

Package leaflet: Information for the user

Nplate 250 micrograms powder and solvent for solution for injection Nplate 500 micrograms powder and solvent for solution for injection Romiplostim

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Nplate is and what it is used for
2. What you need to know before you use Nplate
3. How to use Nplate
4. Possible side effects
5. How to store Nplate
6. Contents of the pack and other information
7. Instructions for preparing and giving an injection of Nplate

1. What Nplate is and what it is used for

Nplate's active ingredient is romiplostim, which is a protein used to treat low platelet counts in patients with immune primary thrombocytopenia (called ITP). ITP is a disease in which your body's immune system destroys its own platelets. Platelets are the cells in your blood that help seal cuts and form blood clots. Very low platelet counts can cause bruising and serious bleeding.

Nplate is used to treat adult patients (aged 18 years and over) with ITP who may or may not have had their spleen removed and who have been previously treated with corticosteroids or immunoglobulins, where these treatments don't work.

Nplate works by stimulating the bone marrow (part of the bone which makes blood cells) to produce more platelets. This should help to prevent bruising and bleeding associated with ITP.

2. What you need to know before you use Nplate

Do not use Nplate:

- if you are allergic to romiplostim or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to other medicines that are produced by DNA technology using the micro-organism *Escherichia coli* (*E. coli*).

Warnings and precautions

- If you stop taking Nplate a low blood platelet count (thrombocytopenia) is likely to reoccur. If you stop taking Nplate your platelet count will have to be monitored, and your doctor will discuss appropriate precautions with you.

- If you are at risk of blood clots or if blood clots are common in your family. The risk of blood clotting may also be increased if you:
 - have liver problems;
 - are elderly (≥ 65 years);
 - are bedridden;
 - have cancer;
 - are taking the contraceptive pill or hormone replacement therapy;
 - have recently had surgery or suffered an injury;
 - are obese (overweight);
 - are a smoker.

Talk to your doctor, pharmacist or nurse before using Nplate.

If you have very high blood platelet counts this may increase the risk of blood clotting. Your doctor will adjust your dose of Nplate to ensure that your platelet count does not become too high.

Bone marrow changes (increased reticulin and possible bone marrow fibrosis)

Long-term use of Nplate may cause changes in your bone marrow. These changes may lead to abnormal blood cells or your body making less blood cells. The mild form of these bone marrow changes is called “increased reticulin” and has been observed in Nplate clinical trials. It is not known if this may progress to a more severe form called “fibrosis.” Signs of bone marrow changes may show up as abnormalities in your blood tests. Your doctor will decide if abnormal blood tests mean that you should have bone marrow tests or if you should stop taking Nplate.

Worsening of blood cancers

Your doctor may decide to take a bone marrow biopsy if they decide it is necessary to ensure that you have ITP, and not another condition such as Myelodysplastic Syndrome (MDS). If you have MDS and receive Nplate you may have an increase in your blast cell counts and your MDS condition may worsen to become an acute myeloid leukaemia, which is a type of cancer of the blood.

Loss of response to romiplostim

If you experience a loss of response or failure to maintain a platelet response with romiplostim treatment, your doctor will investigate the reasons why including whether you are experiencing increased bone marrow fibres (reticulin) or have developed antibodies which neutralise romiplostim’s activity.

Children and adolescents

Nplate is not recommended for use in children below age 18.

Other medicines and Nplate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are also taking medicines which prevent blood clots (anticoagulants or anti-platelet therapy) there is a greater risk of bleeding. Your doctor will discuss this with you.

If you are taking corticosteroids, danazol, and/or azathioprine, which you may be receiving to treat your ITP, these may be reduced or stopped when given together with Nplate.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Nplate is not recommended for use if you are pregnant unless indicated by your doctor.

It is not known whether romiplostim is present in human milk. Nplate is not recommended for use if you are breast-feeding. A decision on whether to discontinue breast-feeding or discontinue therapy with romiplostim should be made taking into account the benefit of breast-feeding to your child and the benefit of romiplostim therapy to you.

Driving and using machines

You should speak with your doctor before driving or using machines, as some side effects (e.g. temporary bouts of dizziness) may impair your ability to do so safely.

3. How to use Nplate

Nplate will be given under the direct supervision of your doctor, who will closely control the amount of Nplate given to you.

Nplate is administered once a week as an injection under the skin (subcutaneous).

Your initial dose is 1 microgram of Nplate per kilogram of your body weight once a week. Your doctor will tell you how much you must take. Nplate should be injected once per week in order to keep your platelet counts up. Your doctor will take regular blood samples to measure how your platelets are responding and may adjust your dose as necessary.

Once your platelet count is under control, your doctor will continue to regularly check your blood. Your dose may be adjusted further in order to maintain long-term control of your platelet count.

Always use Nplate exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure of how to use Nplate.

Instructions for preparing and giving an injection of Nplate

After suitable training, your doctor may also allow you to inject Nplate yourself. Please read the instructions at the end of this leaflet on how to inject Nplate, as discussed with your doctor. If your doctor has allowed you to self-inject, you should follow up with your doctor every month to have the doctor determine if Nplate is working for you or if another treatment needs to be considered.

After the first month of self-injecting Nplate, you will need to show that you can still prepare and inject Nplate correctly.

If you use more Nplate than you should

Your doctor will ensure that you receive the right amount of Nplate. If you have been given more Nplate than you should, you may not experience any physical symptoms but your blood platelet counts may rise to very high levels and this may increase the risk of blood clotting. Therefore if your doctor suspects that you have been given more Nplate than you should, it is recommended that you are monitored for any signs or symptoms of side effects and that you are given appropriate treatment immediately.

If your doctor has allowed you to self-inject and you use more Nplate than you should, then inform your doctor immediately.

If you use less Nplate than you should

Your doctor will ensure that you receive the right amount of Nplate. If you have been given less Nplate than you should, you may not experience any physical symptoms but your blood platelet counts may become low and this may increase the risk of bleeding. Therefore if your doctor suspects that you have been given less Nplate than you should, it is recommended that you are monitored for any signs or symptoms of side effects and that you are given appropriate treatment immediately.

If your doctor has allowed you to self-inject and you use less Nplate than you should, then inform your doctor immediately.

If you forget to use Nplate

If you have missed a dose of Nplate, your doctor will discuss with you when you should have your next dose.

