmacokinetic, blood pressure, or pulse rate differences were identified in 13 patients with stable New York Heart Association Class I to III heart failure after the administration of two 20-mcg doses of teriparatide.

Hepatic insufficiency - Non-specific proteolytic enzymes in the liver (possibly Kupffer cells) cleave PTH(1-34) and PTH(1-84) into fragments that are cleared from the circulation mainly by the kidney. No studies have been performed in patients with hepatic impairment.

SIDE EFFECTS

The following convention has been used for the classification of the adverse reactions: very common (≥1/10), common (≥1/100 to < 1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10.000 to <1/1.000), very rare (<1/10,000), not known (cannot be estimated from the available data). The most commonly reported adverse events in patients treated with teriparatide are nausea, pain in limb, headache and dizziness.

Table I : Very Common Adverse Events (≥1/10)

System Organ Class	Adverse Event	Teriparatide %	Placebo %
Musculoskeletal and connective tissue and bone disorders	Pain in limb	10.0	9.0

Table II : Common Adverse Events (≥1/100 to <1/10)

System Organ Class	Adverse Event	Teriparatide %	Placebo %
Blood and lymphatic system disorders	Anemia	1.7	1.3
Metabolism and nutrition disorders	Hypercholesterolemia	2.6	2.3
Psychiatric disorders	Depression	4.1	2.5
Nervous system disorders	Dizziness	8.0	5.2
	Headache	7.7	7.4
	Sciatica	1.3	0.7
Ear and labyrinth disorders	Vertigo	3.6	2.5
Cardiac disorders	Palpitation	1.4	1.2
Vascular disorders	Hypotension	1.0	1.0
Respiratory, thoracic and mediastinal disorders	Dyspnea	3.3	2.3
Gastro-intestinal disorders	Nausea	8.5	6.2
	Vomitting	3.3	2.6
	Hiatus hernia	1.0	0.9
	Gastro-esophageal reflux disease	1.0	0.4
Skin & subcutaneous tissue disorders	Sweating increased	1.9	1.3
Musculoskeletal and connective tissue and bone disorders	Muscle cramps	3.6	2.9
General disorders and administration site conditions	Fatigue	4.8	4.3
	Chest pain	3.8	3.5
	Asthenia	1.6	1.2

Table III : Uncommon Adverse Events (≥ 111000 to < 1/100)

System Organ Class	Adverse Event	Teriparatide %	Placebo %
Cardiac disorders	Tachycardia	0.9	0.9
Respiratory, thoracic and mediastinal disorders	Emphysema	0.3	0
Gastro-intestinal disorders	Hemorrhoids	0.9	0.4
Renal and urinary disorders	Urinary incontinence	0.6	0.3
	Polyuria	0.3	0.1
	Micturition urgency	0.3	0
General disorders and administration site conditions	Injection site erythema	0.7	0
	Injection site reaction	0.3	0.1
Investigations	Weight increased	0.7	0.3
	Cardiac murmur	0.4	0.1

Teriparatide increases serum uric acid concentrations. However, the hyperuricemia does not result in an increase in gout, arthralgia or urolithiasis. Antibodies that cross-reacted with teriparatide were detected in women receiving teriparatide. Generally, antibodies were first detected following 12 months of treatment and diminished after withdrawal of therapy. There was no evidence of hypersensitivity reactions, allergic reactions, effects on serum calcium, or effects on bone mineral density (BMD) response.

There have been spontaneous reports of the following adverse reactions.

System organ class	Adverse event
General disorders and administration site conditions.	*Rare* : possible allergic events soon after injection: acute dyspnoea, edema, (mainly peripheral) *Common*: mild and transient injection site event, including pain, swelling, erythema, localized brusing, pruritus and minor bleeding at injection site.
Metabolism and nutrition disorders	Uncommon : hyper calcemia greater than 2.76 mmol/l (11 mg/dl). Rare : hypercalcemia greaterthan 3.25 mmol/l (13 mg/dl)
Muscoskeletal and connective tissue and bone disorders.	Uncommon: myalgia, arthralgia.

DRUG INTERACTIONS

Digoxin

A single teriparatide (r-DNA origin) injection dose did not alter the effect of digoxin on the systolic time interval (from electrocardiographic Q-wave onset to aortic valve closure, a measure of digoxin's calcium-mediated cardiac effect). However, because teriparatide (r-DNA origin) injection may transiently increase serum calcium, teriparatide (r-DNA origin) injection should be used with caution in patients taking digoxin.

Hydrochlorothiazide

The coadministration of hydrochlorothiazide 25 mg with teriparatide did not affect the serum calcium response to teriparatide 40 mcg. The effect of coadministration of a higher dose of hydrochlorothiazide with teriparatide on serum calcium levels has not been studied.

Furosemide

Coadministration of intravenous furosemide (20 to 100 mg) with teriparatide 40 mcg in healthy people and patients with mild, moderate or severe renal impairment (CrCl 13 to 72 mL/min) resulted in small increases in the serum calcium (2%) and 24-hour urine calcium (37%) responses to teriparatide that did not appear to be clinically important.

Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. However, transient, orthostatic hypotension or dizziness was observed in some patients. These patients should refrain from driving or the use of machines until symptoms have subsided.

PRECAUTIONS

General

Teriparatide has not been studied in patients with active urolithiasis in reported clinical trials.

Teriparatide should be used with caution in patients with active or recent urolithiasis because of the potential to exacerbate this condition.

In reported short term clinical studies with teriparatide injection, isolated episodes of transient orthostatic hypotension were observed. Typically, an event began within 4 hours of dosing and spontaneously resolved within a few minutes to a few hours. When transient orthostatic hypotension occurred, it happened within the first several doses, was relieved by placing subjects in a reclining position, and did not preclude continued treatment.

In a reported study of 15 healthy people administered digoxin daily to steady state, a single dose of teriparatide did not alter the effect of digoxin on the systolic time interval (from electrocardiographic Q-wave onset to aortic valve closure, a measure of digoxin's calcium mediated cardiac effect).

