Job Order No: 000-BD/04/25 Date: 25-09-2025 **Draft:** 7th

P.M. Code: F5350A Size: Leafinsert (365mm x 145mm)

(FINAL COLOUR APPROVAL WILL BE GIVEN ON PRINT PROOF PROVIDED BY VENDOR)

Developed by: (AP Dept.) _____ **Review by: (BD Dept.)** _____ **Review by: (Med.Aff. Dept.)** _____

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365 mm

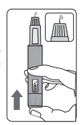
145 mm

• Always use a new needle for each injection.

This may prevent blocked needles, contamination, infection and inaccurate dosing
Never use a bent or damaged needle.

2. Check the flow with each new pen.

• If your pen is already in use, go to step 3 'Select your dose'. Only check the flow before your first injection with each new pen.
• Turn the dose selector to the flow check symbol (••—) right past '0'. Make sure the flow check symbol lines up with the pointer.



• Hold the pen with the needle pointing up. Press and hold in the dose button until the dose counter returns to '0'. The '0' must line up with the dose pointer. A drop of solution should appear at the needle tip.

If no drop appears, repeat step 2 'Check the flow with each new pen' up to 6 times. If there is still no drop, change the needle and repeat step 2 'Check the flow with each new pen' once more. Dispose of the pen and use a new one if a drop of solution still does not appear. Always make sure that a drop appears at the needle tip before you use a new pen for the first time. This makes sure that the solution flows. If no drop appears, you will not inject any medicine, even though the dose counter may move. This may indicate a blocked or damaged needle. If you do not check the flow before your first injection with each new pen, you may not get the prescribed dose and the intended effect of semaglutide.

3. Select your dose.

• Turn the dose selector to select the required dose (0.25mg, 0.5mg or 1mg). Keep turning until the dose counter stops and shows the desired dose.
• Only the dose counter and dose pointer will show that the desired dose that has been selected. You can only select one dose at a time per injection. The dose selector clicks differently when turned forwards, backwards, or past the available dose option, do not count the clicks.

How much solution is left
If there is not enough solution left in your pen for a full dose, do not use it. Use a new Seglutide Pen.

4. Inject your dose.

• Insert the needle into your skin as your doctor or nurse has shown you.
• Make sure you can see the dose counter. Do not cover it with your fingers. This could interrupt the injection.

• Press and hold down the dose button. Watch as the dose counter returns to '0'. The '0' must line up with the dose pointer. You may then hear or feel a click.
• Continue pressing the dose button while keeping the needle in your skin

• Count slowly for atleast 10 seconds, while keeping the dose button pressed.
• If the needle is removed earlier, you may see a stream of solution coming from the needle tip. If so, the full dose will not be delivered.

• Remove the needle from your skin. You can then release the dose button. If blood appears at the injection site, press lightly.

You may see a drop of solution at the needle tip after injecting. This is normal and does not affect your dose.
Always watch the dose counter to know how many mg you inject. Hold the dose button down until the dose counter returns to '0'.

How to identify a blocked or damaged needle
• If '0' does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked or damaged needle.
• In this case, you have not received any medicine – even though the dose counter has moved from the original dose that you have set

How to handle a blocked needle
Change the needle as described in step 5 'After your injection' and repeat all steps starting with step 1 'Prepare your pen with a new needle'. Make sure you select the full dose you need.
Never touch the dose counter when you inject. This can interrupt the injection.

5. After your injection.

Always dispose of the needle after each injection to ensure convenient injections and prevent blocked needles. If the needle is blocked, you will not inject any medicine.

• Carefully place the needle tip into the outer needle cap on a flat surface without touching the needle or the outer needle cap.

• Once the needle is covered, carefully push the outer needle cap completely on.
• Unscrew the needle and dispose of it carefully as instructed by your doctor, nurse, pharmacist or local authorities.

• Put the pen cap on your pen after each use to protect the solution from light.

• When the pen is to be disposed of, do it without a needle on as instructed by your doctor, nurse, pharmacist or local authorities.

• Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.

• Always remove the needle from your pen immediately after each injection. This may prevent blocked needles, contamination, infection, leakage of solution and inaccurate dosing.

Further important information
• Always keep your pen and needles out of the sight and reach of others, especially children.
• Never share your pen or your needles with other people
• Caregivers must be very careful when handling used needles to prevent needle injury and crossinfection.