If your doctor has allowed you to self-inject and you forget to give yourself an injection, you should inform your doctor immediately.

If you stop using Nplate

If you stop using Nplate, your low blood platelet count (thrombocytopenia) is likely to reoccur. Your doctor will decide if you should stop using Nplate.

Injecting Nplate yourself

Your doctor may decide that it is best for you to inject Nplate. Your doctor, nurse or pharmacist will show you how to inject yourself with Nplate. Do not try to inject yourself if you have not been trained. It is very important that you prepare Nplate properly and take the correct dose (see section 7. Instructions for preparing and giving an injection of Nplate, at the end of this leaflet).

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common: may affect more than 1 in 10 people

- headache;
- allergic reaction;
- upper respiratory tract infection.

Common: may affect up to 1 in 10 people

- bone marrow disorder, including increased bone marrow fibres (reticulín);
- trouble sleeping (insomnia);
- dizziness;
- tingling or numbness of the hands or feet (paraesthesia);
- migraine;
- redness of the skin (flushing);
- blood clot in a lung artery (pulmonary embolism);
- nausea;
- diarrhoea;
- abdominal pain;
- indigestion (dyspepsia);
- constipation;
- itching of the skin (pruritis);
- bleeding under the skin (ecchymosis);

- bruising (contusion);
- rash;
- joint pain (arthralgia);
- muscles pain or weakness (myalgia);
- pain in your hands and feet;
- muscle spasm;
- back pain;
- bone pain;
- tiredness (fatigue);
- injection site reactions;
- swelling in the hands and feet (oedema peripheral);
- flu like symptoms (influenza like illness);
- pain;
- weakness (asthenia);
- fever (pyrexia);
- chills;
- contusion;
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema);
- gastroenteritis;
- palpitations;
- inflammation of the sinuses (sinusitis);
- inflammation of the passages that carry air to the lungs (bronchitis).

Common: may affect up to 1 in 10 people (may show up in blood or urine tests)

- low blood platelet count (thrombocytopenia) and low blood platelet count (thrombocytopenia) after stopping Nplate;
- higher than normal platelet counts (thrombocytosis);
- anaemia.

Uncommon: may affect up to 1 in 100 people

- bone marrow failure; disorder of the bone marrow that causes scarring (myelofibrosis); enlarged spleen (splenomegaly); bleeding of the vagina (vaginal haemorrhage), bleeding in the rectum (rectal haemorrhage); bleeding mouth (mouth haemorrhage); injection site bleeding (injection site haemorrhage);
- heart attack (myocardial infarction); increased heart rate;
- dizziness or a spinning sensation (vertigo);
- problems with the eyes including: bleeding in the eye (conjunctival haemorrhage); difficulty focussing or blurred vision (accommodation disorder, papilloedema or eye disorder); blindness; itchy eye (eye pruritus); increased tears (lacrimation increased); or visual disturbances;
- problems with the digestive system including: vomiting; bad breath (breath odour); difficulty swallowing (dysphagia); indigestion or heartburn (gastro-oesophageal reflux disease); blood in the stools (haematochezia); stomach discomfort; mouth ulcers or mouth blistering (stomatitis); discoloured teeth (tooth discolouration);
- weight decreased; weight increased; intolerance of alcohol; loss of appetite (anorexia or decreased appetite); dehydration;
- generally feeling unwell (malaise); chest pain; irritability; swelling of the face (face oedema); feeling hot; increased body temperature; feeling jittery;
- influenza; localised infection; inflammation of the passages in the nose and throat (nasopharyngitis);
- problems with the nose and throat including: cough; runny nose (rhinorrhoea); dry throat; shortness of breath or difficulty breathing (dyspnoea); nasal congestion; painful breathing (painful respiration)
- painful swollen joints caused by uric acid (food breakdown product) (gout);
- muscle tightness; muscular weakness; shoulder pain; muscle twitching;

- problems with your nervous system including involuntary muscle contractions (clonus); distorted sense of taste (dysgeusia); decrease in sense of taste (hypogeusia); decreased feeling of sensitivity, especially in the skin (hypoesthesia); alteration in the nerve functions in the arms and legs (neuropathy peripheral); blood clot in the transverse sinus (transverse sinus thrombosis);
- depression; abnormal dreams;
- hair loss (alopecia); sensitivity to light (photosensitivity reaction); acne; allergic reaction in the skin upon contact with allergen (dermatitis contact); skin manifestation with rash and blisters (eczema); dry skin; redness of the skin (erythema); severe flaking or peeling rash (exfoliative rash); abnormal hair growth; thickening and itching of the skin due to repeated scratching (prurigo); bleeding beneath the surface of the skin or bruising under the skin (purpura); bumpy skin rash (rash papular); itchy skin rash (rash pruritic); generalised itchy rash (urticaria); bump on the skin (skin nodule); abnormal smell to the skin (skin odour abnormal);
- problems with the circulation including blood clot in the vein in the liver (portal vein thrombosis); deep vein thrombosis; low blood pressure (hypotension); increased blood pressure; blocking of a blood vessel or (peripheral embolism); reduced blood flow in the hands, ankles or feet (peripheral ischaemia); swelling and clotting in a vein, which may be extremely tender when touched (phlebitis or thrombophlebitis superficial); blood clot (thrombosis).
- a rare disorder characterised by periods of burning pain, redness and warmth in the feet and hands (erythromelalgia).

Uncommon: may affect up to 1 in 100 people (may show up in blood or urine tests)

- a rare type of anaemia in which the red blood cells, white blood cells and platelets are all reduced in number (aplastic anaemia);
- raised white blood cell count (leucocytosis);
- excess platelet production (thrombocythaemia); increased platelet counts; abnormal count in the cells in the blood that prevents bleeding (platelet count abnormal);
- changes in some blood tests (increase in transaminase; blood lactate dehydrogenase increased);
- or cancer of white blood cells (multiple myeloma);
- protein in the urine.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Nplate

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).

Do not freeze.

Store in the original carton in order to protect from light.

This medicine may be removed from the refrigerator for a period of 30 days at room temperature (up to 25°C) when stored in the original carton.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nplate contains

- The active substance is romiplostim.