However, sporadic case reports have suggested that hypercalcemia may predispose patients to digitalis toxicity. Because teriparatide transiently increases serum calcium, Teriparatide should be used with caution in patients taking digitalis. In normocalcaemic patients, slight and transient elevations of serum calcium concentrations reach a maximum between 4 and 6 hours and return to baseline by 16 to 24 hours after each dose of Teriparatide.

Routine calcium monitoring during therapy is not required.

Therefore, if any blood samples are taken from a patient, this should be done atleast 16 hours after the most recent Teriparatide injection.

Teriparatide may cause small increases in urinary calcium excretion.

Limited information is available to evaluate safety in patients with hepatic, renal and cardiac disease.

No clinically important adverse renal effects were observed in reported clinical studies.

Assessments included creatinine clearance; measurements of blood urea nitrogen (BUN), creatinine, and electrolytes in serum; urine specific gravity and pH; and examination of urine sediment. Longterm evaluation of patients with severe renal insufficiency, patients undergoing acute or chronic dialysis, or patients who have functioning renal transplants has not been reported. Caution should be exercised in patients with moderate renal impairment.

Teriparatide therapy was associated with increased incidence of elevated uric acid, with the incidence being highest in patients with moderately impaired renal function and in those receiving teriparatide 40 mcg/day. Even so, adverse event data did not suggest an increased incidence of gout or arthralgia or of nephrolithiasis in teriparatide treated patients with normal, mild or moderate renal impairment.

Pregnancy

Reported studies in rabbits have shown reproductive toxicity. The potential risk for humans is unknown. Given the indication, Teriparatide should not be used during pregnancy.

OVERDOSE

Signs and symptoms: No cases of overdose were reported. Teriparatide has been administered in single doses of up to 100 mcg and in repeated doses of up to 60 mcg/day for 6 weeks. The effects of overdose that might be expected include delayed hypercalcemia and risk of orthostatic hypotension. Nausea, vomiting, dizziness and headache can also occur.

Overdose experience based on post-marketing spontaneous reports: There have been cases of medication error where the entire contents (up to 800 mcg) of the Teriparatide have been administered as single dose. Transient events reported have included nausea, weakness/lethargy and hypotension. In some cases, no adverse events occurred as a result of the overdose. No fatalities associated with overdose of Teriparatide have been reported.

Overdose management: There is no specific antidote for Teriparatide. Treatment of suspected overdose should include transitory discontinuation of teriparatide, monitoring of serum calcium, and implementation of appropriate supportive measures, such as hydration.

TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Two carcinogenicity bioassays were conducted in Fischer 344 rats. In the first study, male and female rats were given daily subcutaneous teriparatide injections of 5, 30, or 75 mcg/kg/day for 24 months from 2 months of age. These doses resulted in systemic exposures that were, respectively, 3, 20, and 60 times higher than the systemic exposure observed in humans following a subcutaneous dose of 20 mcg (based on AUC comparison). Teriparatide treatment resulted in a marked dose-related increase in the incidence of osteosarcoma, a rare malignant bone tumor, in both male and female rats. Osteosarcomas were observed at all doses and the incidence reached 40% to 50% in the high-dose groups. Teriparatide also caused a dose-related increase in osteoblastoma and osteoma in both sexes. No osteosarcomas, osteoblastomas or osteomas were observed in untreated control rats. The bone tumors in rats occurred in association with a large increase in bone mass and focal osteoblast hyperplasia.

The second 2-year study was carried out in order to determine the effect of treatment duration and animal age on the development of bone tumors. Female rats were treated for different periods between 2 and 26 months of age with subcutaneous doses of 5 and 30 mcg/kg (equivalent to 3 and 20 times the human exposure at the 20-mcg dose, based on AUC comparison). The study showed that the occurrence of osteosarcoma, osteoblastoma and osteoma was dependent upon dose and duration of exposure. Bone tumors were observed when immature 2-month old rats were treated with 30 mcg/kg/day for 24 months or with 5 or 30 mcg/kg/day for 6 months. Bone tumors were also observed when mature 6-month old rats were treated with 30 mcg/kg/day for 6 or 20 months. Tumors were not detected when mature 6-month old rats were treated with 5 mcg/kg/day for 6 or 20 months. The results did not demonstrate a difference in susceptibility to bone tumor formation, associated with teriparatide treatment, between mature and immature rats.

The relevance of these rat findings to humans is uncertain.

Mutagenesis

Teriparatide was not genotoxic in any of the following test systems: the Ames test for bacterial mutagenesis; the mouse lymphoma assay for mammalian cell mutation; the chromosomal aberration assay in Chinese hamster ovary cells, with and without metabolic activation; and the *in vivo* micronucleus test in mice.

Impairment of fertility

No effects on fertility were observed in male and female rats given subcutaneous teriparatide doses of 30, 100, or 300 mcg/kg/day prior to mating and in females continuing through gestation Day 6 (16 to 160 times the human dose of 20 mcg based on surface area, meg/m^2).

Pregnancy

Pregnancy Category C - In pregnant rats given subcutaneous teriparatide doses up to 1000 mcg/kg/day, there were no mortality. In pregnant mice given subcutaneous doses of 225 or 1000 mcg/kg/day (≥ 60 times the human dose based on surface area, meg/m^2) from gestation Day 6 through 15, the fetuses showed an increased incidence of skeletal deviations or variations (interrupted rib, extra vertebra or rib).

Developmental effects in a perinatal/postnatal study in pregnant rats given subcutaneous doses of teriparatide from gestation day 6 through postpartum Day 20 included mild growth retardation in female offspring at doses ≥ 225 mcg/kg/day (≥ 120 times the human dose based on surface area, meg/m^2), and in male offspring at 1000 mcg/kg/day (540 times the human dose based on surface area, meg/m^2). There was also reduced motor activity in both male and female offspring at 1000 mcg/kg/day. There were no developmental or reproductive effects in mice or rats at a dose of 30 mcg/kg (8 or 16 times the human dose based on surface area, meg/m^2). The effect of teriparatide treatment on human fetal development has not been studied. Teriparatide (rDNA origin) is not indicated for use in pregnancy.