Caring for your pen
Treat your pen with care. Rough handling or misuse may cause inaccurate dosing. If this happens you might not get the intended effect of this medicine.
• Do not leave the pen in a car or another place where it can get too hot or too cold.
• Do not inject Seglutide which has been frozen. If you do that, you might not get the intended effect of this medicine.
• Do not inject Seglutide which has been exposed to direct sunlight. If you do that, you might not get the intended effect of this medicine.
• Do not expose your pen to dust, dirt or liquid.
• Do not wash, soak or lubricate your pen. It may be cleaned with a mild detergent on a moistened cloth.
• Do not drop your pen or knock it against hard surfaces. If you drop it or suspect a problem, attach a new needle and check the flow before you inject.
• Do not try to refill your pen.
• Do not try to repair your pen or pull it apart.

DOSAGE
As directed by the physician

STORAGE AND INSTRUCTIONS
FOR SUBCUTANEOUS USE ONLY.
Store in a refrigerator at 2° C to 8° C
and do not freeze.
Protect from sunlight and heat.
Do not use if particulate matter is present.
Keep out of the reach of children.
Multidose Prefilled Pen.
Discard Pen 6 weeks after first use.
For use by one person only.
Keep the Pen cap on when not in use.
Do not store the Pen with needle attached.
Always remove and safely discard the needle after each injection.
Always use a new needle for each injection.
Patients and healthcare professionals can aslo report suspected adverse drug reaction at ade@macter.com.
The expiration date refers to the product correctly stored at the required conditions.

HOW SUPPLIED
SEGLUTIDE 2mg/3ml is supplied as:
SEGLUTIDE 2mg/3ml – One prefilled pen of SEGLUTIDE 2mg/3ml solution for injection with 6 needles.
SEGLUTIDE 4mg/3ml is supplied as
SEGLUTIDE 4mg/3ml – One prefilled pen of SEGLUTIDE 4mg/3ml solution for injection with 4 needles.

To be sold on the prescription of a registered medical practitioner only.

خوراک:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات:
صرف زیر جلد استعمال کیلئے۔
دوا کو ۲ سے ۸ ڈگری سینٹی گریڈ درجہ حرارت پر
فریج میں رکھیں اور منجمد نہ کریں۔
دھوپ اور گرمی سے محفوظ رکھیں۔
اگر ذرات موجود ہوں تو استعمال نہ کریں۔
بچوں کی پہنچ سے دور رکھیں۔
متعدد بار استعمال کیلئے۔
پہلی بار استعمال کے چھ ہفتے بعد پین کو تلف کر دیں۔
ایک فرد کے استعمال کیلئے۔
پین کا کیپ لگا کر رکھیں جب استعمال میں نہ ہو۔
پین کو سوئی لگا کر نہ چھوڑیں۔
انجکشن لگانے کے بعد ہمیشہ سوئی کو احتیاط سے ہٹادیں اور محفوظ طریقہ سے پھینک دیں۔
ہر انجکشن کیلئے ہمیشہ ایک نئی سوئی استعمال کریں۔
مریض اور صحت کی دیکھ بھال کرنے والے پیشہ ور افراد ade@macter.com پر دوا کے مضر منفی ردعمل کی اطلاع بھی دے سکتے ہیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کی جائے۔

Manufactured by:
Macter International Limited
F-216, S.I.T.E., Karachi - Pakistan

F5350A

(r-DNA Origin)

Seglutide (Semaglutide)

انجکشن
سیگلوٹائیڈ
پری فلڈ پین
(آر-ڈی این اے اوریجن)
(سیماگلوٹائیڈ)

Solution for Injection (Multidose Prefilled Pen)

For Subcutaneous Use Only

WARNING: RISK OF THYROID C-CELL TUMORS
See full prescribing information for complete boxed warning.

- **In rodents, semaglutide causes thyroid C-cell tumors. It is unknown whether semaglutide causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as the human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined.**
- **Semaglutide is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC and symptoms of thyroid tumors.**

COMPOSITION
Seglutide 2mg / 3ml injection
Each ml contains:
Semaglutide 0.68mg
(As per Innovator's Specifications)
Seglutide 4mg / 3ml injection
Each ml contains:
Semaglutide 1.34mg
(As per Innovator's Specifications)

DESCRIPTION
SEGLUTIDE injection, for subcutaneous use, contains semaglutide, a human GLP-1 receptor agonist (or GLP-1 analog). The molecular formula is $C_{187}H_{291}N_{45}O_{59}$ and the molecular weight is 4113.58 g/mol.