Each vial of Nplate 250 micrograms powder for solution for injection contains a total of 375 micrograms of romiplostim. An additional overfill is included in each vial to ensure that 250 micrograms of romiplostim can be delivered. After dissolving, a deliverable amount of 0.5 mL solution contains 250 micrograms of romiplostim (500 micrograms/mL).

Each vial of Nplate 500 micrograms powder for solution for injection contains a total of 625 micrograms of romiplostim. An additional overfill is included in each vial to ensure that 500 micrograms of romiplostim can be delivered. After dissolving, a deliverable amount of 1 mL solution contains 500 micrograms of romiplostim (500 micrograms/mL).

- The other ingredients are:
Powder: mannitol (E421), sucrose, L-histidine, hydrochloric acid (for pH adjustment) and polysorbate 20.
Solvent: water for injections.

What Nplate looks like and contents of the pack

Nplate is a white powder for solution for injection supplied in a 5 mL single-dose glass vial.

Nplate is supplied as a 1 pack or multipack comprising 4 packs. Each pack contains:

- 1 vial of 250 micrograms or 500 micrograms of romiplostim.
- 1 pre-filled syringe containing 0.72 or 1.2 mL of water for injections.
- 1 plunger rod for pre-filled syringe.
- 1 sterile vial adapter.
- 1 sterile 1 mL Luer lock syringe.
- 1 sterile safety needle.
- 4 alcohol swabs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Amgen Limited
216 Cambridge Science Park
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Cambridge
CB4 0WA
United Kingdom

Manufacturer

Amgen Europe B.V.
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The Netherlands

Manufacturer

Amgen Technology (Ireland) Unlimited Company
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

Amgen Limited
Tel: +44 (0)1223 420305

This leaflet was last revised in October 2021.

7. Instructions for preparing and giving an injection of Nplate

This section contains information on how to give yourself an injection of Nplate. It is important that you do not try to give yourself the injection unless you have received training from your doctor, nurse or pharmacist. If you have questions about how to inject, please ask your doctor, nurse or pharmacist for assistance. It is very important the product is prepared correctly and the correct dose is taken.

This section is divided into the following subsections:

Before you begin

- Step 1. Set up materials for an injection
- Step 2. Prepare vial for use, attach vial adapter
- Step 3. Prepare sterile water syringe
- Step 4. Dissolving Nplate by injecting water into vial
- Step 5. Prepare new syringe for injection
- Step 6. Prepare injection needle
- Step 7. Choose and prepare an injection site
- Step 8. Injecting the Nplate liquid
- Step 9. Disposing of supplies

Before you begin

Read all instructions for use thoroughly. These instructions are for patients who are already trained by their healthcare professional, such as your doctor, nurse, or pharmacist, in self injection. If you have not been trained, please contact your healthcare professional.

The Nplate self injection kit must be kept in the original package until use in order to protect the Nplate vial from light. Keep the Nplate self injection kit refrigerated at 2°C to 8°C.

Once Nplate has been dissolved, inject immediately.

You may have excess Nplate left over after administering your prescribed dose. Do not re-use Nplate! Any excess dissolved Nplate must be thrown away immediately after completing the injection process. Left over Nplate in vial must NEVER be re-used for another injection.

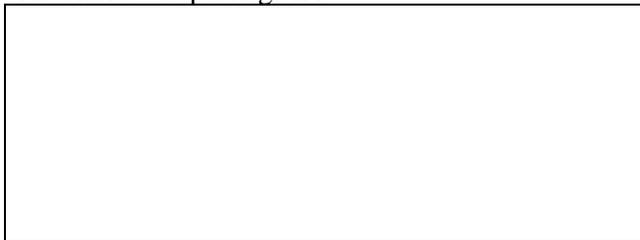
Step 1. Set up materials for an injection

Do the following:

- Select a well lit, flat work surface, such as a table.

- Take the Nplate self injection kit out of the refrigerator. **Do not use if frozen.** If you have any questions about storage, contact your healthcare professional for further instructions. **Check the expiry date on the self injection kit. If the expiry date has passed, do not use.** Stop and contact your healthcare professional.
- **Note:** If your healthcare professional has instructed you that your Nplate dose requires more than one injection of Nplate, you will need to use more than one self injection kit. Follow the steps as described in this leaflet and use as many self injection kits as necessary to complete your prescribed dose of Nplate.
- **Make sure you have the following items:**

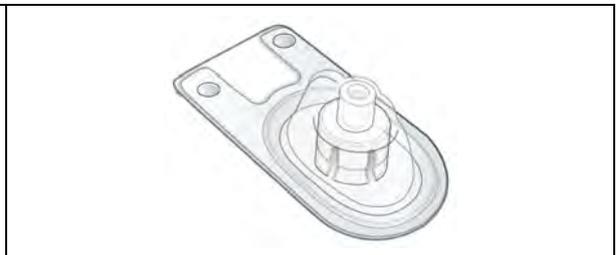
Alcohol swab package **x4**



A vial of powder, either 250 micrograms OR 500 micrograms **x1**



13 mm vial adapter **x1**



Plunger rod for pre-filled sterile water syringe **x1**



Pre-filled sterile water syringe **x1**



1 mL Luer-lock tip syringe **x1**



Injection safety needle **x1**



- **Do not** open items until directed in instructions.
- **Do not** use components that have evidence of tampering or damage.

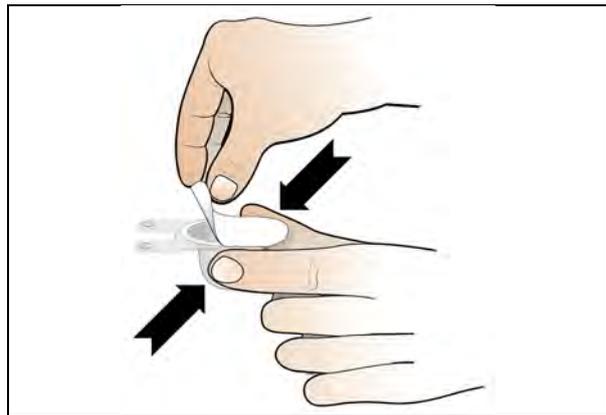
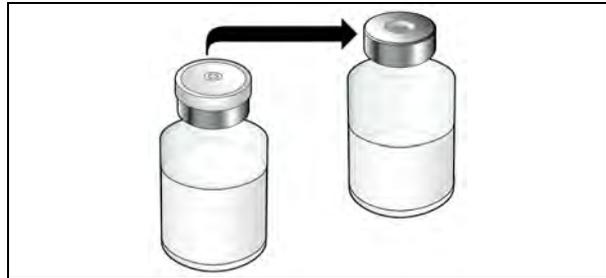
- **Do not** re-use items.