Nursing Mothers

Because Teriparatide (rDNA origin) is indicated for the treatment of osteoporosis in postmenopausal women, it should not be administered to women who are nursing their children. There have been no clinical studies to determine if teriparatide is secreted into breast milk.

Pediatric Use

The safety and efficacy of Teriparatide (rDNA origin) have not been established in pediatric populations. Teriparatide is not indicated for use in pediatric patients.

Geriatric Use

Of the patients receiving Teriparatide (rDNA origin) in the osteoporosis trial of 1637 postmenopausal women, 75% were 65 years of age and over and 23% were 75 years of age and over. Of the patients receiving Teriparatide in the osteoporosis trial of 437 men, 39% were 65 years of age and over and 13% were 75 years of age and over. No significant differences in bone response or adverse reactions were seen in geriatric patients receiving Teriparatide as compared with younger patients. Nonetheless, as with many medications, elderly patients may have greater sensitivity to the adverse effects of Teriparatide.

SHELF LIFE : Not more than 24 months from the date of manufacture when stored at temparature 2 - 8°C.

STORAGE

Keep out of reach of children.
Protect from light and moisture.
Store between 2 to 8°C.
Do not freeze.

Shelf life after first opening : 28 days

PRESENTATION : MEGAPTH Prefilled Disposable Pen Device (3 mL) is supplied in multi dose USP type-I glass cartridge and the cartridge is stoppered at one end with bromobutyl solid rubber plunger and at the other end sealed with lined aluminum seal. Each 3 ml Cartridge is fitted in Disposable Pen Device. Each Disposable pen device is then packed in carton along with Pen user manual and Product prescribing information.

Use MEGAPTH pre-filled pen device up to 28 days including the first injection, After 28 days throw away the pen even if it is not completely empty.

Reg. No. xxxx xxxx

HARUS DENGAN RESEP DOKTER

Imported by :
PT MEGA LIFESCIENCES INDONESIA
We care Bogor - Indonesia.

Manufactured by:
VIRCHOW BIOTECH PRIVATE LIMITED
Survey No.172 Part, Gagillapur(V), Dundigal Gandimaisamma (M), Medchal- Malkajgiri (D), Telangana-500043, India.

DISETUJUI OLEH BPOM: 07/08/26

ID EREG10027212200066

280mm
200mm

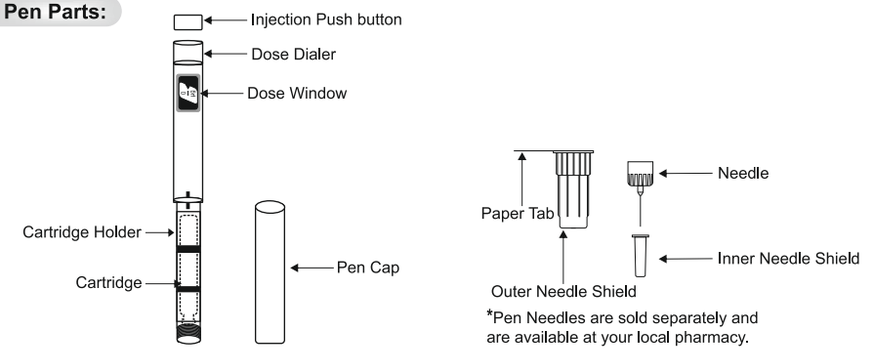
MEGAPTH PRE-FILLED PEN DEVICE - USER MANUAL

Before using **MEGAPTH PRE-FILLED PEN DEVICE** please read and follow the instructions carefully. If you do not follow the instructions, you may get the wrong dose.

Pen Features:

1. **MEGAPTH PRE-FILLED PEN DEVICE** containing 28 days supply of Teriparatide Injection.
2. Dose setting indication delivers the prescribed 20µg dose.

Pen Parts:



*Pen Needles are sold separately and are available at your local pharmacy.

Important Notes:

1. Number of medicines come in the Pen Delivery Devices. Check the label on your Pen Delivery Device before each use to make sure you are using your **MEGAPTH PRE-FILLED PEN DEVICE.**
2. Wash your hands and prepare your skin using the under-the-skin (subcutaneous) injection method recommended by your healthcare professional.
3. Use a new needle for each injection.
4. Be sure the needle is firmly attached to the **MEGAPTH PRE-FILLED PEN DEVICE** before setting (dialing) the dose.
5. Do not share your **MEGAPTH PRE-FILLED PEN DEVICE**.
6. Keep your **MEGAPTH PRE-FILLED PEN DEVICE** out of reach of children.
7. Do inject once daily.
8. DO NOT inject all the medicine at once (It is a multi-dose cartridge).
9. DO NOT transfer to a syringe.
10. Store your **MEGAPTH PRE-FILLED PEN DEVICE** in the refrigerator at all times, but not in a freezer. DO NOT let your **MEGAPTH PRE-FILLED PEN DEVICE** freeze. **DO NOT use MEGAPTH PRE-FILLED PEN DEVICE** if it has been frozen.
11. You can use **MEGAPTH PRE-FILLED PEN DEVICE** up to 28 days including the first injection from that Pen. Throw away the **MEGAPTH PRE-FILLED PEN DEVICE** after 28 days, even if it is not completely empty. Throw away the **MEGAPTH PRE-FILLED PEN DEVICE** and needle as directed by your healthcare professional. Always use a puncture-resistant container to throw away the needle.
12. DO NOT store or throw away the **MEGAPTH PRE-FILLED PEN DEVICE** with the needle attached. Keeping the needle attached may let the **MEGAPTH PRE-FILLED PEN DEVICE** to leak and air bubbles can form in the cartridge.
13. The directions regarding needle handling are not intended to replace local, healthcare professional or institutional policies.
14. The **MEGAPTH PRE-FILLED PEN DEVICE** is not recommended for use by the people who are blind or by those who have the vision problems without help from a person trained in the proper use of the product.
15. DO NOT use the **MEGAPTH PRE-FILLED PEN DEVICE** after the expiration date printed on the Carton and Pen Label.