CLINICAL PHARMACOLOGY
MECHANISM OF ACTION
Semaglutide is a GLP-1 analogue with 94% sequence homology to human GLP-1.
Semaglutide acts as a GLP-1 receptor agonist that selectively binds to and activates the GLP-1 receptor, the target for native GLP-1. GLP-1 is a physiological hormone that has multiple actions on glucose, mediated by the GLP-1 receptors.
The principal mechanism of protraction resulting in the long half-life of semaglutide is albumin binding, which results in decreased renal clearance and protection from metabolic degradation. Furthermore, semaglutide is stabilized against degradation by the DPP-4 enzyme. Semaglutide reduces blood glucose through a mechanism where it stimulates insulin secretion and lowers glucagon secretion, both in a glucose-dependent manner. Thus, when blood glucose is high, insulin secretion is stimulated, and glucagon secretion is inhibited. The mechanism of blood glucose lowering also involves a minor delay in gastric emptying in the early postprandial phase.

PHARMACODYNAMICS
Semaglutide lowers fasting and postprandial blood glucose and reduces body weight. All pharmacodynamics evaluations were performed after 12 weeks of treatment (including dose escalation) at steady state with semaglutide 1 mg.

PHARMACOKINETICS
Absorption
Absolute bioavailability of semaglutide is 89%. Maximum concentration of semaglutide is reached 1 to 3 days post dose. Similar exposure is achieved with subcutaneous administration of semaglutide in the abdomen, thigh, or upper arm. In patients with type 2

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diabetes, semaglutide exposure increases in a dose-proportional manner for once-weekly doses of 0.5 mg, 1 mg and 2 mg. Steady-state exposure is achieved following 4-5 weeks of once-weekly administration. In patients with type 2 diabetes, the mean population-PK estimated steady-state concentrations following once weekly subcutaneous administration of 0.5 mg and 1 mg semaglutide were approximately 65.0 ng/mL and 123.0 ng/mL, respectively. In the trial comparing semaglutide 1 mg and 2 mg, the mean steady state concentrations were 111.1 ng/ mL and 222.1 ng/mL, respectively.

Distribution

The mean apparent volume of distribution of semaglutide following subcutaneous administration in patients with type 2 diabetes is approximately 12.5 L. Semaglutide is extensively bound to plasma albumin (>99%).

Elimination

The apparent clearance of semaglutide in patients with type 2 diabetes is approximately 0.05 L/h. With an elimination half-life of approximately 1 week, semaglutide will be present in the circulation for about 5 weeks after the last dose.

Metabolism

The primary route of elimination for semaglutide is metabolism following proteolytic cleavage of the peptide backbone and sequential beta-oxidation of the fatty acid sidechain.

Excretion

The primary excretion routes of semaglutide-related material are via the urine and feces. Approximately 3% of the dose is excreted in the urine as intact semaglutide.

INDICATIONS

SEGLUTIDE is a glucagon-like peptide 1 (GLP-1) receptor agonist indicated as:

- An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.

Limitations of Use:

- Semaglutide has not been studied in patients with a history of pancreatitis. Consider another anti diabetic therapy.
- Not indicated for the treatment of type 1 diabetes mellitus.

DOSAGE AND ADMINISTRATION

Recommended Dosage

Recommended Initiation Dosage

Initiate semaglutide with a dosage of 0.25 mg injected subcutaneously once weekly for 4 weeks, After 4 weeks on the 0.25 mg dosage, increase the dosage to 0.5 mg once weekly.

Recommended Maintenance and Maximum Dosages for Glycemic Control

The recommended maintenance dosage is 0.5 mg, 1 mg, or 2 mg, injected subcutaneously once weekly, based on glycemic control.

If additional glycemic control is needed after at least 4 weeks on the:

- 0.5 mg dosage, the dosage may be increased to 1 mg once weekly.
- 1 mg dosage, the dosage may be increased to 2 mg once weekly. The maximum recommended dosage is 2 mg once weekly.

Recommended Maintenance Dosage in Patients with Type 2 Diabetes Mellitus and Chronic Kidney Disease

Increase the dosage to the maintenance dosage, 1 mg once weekly, after at least 4 weeks on the 0.5 mg dosage.