Step 2. Prepare vial for use, attach vial adapter

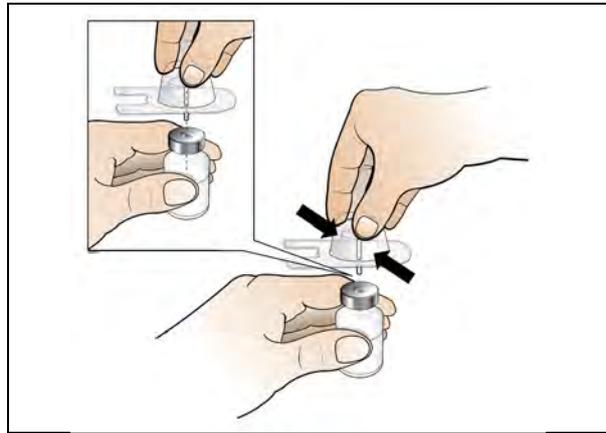
Using: 2 alcohol swab packages, 1 vial, and 1 vial adapter package.

Do the following:

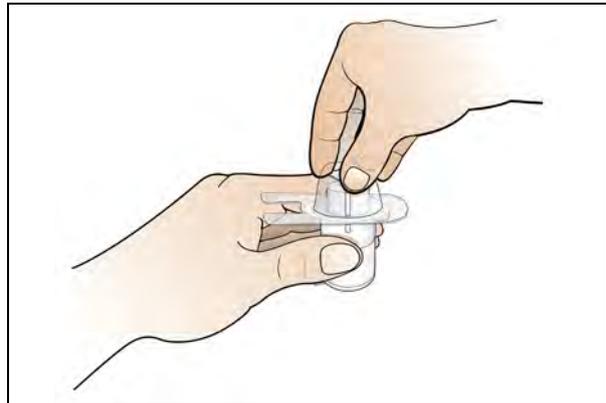
- **Wash your hands** with soap and warm water.
- **Clean the flat work surface with a new alcohol swab.**
- **Remove red (250 micrograms) or blue (500 micrograms) plastic cap from vial.**
- Using a new alcohol swab **clean vial stopper.**
- **Do not** touch vial stopper after cleaning it.
- **Peel off paper backing slowly from vial adapter while keeping vial adapter in the plastic package.**
- **Do not** touch vial stopper or spike of vial adapter.



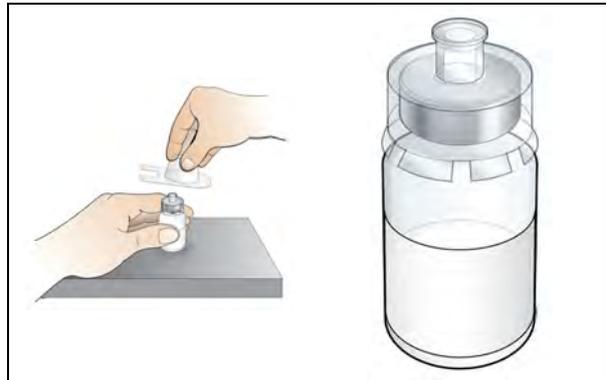
- Keeping the **vial on a table**, and keeping the vial adapter in the plastic packaging, **line up spike on the vial adapter to the centre of the stopper on the vial.**



- **Push the vial adapter down onto the vial until it is firmly in place** and you can't push down any more.



- **Lift off plastic vial adapter packaging, leaving vial adapter on vial.**
- **Do not touch the top of vial adapter.**



Step 3. Prepare sterile water syringe

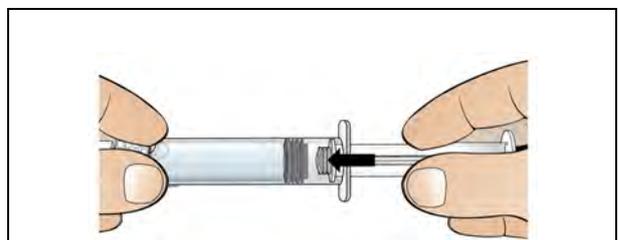
Using: Pre-filled sterile water syringe and plunger rod.

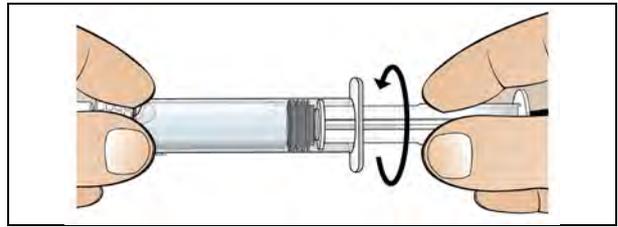
Before you begin Step 3 please note the following:

- The clear plastic plunger rod **MUST** always be attached first before breaking the white tip off of the pre-filled water syringe. Perform step 3a before step 3b.

Do the following:

- **Step 3a: Attach clear plastic plunger rod to pre-filled sterile water syringe** by placing the threaded end of the plunger rod into the syringe and carefully twisting the rod clockwise onto the grey syringe plunger, until you feel a slight resistance. Do not over tighten.

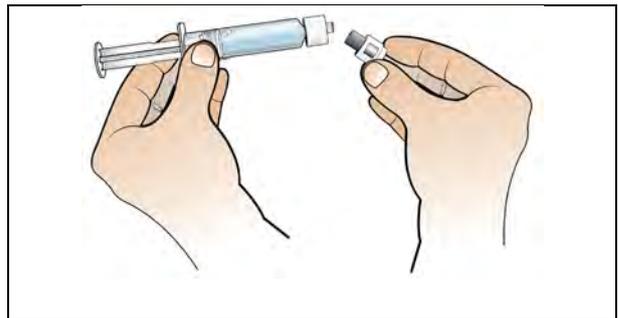




- **Step 3b: Holding the syringe with one hand, bend the tip of the white plastic cover downward with your other hand.** This will break the seal of the white plastic cover.



- Once the seal is broken, **pull the white plastic cover off.** You will see grey rubber in the cap.