Instructions for Use:

Make sure that you have the following items:
1. MEGAPTH PRE-FILLED PEN DEVICE
2. *Pen needle (disposable 32G and ¼ inch type-A)
3. Alcohol swabs

*Pen needles are sold separately and are available at your local pharmacy

I. Preparing the MEGAPTH PRE-FILLED PEN DEVICE



1. Wash your hands before preparing the **MEGAPTH PRE-FILLED PEN DEVICE** for use.
2. Remove the **MEGAPTH PRE-FILLED PEN DEVICE** from refrigerator.
3. Remove the Pen Cap by pulling it off.

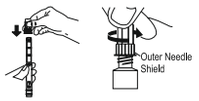


4. Look at the solution in the cartridge it should not have particles in it. If it is not clear, and if it has particles DO NOT USE IT.
5. Use an alcohol swab to wipe the rubber seal on the end of the Pen where the Pen Needle would be fixed.

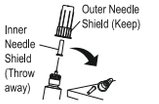
II. Attaching the Pen Needle



1. Pull off the Paper Tab from the Outer Needle Shield and throw the Paper Tab away.



2. Attach the capped Pen Needle to the end of the Pen by pushing it on and turning it clockwise (to the right). DO NOT over-tighten the needle since it must be removed after the injection.



3. Hold the Pen with the Needle pointing up and remove the Outer Needle Shield. Keep the Outer Needle Shield because you will need it to remove the Needle after injection is finished.
4. Pull off the Inner Needle Shield and throw it away.

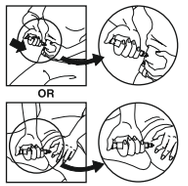
Priming of pen: Before first use, prime the pen as follows:
Dial the dose to "20 µg" as mentioned in Step III. Setting the Dose. Hold the pen with the needle pointing up. Tap the cartridge to move the air bubbles towards needle and expel one complete dose
Note: Prime your MEGAPTH PEN at one time only i.e. before first injection out of 28 injections

III. Setting the Dose

1. Turn the dose dialer clockwise (to the right) until you see the "20 µg" in the dose window. 

IV. Injecting the Dose:

1. The "20 µg" in the dose window means the dose is "ready to inject". Do not rotate the dose dailer back once the dose is set. If dialed back, redial it to "20 µg"
2. Make injections just below the surface of the skin (subcutaneous tissue).
3. Prepare your skin for the injection as instructed by the healthcare professional.
4. Gently hold a fold of skin as shown in the picture and push the Needle straight in to the skin. The skin may need to avoid a deep injection in to a muscle (intramuscular), especially in the thigh area.



5. Ask your healthcare professional for more instructions about injection technique and changing sites.
6. Make sure you can still see "20 µg" in the dose window. Inject the dose by using your thumb, if possible, to push in the injection button all the way.
7. Continue to hold down the injection button firmly and count s-l-o-w-l-y to 10 to ensure that the dose has been completely injected in to the skin. Remove the Needle from your skin when you finish counting.
8. When the injection is complete, you must see "0 µg" in the dose window. The "0 µg" tells you the injection button has been pushed all the way and your full dose has been injected.

V. After Injection

1. Carefully replace the Outer Needle Shield as instructed by your healthcare professional.
2. Remove the capped Needle by turning it counterclockwise (to the left). Place the used Needle in a puncture-resistant disposable container and properly throw it away as directed by your healthcare professional.
3. Replace the Cap on the Pen.
4. Store **MEGAPTH PRE-FILLED PEN DEVICE** in the refrigerator at 36° to 46° F (2° - 8°C) at all times. You should inject MEGAPTH right after you take the pen out of the refrigerator. Put the pen back in to the refrigerator right after use.

VI. Preparation for next day dose:

Follow the Steps I and II. Then follow procedures described in steps from Step III to Step V for next day's dose

DISETUJUI OLEH BPOM: 07/08/26 ID EREG10027212200066
Z:\New\Under Register\MegaPTH Prefilled Pen\Indonesia\Amey's file\MegaPTH Prefilled Pen PI 3_1.cdr
BASF

Informasi untuk Pasien

MEGAPTH
Teriparatide (r-Human Parathyroid Hormone) (1-34)
ALAT INJEKSI PEN YANG TELAH DIISI

Bacalah Lembar Informasi Pasien ini sebelum Anda mulai menggunakan MEGAPTH dan setiap kali Anda mendapat pengisian ulang. Mungkin ada informasi baru. Selain itu, bacalah Petunjuk Penggunaan yang disertakan dengan alat injeksi (pen) MEGAPTH untuk informasi tentang cara menggunakan alat tersebut untuk menyuntikkan obat Anda dengan benar. Panduan Pengobatan ini tidak menggantikan konsultasi dengan penyedia layanan kesehatan Anda tentang kondisi medis atau pengobatan Anda.

Apa informasi terpenting yang harus saya ketahui tentang MEGAPTH?

1. Kemungkinan kanker tulang. Selama pengujian obat, obat dalam MEGAPTH menyebabkan beberapa tikus mengembangkan kanker tulang yang disebut osteosarcoma. Pada manusia, osteosarcoma adalah kanker serius tetapi jarang. Osteosarcoma telah jarang dilaporkan pada orang yang menggunakan MEGAPTH. Belum diketahui apakah orang yang menggunakan MEGAPTH memiliki kemungkinan lebih tinggi terkena osteosarcoma.
2. Anda tidak boleh menggunakan MEGAPTH selama lebih dari 2 tahun selama masa hidup Anda.

Apa itu MEGAPTH?