Important Administration Instructions

- Administer SEGLUTIDE subcutaneously to the abdomen, thigh, or upper arm.
- Instruct patients to use a different injection site each week when injecting in the same body region.
- Inspect SEGLUTIDE visually before use. It should appear clear and colorless.
- Do not use SEGLUTIDE if particulate matter and coloration is seen.
- Never share Pen with other patients even if needle is changed. It carries a risk for transmission of blood borne pathogens.
- Administer SEGLUTIDE once weekly, on the same day each week, at any time of the day, with or without meals.
- The day of weekly administration can be changed if necessary as long as the time between two doses is at least 2 days (>48 hours).
- If a dose is missed, administer SEGLUTIDE as soon as possible within 5 days after the missed dose. If more than 5 days have passed, skip the missed dose and administer the next dose on the regular scheduled day. In each case, patients can then resume their regular once weekly dosing schedule.

USE IN SPECIFIC POPULATION

Pregnancy

Risk Summary

There are limited data with semaglutide use in pregnant women to inform a drug-associated risk for adverse developmental outcomes. There are clinical considerations regarding the risks of poorly controlled diabetes in pregnancy. Based on animal reproduction studies, there may be potential risks to the fetus from exposure to semaglutide during pregnancy. Semaglutide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation

Risk Summary

There are no data on the presence of semaglutide in human milk, the effects on the breastfed infant, or the effects on milk production. Semaglutide was present in the milk of lactating rats, however, due to species specific differences in lactation physiology, the clinical relevance of these data are not clear. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for semaglutide and any potential adverse effects on the breastfed infant from semaglutide or from the underlying maternal condition.

Pediatric Use

Safety and efficacy of semaglutide have not been established in pediatric patients.

Renal Impairment

No dose adjustment of semaglutide is recommended for patients with renal impairment. In subjects with renal impairment including end-stage renal disease (ESRD), no clinically relevant change in semaglutide pharmacokinetics (PK) was observed.

Hepatic Impairment

No dose adjustment of semaglutide is recommended for patients with hepatic impairment. In a study in subjects with different degrees of hepatic impairment, no clinically relevant change in semaglutide pharmacokinetics (PK) was observed.

WARNINGS and PRECAUTIONS

Risk of Thyroid C-Cell Tumors

Semaglutide is contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia Syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Semaglutide and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness).

Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with semaglutide. Such monitoring may increase the risk of unnecessary procedures, due to the low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin value may indicate MTC and patients with MTC usually have calcitonin values >50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated.

Acute Pancreatitis

Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists, including semaglutide. After initiation of semaglutide, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, discontinue semaglutide and initiate appropriate management.

Diabetic Retinopathy Complications

Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. The effect of long-term glycemic control with semaglutide on diabetic retinopathy complications has not been studied. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.

Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin

Patients receiving semaglutide in combination with an insulin secretagogue (e.g., sulfonylurea) or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia treatment.

The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogue) or insulin. Inform patients using these concomitant medications of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia.

Acute Kidney Injury due to Volume Depletion

There have been postmarketing reports of acute kidney injury, in some cases requiring hemodialysis, in patients treated with semaglutide. The majority of the reported events occurred in patients who experienced gastrointestinal reactions leading to dehydration such as nausea, vomiting, or diarrhea. Monitor renal function in patients reporting adverse reactions to Semaglutide that could lead to volume depletion, especially during dosage initiation and escalation of semaglutide.

Severe Gastrointestinal Adverse Reactions:

Use of semaglutide has been associated with gastrointestinal adverse reactions, sometimes severe.

Semaglutide is not recommended in patients with severe gastroparesis.

Hypersensitivity

Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) have been reported in patients treated with semaglutide. If hypersensitivity reactions occur, discontinue use of semaglutide; treat promptly per standard of care, and monitor until signs and symptoms resolve. Do not use in patients with a previous hypersensitivity to semaglutide.

Anaphylaxis and angioedema have been reported with other GLP-1 receptor agonists. Use caution in a patient with a history of angioedema or anaphylaxis with another GLP-1 receptor agonist because it is unknown whether such patients will be predisposed to anaphylaxis with semaglutide.

Acute Gallbladder Disease

Acute events of gallbladder disease such as cholelithiasis or cholecystitis have been reported in GLP-1 receptor agonist trials and post marketing. In placebo-controlled trials, cholelithiasis was reported in 1.5% and 0.4% of patients-treated with semaglutide 0.5 mg and 1 mg, respectively. Cholelithiasis was not reported in placebo treated patients. If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated.

Pulmonary Aspiration during General Anesthesia or Deep Sedation

semaglutide delays gastric emptying .There have been rare post marketing reports of pulmonary aspiration in patients receiving GLP-1 receptor agonists undergoing elective surgeries or procedures requiring general anesthesia or deep sedation who had residual gastric contents despite reported adherence to preoperative fasting recommendations. Instruct patients to inform healthcare providers prior to any planned surgeries or procedures if they are taking semaglutide.