Step 4. Dissolving Nplate by injecting water into vial

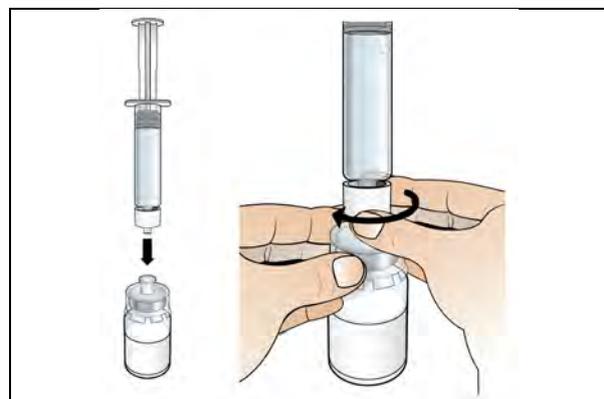
Using: Pre-filled sterile water syringe and vial with vial adapter attached.

Before you begin Step 4 please note the following:

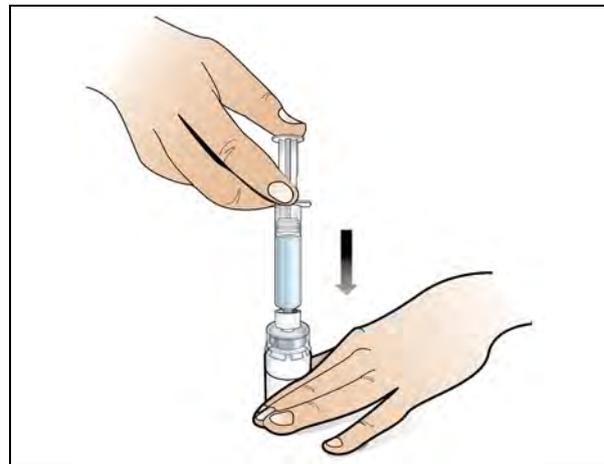
- **Do** dissolve slowly and carefully. This is a protein product and proteins can be easily damaged by improper mixing and excessive shaking.

Do the following:

- **Keeping the vial on the table, attach water-filled syringe to vial adapter** by holding the side of the vial adapter with one hand and twisting the syringe tip clockwise onto the adapter with the other hand until you feel a slight resistance.



- **Very slowly and gently push down on plunger rod to inject all water in the syringe into the vial.** Water must flow slowly onto powder.
- **Do not** force the water into the vial.
- **Note:** After injecting the water into the vial it is common for the plunger to move back up. You do not have to maintain pressure on the plunger for the rest of Step 4.



Push slowly and gently

Before continuing:

- **Do** ensure that all water is injected from the syringe into the vial before dissolving.

- **Holding the area where the vial and vial adapter connect between your fingers, gently swirl the vial by rotating your wrist until all of the powder has dissolved and the liquid in the vial is clear and colourless.**



Correct

- **Do** gently swirl the vial.
- **Do not** shake the vial.
- **Do not** roll vial between palms.
- **Note:** It may take up to 2 minutes for the powder to completely dissolve.

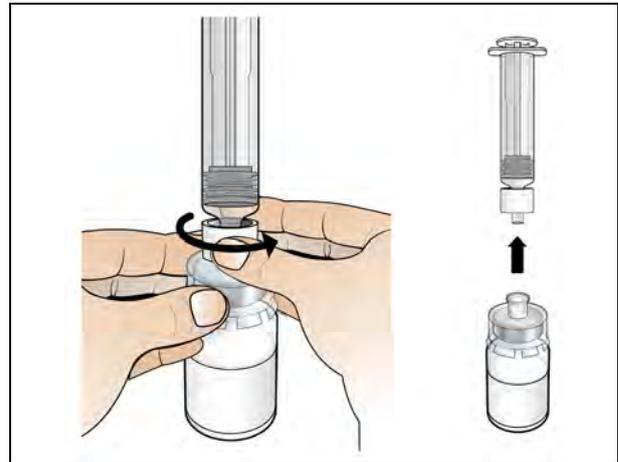


Incorrect

Before continuing:

- **Do** visually inspect the dissolved liquid for particles and/or discolouration. It must be clear and colourless and fully dissolved.
- **Note:** If there is **any colour or particles in the liquid**, contact your healthcare professional.
- **Do** make sure liquid is fully dissolved before removing syringe.

- **When Nplate is completely dissolved, remove the empty syringe by twisting it anti-clockwise off of the vial adapter.**



- **Discard the empty syringe** into sharps or hazard container. Keep the dissolved Nplate Vial. Immediately prepare new syringe for injection.
- **Do not** delay injecting Nplate.

Step 5. Prepare new syringe for injection

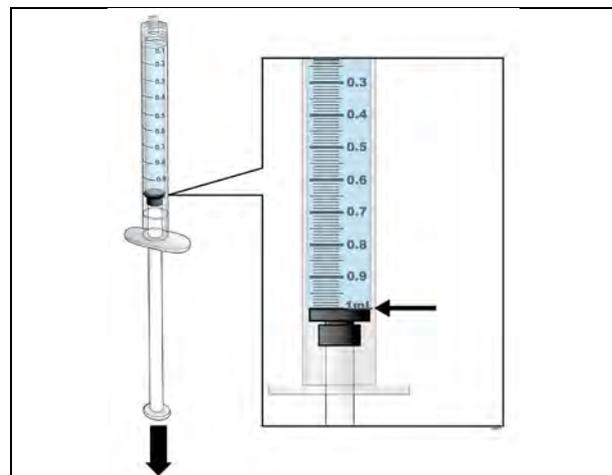
Using: A new 1 mL syringe package and the vial of dissolved, clear Nplate.

Before continuing:

- **Do** check your dose before starting this step.
- **Note:** The Nplate liquid is highly potent which is why accuracy and dose measurement are important.
- **Do** make sure that all air bubbles are removed before injection.