- MEGAPTH adalah obat resep yang mirip dengan hormon yang dibuat oleh tubuh yang disebut hormon paratiroid atau PTH. MEGAPTH dapat membantu membentuk tulang baru, meningkatkan kepadatan mineral tulang dan kekuatan tulang.
- MEGAPTH dapat mengurangi jumlah patah tulang pada tulang belakang dan tulang lainnya pada wanita pascamenopause dengan osteoporosis.
- Efek pada patah tulang belum dipelajari pada pria.
- MEGAPTH digunakan pada pria dan wanita pascamenopause dengan osteoporosis yang berisiko tinggi mengalami patah tulang. MEGAPTH dapat digunakan oleh orang yang telah mengalami patah tulang terkait osteoporosis, atau yang memiliki beberapa faktor risiko patah tulang, atau yang tidak dapat menggunakan pengobatan osteoporosis lainnya.
- MEGAPTH digunakan pada pria dan wanita dengan osteoporosis karena penggunaan obat glukokortikoid, seperti prednisone, selama beberapa bulan, yang berisiko tinggi mengalami patah tulang. Ini termasuk pria dan wanita dengan riwayat patah tulang, yang memiliki beberapa faktor risiko patah tulang, atau yang tidak dapat menggunakan pengobatan osteoporosis lainnya.

DISETUJUI OLEH BPOM: 07108726G10027212200066

Belum diketahui apakah MEGAPTH aman dan efektif pada anak-anak.

MEGAPTH tidak boleh digunakan pada anak-anak dan dewasa muda yang tulangnya masih dalam masa pertumbuhan.

Siapa yang tidak boleh menggunakan MEGAPTH?

Jangan gunakan MEGAPTH jika Anda:

- alergi terhadap bahan apa pun dalam MEGAPTH. Lihat bagian akhir Lembar Informasi Pasien ini untuk daftar lengkap bahan dalam MEGAPTH.

Apa yang harus saya beritahukan kepada penyedia layanan kesehatan saya sebelum menggunakan MEGAPTH?

Sebelum Anda menggunakan MEGAPTH, beritahu penyedia layanan kesehatan Anda jika Anda:

- memiliki kondisi yang tercantum dalam bagian "Siapa yang tidak boleh menggunakan MEGAPTH?"
- memiliki Penyakit Paget atau penyakit tulang lainnya
- memiliki kanker dalam tulang Anda
- mengalami kesulitan menyuntik sendiri dan tidak memiliki seseorang yang dapat membantu Anda
- adalah anak atau dewasa muda yang tulangnya masih dalam masa pertumbuhan
- memiliki atau pernah memiliki batu ginjal
- telah menjalani terapi radiasi
- memiliki atau pernah memiliki terlalu banyak kalsium dalam darah Anda
- memiliki kondisi medis lainnya
- sedang hamil atau berpikir untuk menjadi hamil. Belum diketahui apakah MEGAPTH akan membahayakan bayi dalam kandungan Anda.
- sedang menyusui atau berencana untuk menyusui. Anda tidak boleh menyusui saat menggunakan MEGAPTH.

Beritahu penyedia layanan kesehatan Anda tentang semua obat yang Anda gunakan termasuk obat resep dan obat bebas, vitamin, dan suplemen herbal. Penyedia layanan kesehatan Anda memerlukan informasi ini untuk membantu mencegah Anda menggunakan MEGAPTH dengan obat lain yang mungkin membahayakan Anda.

- Khususnya, beritahu dokter Anda jika Anda menggunakan obat yang mengandung digoksin.

DISETUJUI OLEH BPOM: 07108726 G10027212200066

Bagaimana saya harus menggunakan MEGAPTH?

- Suntikkan MEGAPTH satu kali setiap hari di paha atau perut Anda (area perut bagian bawah). Bicaralah dengan penyedia layanan kesehatan tentang cara merotasi tempat suntikan.
- Sebelum Anda mencoba menyuntikkan MEGAPTH sendiri, penyedia layanan kesehatan harus mengajari Anda cara menggunakan alat injeksi MEGAPTH untuk memberikan suntikan Anda dengan benar.
- Bacalah Petunjuk Penggunaan yang terperinci yang disertakan dengan alat injeksi MEGAPTH Anda.
- Anda dapat menggunakan MEGAPTH dengan atau tanpa makanan atau minuman.
- Alat injeksi MEGAPTH memiliki obat yang cukup untuk 28 hari. Alat ini diatur untuk memberikan dosis 20 mikrogram obat setiap hari. Jangan menyuntikkan semua obat dalam alat injeksi MEGAPTH sekaligus.
- Jangan memindahkan obat dari alat injeksi MEGAPTH ke jarum suntik. Hal ini dapat mengakibatkan pengambilan dosis MEGAPTH yang salah. Jika Anda tidak memiliki jarum pen untuk digunakan dengan alat injeksi MEGAPTH Anda, bicaralah dengan penyedia layanan kesehatan Anda.
- MEGAPTH harus terlihat bening dan tidak berwarna. Jangan gunakan MEGAPTH jika mengandung partikel, atau jika keruh atau berwarna.
- Suntikkan MEGAPTH segera setelah Anda mengeluarkan alat injeksi dari lemari es.
- Setelah setiap penggunaan, lepaskan jarum dengan aman, tutup kembali alat injeksi, dan masukkan kembali ke dalam lemari es segera.
- Anda dapat menggunakan MEGAPTH pada waktu kapan saja dalam sehari. Untuk membantu Anda mengingat untuk menggunakan MEGAPTH, gunakanlah pada waktu yang sama setiap hari.
- Jika Anda lupa atau tidak dapat menggunakan MEGAPTH pada waktu biasa Anda, gunakanlah segera setelah Anda bisa pada hari itu. Jangan menggunakan lebih dari satu suntikan dalam hari yang sama.
- Jika Anda menggunakan MEGAPTH lebih dari yang diresepkan, hubungi penyedia layanan kesehatan Anda. Jika Anda menggunakan terlalu banyak MEGAPTH, Anda mungkin mengalami mual, muntah, kelemahan, atau pusing.

Ikuti instruksi penyedia layanan kesehatan Anda tentang cara lain yang dapat membantu osteoporosis Anda, seperti olahraga, diet, dan mengurangi atau berhenti penggunaan tembakau dan alkohol. Jika penyedia layanan kesehatan Anda merekomendasikan suplemen kalsium dan vitamin D, Anda dapat menggunakannya pada waktu yang sama dengan menggunakan MEGAPTH.