CONTRAINDICATIONS

Semaglutide is contraindicated in patients with:

A personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

A serious hypersensitivity reaction to semaglutide or to any of the excipients in semaglutide. Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported with semaglutide.

ADVERSE REACTIONS

The following serious adverse reactions are described below.

- Risk of Thyroid C-cell Tumors.
- Acute Pancreatitis.
- Diabetic Retinopathy Complications.
- Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin.
- Acute Kidney Injury Due to Volume Depletion .
- Hypersensitivity Reactions .
- Acute Gallbladder Disease.
- Pulmonary Aspiration during General Anesthesia or Deep Sedation.

Common Adverse Reactions

- Nausea
- Vomiting
- Diarrhea
- Abdominal pain
- Constipation

Other Adverse Reactions

- Hypoglycemia
- Injection site reaction (injection-site discomfort, erythema)
- Increases in Amylase and Lipase
- Acute Pancreatitis
- Cholelithiasis
- Increases in Heart Rate
- Fatigue, Dysgeusia and Dizziness

Post marketing Experience

The following adverse reactions have been reported during post-approval use of semaglutide because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Gastrointestinal Disorders: Ileus

Hypersensitivity: anaphylaxis, angioedema, rash, urticaria.

Hepatobiliary: cholecystitis, cholecystectomy

Neurologic: dysesthesia

Pulmonary: Pulmonary aspiration has occurred in patients receiving GLP-1 receptor agonists undergoing elective surgeries or procedures requiring general anesthesia or deep sedation.

Skin and Subcutaneous Tissue: alopecia.

OVERDOSAGE

In the event of overdose, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms. A prolonged period of observation and treatment for these symptoms may be necessary, taking into account the long half-life of semaglutide of approximately 1 week.

DRUG INTERACTIONS

Concomitant Use with an Insulin Secretagogue (e.g., Sulfonylurea) or with Insulin

When initiating semaglutide, consider reducing the dose of concomitantly administered insulin secretagogue (such as sulfonylureas) or insulin to reduce the risk of hypoglycemia.

Oral Medications

Semaglutide causes a delay of gastric emptying, and thereby has the potential to impact the absorption of concomitantly administered oral medications. In clinical pharmacology trials, semaglutide did not affect the absorption of orally administered medications to any clinically relevant degree. Nonetheless, caution should be exercised when oral medications are concomitantly administered with semaglutide.

Instructions on how to use Seglutide solution for injection in pre-filled pen

Please read these instructions carefully before using your Seglutide pre-filled pen. Talk to your doctor, nurse or pharmacist about how to inject Seglutide correctly. Only use the medicine in this pen as prescribed. Start by checking your pen to make sure that it contains the medicine, then read the illustrations below to get to know the different parts of your pen and needle.

If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help. Get help from a person with good eyesight who knows how to use the Seglutide pre-filled pen.

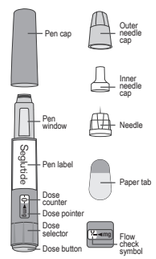
Your pen is a pre-filled dial-a-dose pen.

After 6 weeks of use, any remaining dose in the Pen should be disposed of.

Use the table inside the lid of the carton to keep track of injections you have taken.

Your pen is designed to be used with 32G disposable needles up to a length of 4 mm.

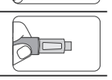
Seglutide pre-filled pen and needle (example)



1. Prepare your pen with a new needle.

- Check the name and colored label of your pen, to make sure that it contains semaglutide this is especially important if you take more than one type of injectable medicine. Using the wrong medicine could be harmful to your health.
- Pull off the pen cap.

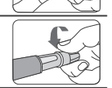
- Check that the solution in your pen is clear and colourless. Look through the pen window. If the solution looks cloudy or coloured, do not use the pen.



- Take a new needle. Check the paper tab and the outer needle cap for damages that could affect sterility. If any damage is seen use a new needle.
- Tear off the paper tab.

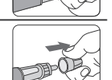
Make sure to attach the needle correctly.

- Push the needle straight onto the pen.
- Turn until it is on tight.



The needle is covered by two caps. You must remove both caps. If you forget to remove both caps, you will not inject any solution

- Pull off the outer needle cap and keep it for later. You will need it after the injection, to safely remove the needle from the pen.



- Pull off the inner needle cap and throw it away. If you try to put it back on, you may accidentally stick yourself with the needle.