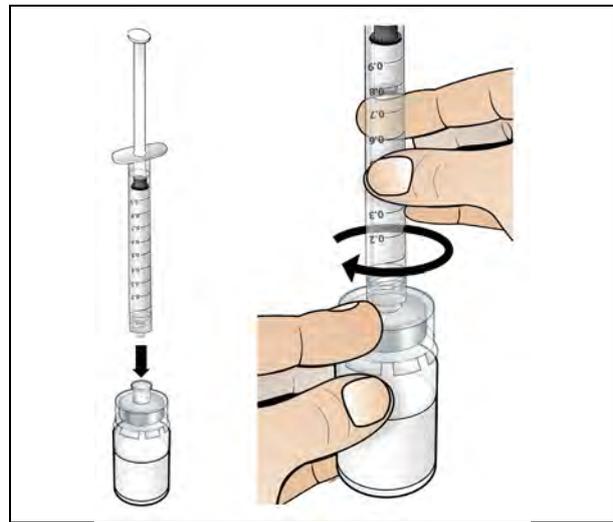
Do the following:

- **Remove 1 mL syringe from package.**
- **Draw air into syringe to 1 mL marking.**
- **Do not** pull plunger back to more than 1 mL.

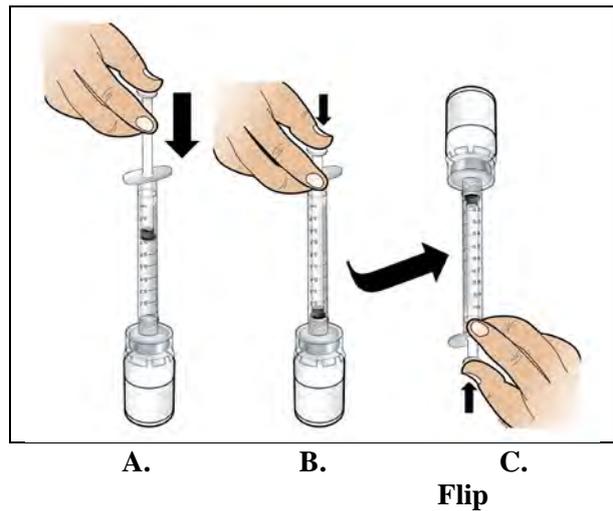


Draw air into syringe to the 1 mL mark

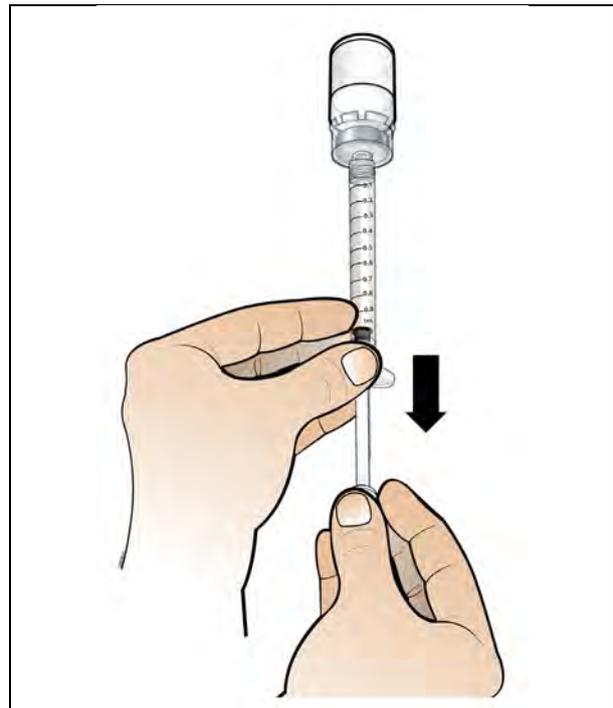
- **Attach 1 mL syringe to vial adapter** of the dissolved Nplate by twisting the syringe tip clockwise onto the vial adapter until you feel a slight resistance.



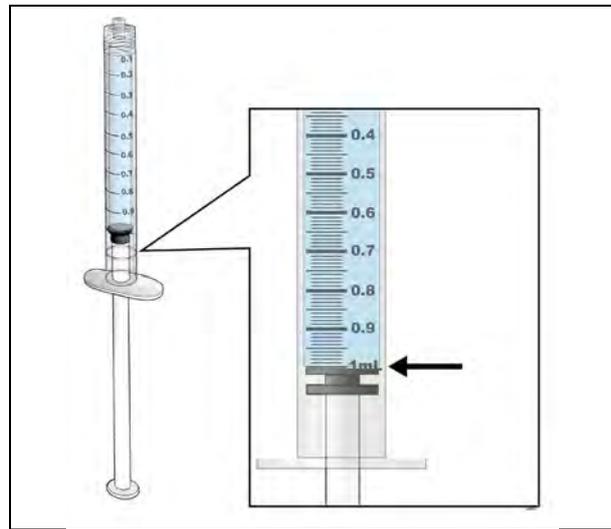
- Push air into vial.**
- Maintain pressure on plunger.**
- Turn vial assembly and syringe upside down**, so the vial is directly above the syringe.



- **Withdraw the full amount of liquid into the syringe.**
 - The maximum deliverable volume for the 250 microgram vial is 0.5 mL and for the 500 microgram vial is 1 mL.
- **Do not pull the plunger out of the back of the syringe.**



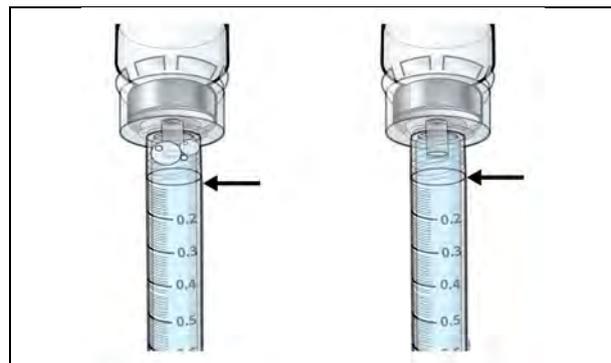
- **Do** ensure that the plunger remains in the syringe.