Apa saja efek samping yang mungkin dari MEGAPTH?

MEGAPTH dapat menyebabkan efek samping serius termasuk:

- Lihat "Apa informasi terpenting yang harus saya ketahui tentang MEGAPTH?"

DISETUJUI OLEH BPOM: 07108726G10027212200066

- **Penurunan tekanan darah ketika Anda mengubah posisi.** Beberapa orang merasa pusing, mendapatkan detak jantung yang cepat, atau merasa lemah segera setelah beberapa dosis pertama. Ini biasanya terjadi dalam waktu 4 jam setelah menggunakan MEGAPTH dan hilang dalam beberapa jam. Untuk beberapa dosis pertama, lakukan suntikan MEGAPTH Anda di tempat di mana Anda dapat duduk atau berbaring segera jika Anda mengalami gejala ini. Jika gejala Anda semakin parah atau tidak hilang, hentikan penggunaan MEGAPTH dan hubungi penyedia layanan kesehatan Anda.
- **Peningkatan kalsium dalam darah Anda.** Beritahu penyedia layanan kesehatan Anda jika Anda mengalami mual, muntah, sembelit, energi rendah, atau kelemahan otot. Ini mungkin merupakan tanda bahwa terlalu banyak kalsium dalam darah Anda.

Efek samping lainnya meliputi:

Umum: dapat memengaruhi hingga 1 dari 10 orang

- peningkatan kadar kolesterol darah
- depresi
- nyeri saraf pada kaki
- merasa lemah
- detak jantung tidak teratur
- sesak napas
- keringat berlebih
- kram otot
- kehilangan energi
- kelelahan
- nyeri dada
- tekanan darah rendah
- mulas (sensasi nyeri atau terbakar tepat di bawah tulang dada)
- muntah
- hernia pada tabung yang membawa makanan ke perut Anda
- hemoglobin rendah atau jumlah sel darah merah rendah (anemia)

Tidak umum: dapat memengaruhi hingga 1 dari 100 orang

- peningkatan detak jantung
- suara jantung abnormal
- sesak napas
- wasir
- kehilangan atau kebocoran urine yang tidak disengaja
- peningkatan kebutuhan untuk buang air kecil
- peningkatan berat badan
- batu ginjal
- nyeri pada otot dan nyeri pada sendi. Beberapa pasien telah mengalami kram punggung yang parah atau nyeri yang menyebabkan rawat inap.
- peningkatan kadar kalsium darah

DISETUJUI OLEH BPOM: 07108226100272122000066

- peningkatan kadar asam urat darah
- peningkatan enzim yang disebut alkaline phosphatase.

Jarang: dapat memengaruhi hingga 1 dari 1.000 orang

- penurunan fungsi ginjal, termasuk gagal ginjal
- pembengkakan, terutama pada tangan, kaki, dan kaki.

Pelaporan efek samping

Beritahu penyedia layanan kesehatan Anda jika Anda memiliki efek samping yang mengganggu Anda atau yang tidak hilang.

Ini bukanlah semua efek samping yang mungkin dari MEGAPTH. Untuk informasi lebih lanjut, tanyakan kepada dokter atau apoteker Anda.

Bagaimana saya harus menyimpan MEGAPTH?

- MEGAPTH dapat disimpan selama 2 tahun (24 bulan) pada suhu 2° hingga 8°C.
- Setelah dibuka, simpan alat injeksi MEGAPTH Anda di dalam lemari es antara 36° hingga 46°F (2° hingga 8°C).
- Jangan membekukan alat injeksi MEGAPTH. Jangan gunakan MEGAPTH jika telah dibekukan.
- Jangan gunakan MEGAPTH setelah tanggal kedaluwarsa yang tercetak pada alat injeksi dan kemasan.
- Buang alat injeksi MEGAPTH setelah 28 hari meskipun masih mengandung obat.

Jauhkan MEGAPTH dan semua obat dari jangkauan anak-anak.

Informasi umum tentang MEGAPTH

Obat terkadang diresepkan untuk tujuan selain yang tercantum dalam Panduan Pengobatan. Jangan gunakan MEGAPTH untuk kondisi yang tidak diresepkan.

Jangan memberikan MEGAPTH kepada orang lain, meskipun mereka memiliki kondisi yang sama dengan Anda. Panduan Pengobatan ini merangkum informasi terpenting tentang MEGAPTH. Jika Anda ingin informasi lebih lanjut, bicaralah dengan penyedia layanan kesehatan Anda. Anda dapat meminta apoteker atau penyedia layanan kesehatan Anda untuk informasi tentang MEGAPTH yang ditulis untuk profesional kesehatan.

Apa saja bahan dalam MEGAPTH?

Bahan aktif: teriparatide

Bahan tidak aktif: Asam Succinic USP/NF, Natrium hidroksida USP/NF, Gliserol USP/NF, m-cresol USP/NF, Air untuk Injeksi USP/NF, Hydrochloric Acid.

DISETUJUI OLEH BPOM: 07108726G10027212200066

Apa itu Osteoporosis?

Osteoporosis adalah penyakit di mana tulang menjadi tipis dan lemah, meningkatkan kemungkinan mengalami patah tulang. Osteoporosis biasanya tidak menimbulkan gejala sampai patah tulang terjadi. Patah tulang yang paling umum adalah di tulang belakang. Patah tulang dapat memendekkan tinggi badan, bahkan tanpa menyebabkan nyeri. Seiring waktu, tulang belakang dapat menjadi melengkung atau cacat dan tubuh membungkuk. Patah tulang dari osteoporosis juga dapat terjadi di hampir tulang mana pun dalam tubuh, misalnya, pergelangan tangan, tulang rusuk, atau pinggul. Setelah Anda mengalami patah tulang, kemungkinan untuk patah tulang lebih lanjut sangat meningkat.

Faktor risiko berikut meningkatkan kemungkinan Anda mengalami patah tulang dari osteoporosis:

- riwayat patah tulang dari osteoporosis
- kepadatan mineral tulang (BMD) yang sangat rendah
- sering jatuh
- gerakan terbatas, seperti menggunakan kursi roda
- kondisi medis yang kemungkinan menyebabkan kehilangan tulang, seperti beberapa jenis artritis yang menggunakan obat steroid yang disebut glukokortikoid, seperti prednisone
- obat lain yang dapat menyebabkan kehilangan tulang, misalnya: obat kejang (seperti phenytoin), pengencer darah (seperti heparin), dan dosis tinggi vitamin A

ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH - PETUNJUK PENGGUNAAN

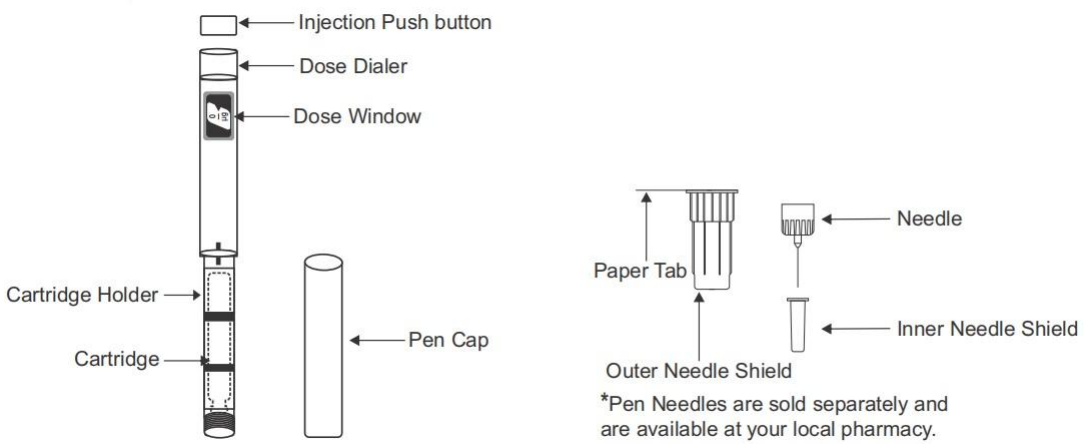
Sebelum menggunakan ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH, bacalah dan ikuti instruksi dengan hati-hati. Jika Anda tidak mengikuti instruksi, Anda mungkin mendapatkan dosis yang salah.

Fitur Pen:

1. ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH berisi persediaan 28 hari Suntikan Teriparatide.
2. Indikasi pengaturan dosis memberikan dosis yang diresepkan 20µg.

DISETUJUI OLEH BPOM: 07108726EG10027212200066

Bagian-bagian Pen:



Catatan Penting:

1. Sejumlah obat datang dalam Alat Injeksi Pen. Periksa label pada Alat Injeksi Pen Anda sebelum setiap penggunaan untuk memastikan Anda menggunakan ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH Anda.
2. Cuci tangan Anda dan siapkan kulit Anda menggunakan metode injeksi di bawah kulit (subkutan) yang direkomendasikan oleh profesional kesehatan Anda.
3. Gunakan jarum baru untuk setiap injeksi.
4. Pastikan jarum terpasang dengan kuat pada ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH sebelum mengatur (memutar) dosis.
5. Jangan berbagi ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH Anda.
6. Jauhkan ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH Anda dari jangkauan anak-anak.
7. Suntikkan sekali sehari.
8. JANGAN menyuntikkan semua obat sekaligus (Ini adalah kartrid multi-dosis).
9. JANGAN memindahkan ke jarum suntik.
10. Simpan ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH Anda di dalam lemari es setiap saat, tetapi bukan di freezer. JANGAN biarkan ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH Anda membeku. JANGAN gunakan ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH jika telah membeku.
11. Anda dapat menggunakan ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH hingga 28 hari termasuk injeksi pertama dari Pen tersebut. Buang ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH setelah 28 hari, meskipun belum sepenuhnya kosong. Buang ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH dan jarum sesuai petunjuk profesional kesehatan Anda. Selalu gunakan wadah tahan tusukan untuk membuang jarum.
12. JANGAN menyimpan atau membuang ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH dengan jarum terpasang. Membiarkan jarum terpasang dapat membuat ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH bocor dan gelembung udara dapat terbentuk dalam kartrid.
13. Petunjuk mengenai penanganan jarum tidak dimaksudkan untuk menggantikan kebijakan lokal, profesional kesehatan, atau institusional.

DISETUJUI OLEH BPOM: 07108726G10027212200066

14. ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH tidak direkomendasikan untuk digunakan oleh orang yang buta atau oleh mereka yang memiliki masalah penglihatan tanpa bantuan dari orang yang terlatih dalam penggunaan produk yang benar.
15. JANGAN gunakan ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH setelah tanggal kedaluwarsa yang tercetak pada Karton dan Label Pen.

Petunjuk Penggunaan:

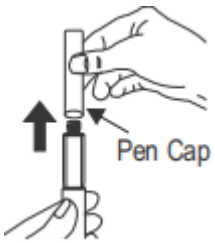
Pastikan bahwa Anda memiliki item-item berikut:

1. ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH
2. *Jarum Pen (sekali pakai tipe-A 32G dan ¼ inci)
3. Kapas alkohol

*Jarum Pen dijual terpisah dan tersedia di apotek lokal Anda

I. **Menyiapkan ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH**

1. Cuci tangan Anda sebelum menyiapkan ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH untuk digunakan.
2. Keluarkan ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH dari lemari es.
3. Lepaskan Tutup Pen dengan menariknya.



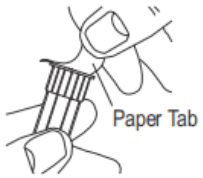
4. Lihat larutan dalam kartrid, tidak boleh memiliki partikel di dalamnya.
5. Jika tidak jernih, dan jika memiliki partikel JANGAN GUNAKAN.
6. Gunakan kapas alkohol untuk membersihkan segel karet di ujung Pen di mana Jarum Pen akan dipasang.