Correct

- **Check and remove all air bubbles in the syringe.**

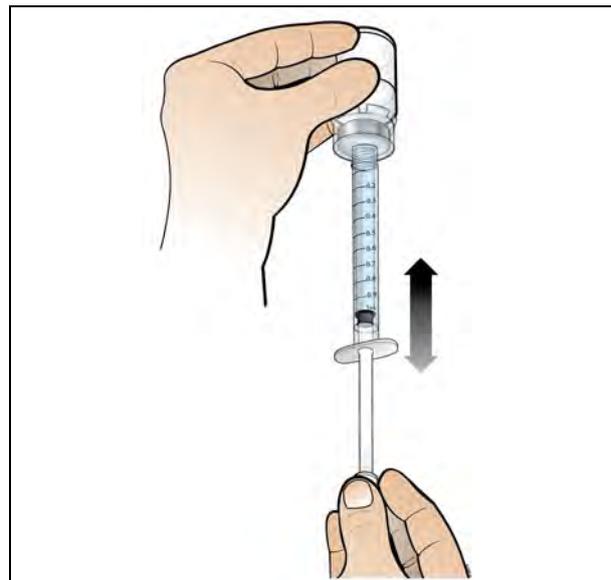
- Gently tap the syringe with your fingers to separate the bubbles from the liquid.
- Slowly **push the plunger up** to force the air bubbles out of the syringe.



**Air bubbles:
Incorrect**

Correct

- **Slowly push back on the plunger to leave only the amount prescribed by your healthcare professional.**
- **Make sure the top of the plunger head lines up with the syringe marking that matches your prescribed dose.** If necessary push liquid back into the vial to achieve the desired dose.

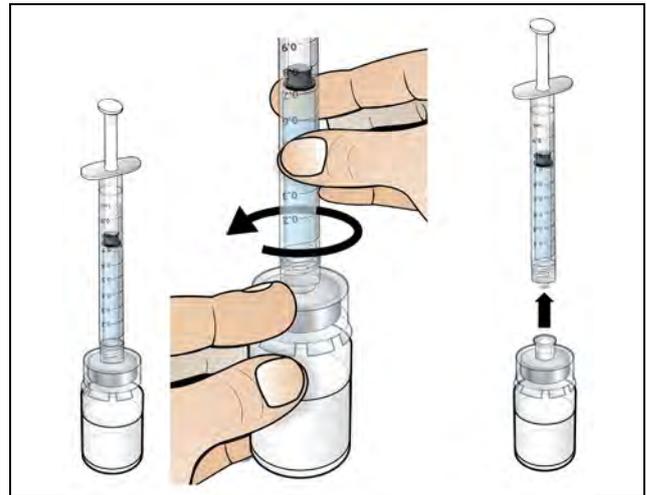


Adjust the amount to your prescribed dose

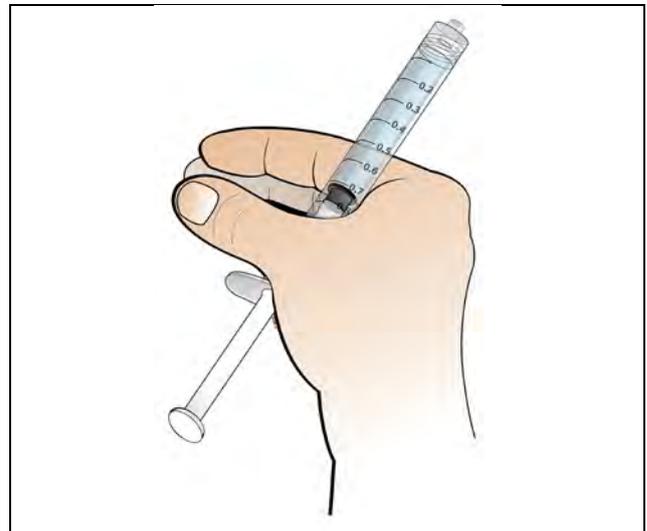
- **Do a final check to ensure the correct amount of liquid for your dose is in the syringe** and all air bubbles have been removed.

Before continuing:

- **Do** make sure the correct amount of liquid for your dose remains in the syringe.
- **Do** make sure all air bubbles are removed from the syringe.
- Once all air bubbles are removed and syringe is filled with your correct dose, **twist off syringe from vial adapter.**



- **Keep filled syringe in your hand and do not touch syringe tip.**
- **Do not** set filled syringe down after removing from vial.



Step 6. Prepare injection needle

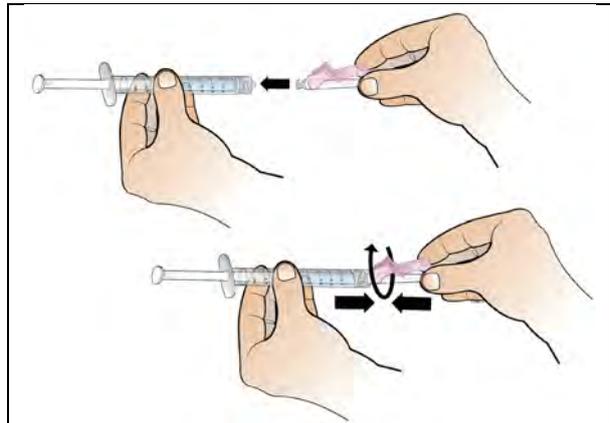
Using: Filled syringe with measured Nplate dose and safety needle.

Do the following:

- Holding the syringe in the palm of your hand with the tip facing up, **remove the safety needle from the package.**



- **Attach safety needle** to filled syringe. **Apply strong force while twisting to attach** the safety needle onto syringe. **Turn clockwise** to lock into Luer lock tip.
- The product is now ready for injection. **IMMEDIATELY** continue to step 7.