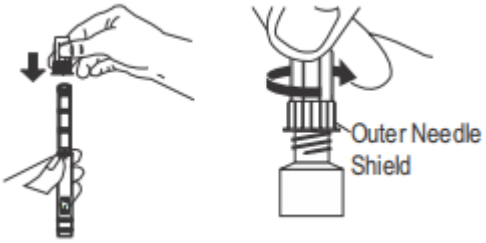
DISETUJUI OLEH BPOM: 07108726G10027212200066

II. **Memasang Jarum Pen**

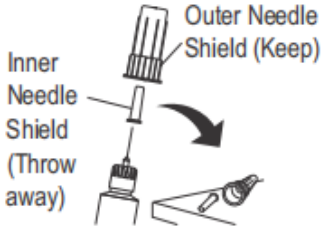
1. Lepaskan Tab Kertas dari Pelindung Jarum Luar dan buang Tab Kertas



2. Pasang Jarum Pen yang bertutup ke ujung Pen dengan mendorongnya dan memutarnya searah jarum jam (ke kanan). JANGAN terlalu kencangkan jarum karena harus dilepas setelah injeksi.



3. Pegang Pen dengan Jarum mengarah ke atas dan lepaskan Pelindung Jarum Luar. Simpan Pelindung Jarum Luar karena Anda akan membutuhkannya untuk melepaskan Jarum setelah injeksi selesai.
4. Lepaskan Pelindung Jarum Dalam dan buang.

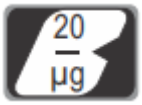


Persiapan pen: Sebelum penggunaan pertama, siapkan pen sebagai berikut: | | | | Putar dosis ke "20/µg" seperti yang disebutkan dalam Langkah III. Mengatur Dosis. | | Pegang pen dengan jarum mengarah ke atas. Ketuk kartrid untuk memindahkan | | gelembung udara ke arah jarum dan keluarkan satu dosis lengkap | | | | **Catatan:** Siapkan PEN MEGAPTH Anda hanya satu kali yaitu sebelum injeksi pertama | | dari 28 injeksi

DISETUJUI OLEH BPOM: 07108726EG10027212200066

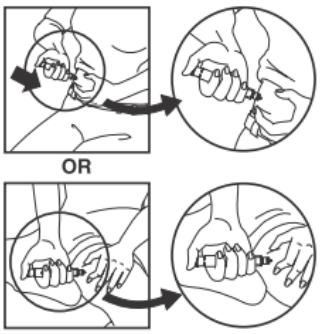
III. **Mengatur Dosis**

1. Putar tombol dosis searah jarum jam (ke kanan) sampai Anda melihat di jendela dosis.



IV. **Menyuntikkan Dosis:**

1. "20/µg" dalam jendela dosis berarti dosis "siap untuk disuntikkan". Jangan memutar tombol dosis ke belakang setelah dosis diatur. Jika diputar kembali, putar kembali ke "20/µg"
2. Lakukan injeksi tepat di bawah permukaan kulit (jaringan subkutan).
3. Siapkan kulit Anda untuk injeksi seperti yang diinstruksikan oleh profesional kesehatan.
4. Pegang lipatan kulit dengan lembut seperti yang ditunjukkan dalam gambar dan dorong Jarum lurus ke kulit. Kulit mungkin perlu untuk menghindari injeksi dalam ke otot (intramuskular), terutama di area paha.



5. Tanyakan kepada profesional kesehatan Anda untuk instruksi lebih lanjut tentang teknik injeksi dan mengubah tempat.
6. Pastikan Anda masih dapat melihat "20/µg" di jendela dosis. Suntikkan dosis dengan menggunakan jempol Anda, jika memungkinkan, untuk mendorong tombol injeksi sepenuhnya.
7. Terus tahan tombol injeksi dengan kuat dan hitung p-e-r-l-a-h-a-n sampai 10 untuk memastikan bahwa dosis telah sepenuhnya disuntikkan ke dalam kulit. Lepaskan Jarum dari kulit Anda ketika Anda selesai menghitung.
8. Ketika injeksi selesai, Anda harus melihat di jendela dosis. memberi tahu Anda bahwa tombol injeksi telah didorong sepenuhnya dan dosis penuh Anda telah disuntikkan.

DISETUJUI OLEH BPOM: 07108726G10027212200066

V. **Setelah Injeksi:**

1. Pasang kembali Pelindung Jarum Luar dengan hati-hati seperti yang diinstruksikan oleh profesional kesehatan Anda.
2. Lepaskan Jarum yang bertutup dengan memutarnya berlawanan arah jarum jam (ke kiri). Tempatkan Jarum yang telah digunakan dalam wadah sekali pakai yang tahan tusukan dan buang dengan benar sesuai petunjuk profesional kesehatan Anda.
3. Pasang kembali Tutup pada Pen.
4. Simpan ALAT INJEKSI PEN YANG TELAH DIISI MEGAPTH di dalam lemari es pada suhu 36 hingga 46 F (2 - 8 C) setiap saat. Anda harus menyuntikkan MEGAPTH segera setelah Anda mengeluarkan pen dari lemari es. Masukkan pen kembali ke lemari es segera setelah digunakan.

VI. **Persiapan untuk dosis hari berikutnya:**

Ikuti Langkah I dan II. Kemudian ikuti prosedur yang dijelaskan dalam langkah dari Langkah III hingga Langkah V untuk dosis hari berikutnya

No REGISTRASI: DKI xxxxxxxx

Pendaftar:

PT MEGA LIFESCIENCES INDONESIA.

Bogor - Indonesia.

Diproduksi oleh:

VIRCHOW BIOTECH PRIVATE LIMITED

Survey no. 172 Part, Gagillapur (V), Dundigal Gradimaisamma (M), medchal-Malkajgiri (D), Telangana - 500043, India.

Tanggal Revisi: 5 Mei 2025.

DISETUJUI OLEH BPOM: 07/08/26 10027212200066