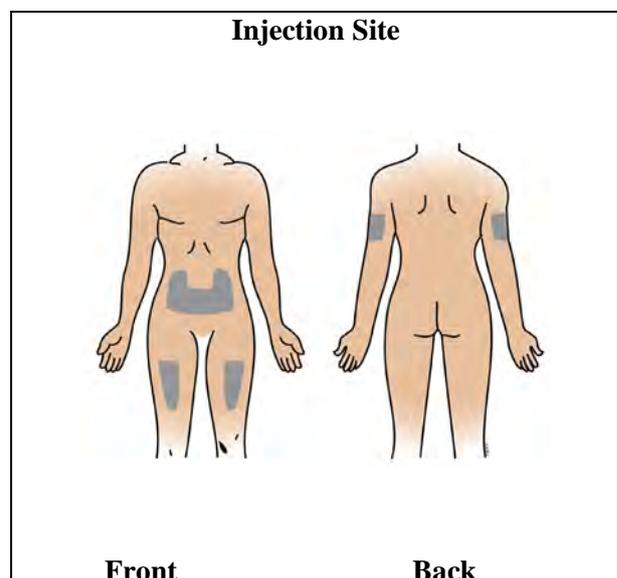


Step 7. Choose and prepare an injection site

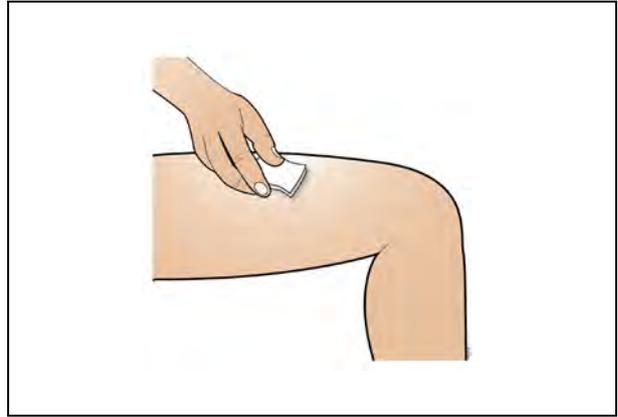
Using: New alcohol swab.

Do the following:

- **Select your injection site.** Three recommended injection sites for Nplate include:
 - Front of the middle thighs
 - Abdomen, except for the 5 centimetre area right around the navel
 - If someone else is giving you the injection, they can also use the outer area of the upper arms
 - **Do** rotate the site for each injection.



- **Do not inject into areas where the skin is tender, bruised and hard.**
- **Do not** inject into areas with scars or stretch marks.
- Wipe the site where Nplate is to be injected with an alcohol swab, using a circular motion.
- **Do not** touch this area again before giving the injection.

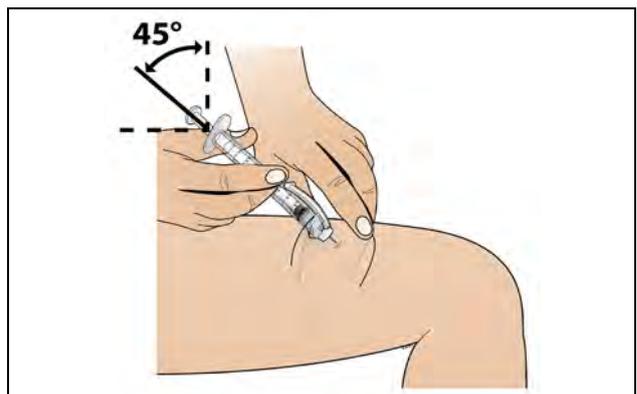


Step 8. Injecting the Nplate liquid

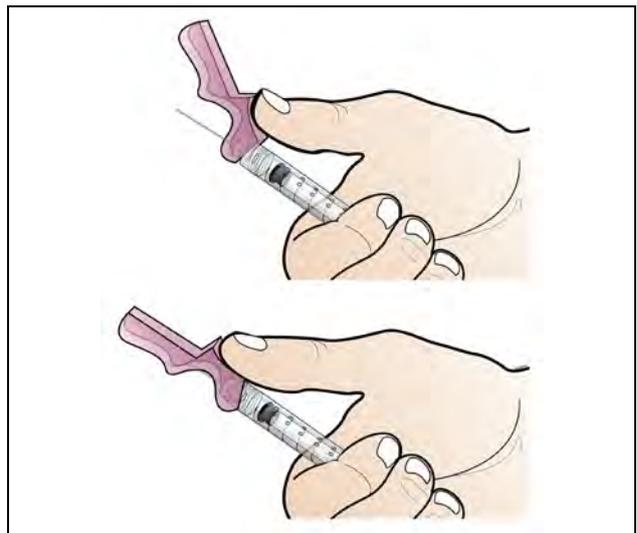
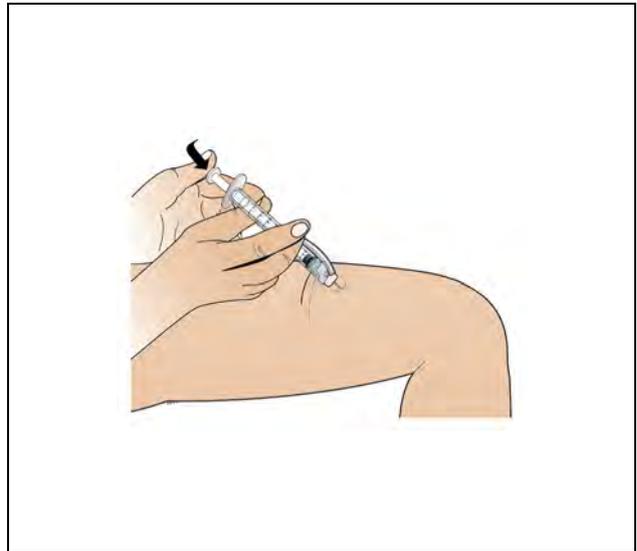
Using: Filled syringe and needle assembly.

Do the following:

- **Pull back on the pink safety cover** (toward the syringe and away from the needle).
- **Remove clear needle shield** by holding syringe in one hand and carefully pulling shield straight off with the other hand.
- **Do** remove the clear needle shield before injecting.
- With one hand, **gently pinch the cleaned area** of skin and hold it firmly. With the other hand, **hold the syringe (like a pencil)** at a **45-degree angle** to the skin.
- With a short, sharp motion, **push the needle into the skin.**



- Inject the prescribed dose subcutaneously as directed by your doctor, nurse or pharmacist.
- When the syringe is empty, pull the needle out of the skin, **being careful to keep it at the same angle as inserted.**
- There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site for 10 seconds.
- **Do not rub the injection site.** If needed, you may cover the injection site with a plaster.
- **After injecting, use your thumb (or tip of your finger) to activate the pink safety cover** by pushing the cover forward using the same hand until you hear and/or feel it click and lock into place over the needle.



- **Visually confirm** that the needle tip is covered. Always cover the needle with the pink safety cover before disposal.



Step 9. Disposing of supplies

Do the following:

- **Immediately discard syringe with covered needle** into a sharps container.
- **Immediately discard used Nplate vial** into an appropriate waste container.
- **Make sure all other materials are discarded into proper containers.**

The injection device and Nplate vial must **NEVER** be reused.

- **Do** dispose of the used needle and syringe in a puncture-resistant container.
- **Do** dispose of any left-over Nplate in proper waste container. **Left over Nplate in the vial must NEVER be re-used for another injection.**