

# STEP-BY-STEP GUIDE TO PREPARATION AND ADMINISTRATION OF THE NPLATE<sup>®</sup> INJECTION

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## A visual aid for your home-administration of Nplate<sup>®</sup>

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This booklet will guide you through all the steps you'll need to perform to successfully prepare and administer your weekly Nplate<sup>®</sup> injection at home.

During training, your healthcare professional will have shown you all of the steps in this *Step-by-step guide*. When you administer at home, this booklet will remind you of all the preparation and administration steps, so you can be confident you're performing every step correctly.

### 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. Side effects can be reported directly to the Health Products Regulatory Authority (HPRA) using the available methods via [www.hpra.ie](http://www.hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

PLEASE CONTACT YOUR DOCTOR WITH ANY QUESTIONS OR CONCERNS YOU HAVE

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## BEFORE YOU BEGIN

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### Read all instructions for use thoroughly.

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The instructions in this *Step-by-step guide* are intended for patients who have already been trained in self-injection by their healthcare professional. If you have not been trained, please contact your healthcare professional and do not self-administer Nplate®.

### A few notes on storage and use

Keep your Nplate® in the original package and in the refrigerator until you're ready to use it

- Nplate® should not be frozen
- Nplate® should be protected from light
- Nplate® may be removed from the refrigerator for a maximum period of 30 days at room temperature (up to 25°C)
- Do not use this medicine after the expiry date. The expiry date is stated on the carton and vial label after EXP. The expiry date refers to the last day of that month

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

First, prepare your workspace and the *Nplate*<sup>®</sup> preparation mat:

Place the mat on a clean, well-lit, flat surface (such as a table)

Wash your hands with soap and water, and dry them thoroughly with a clean towel

Clean the mat with an alcohol swab (item F)

## NPLATE<sup>®</sup> PREPARATION MAT

**You must be trained by your healthcare provider before you can administer Nplate<sup>®</sup>.**









**BEFORE YOU BEGIN**

- Read all instructions for use thoroughly.
- You should establish a regular treatment schedule, even when travelling.
- Make sure you have all the supplies that you will need (refer to the images below).
- Check the expiration dates on all vials.
- Do not use if expired or left at room temperature for more than 30 days.
- Wash your hands with soap.
- Use an alcohol swab to clean the surface where you will be preparing product.

**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 via HPRA Pharmacovigilance, Earldown Terrace, RI - Dublin 2,  
Tel: +353 1 6264077, Fax: +353 1 6262517, Website: www.hpra.ie, E-mail: medwatch@hpra.ie.  
By reporting side effects you can help provide more information on the safety of this medicine.

**NOTE:**  
Please use this mat along with the *Step-by-step guide* and/or *Package leaflet* and *Self-administration DVD* to prepare your Nplate<sup>®</sup> injection. You may be required to use more than one injection of Nplate<sup>®</sup>. If your doctor has instructed you to take more than one injection of Nplate<sup>®</sup>, follow the steps as defined in the *Step-by-step guide* to complete your prescribed dose of product using a new self-administration kit(s).

**Make sure you have the following materials before you begin**

<b>A</b> Product vial (1) 	<b>B1</b> Plunger rod (1) 	<b>B2</b> Prefilled sterile water syringe (1) 
<b>C</b> Disposable 1 ml syringe with Luer lock (1) 	<b>D</b> Safety needle: 27 G*, 13 mm (1) 	
<b>E</b> Vial adapter (1) 	<b>F</b> Alcohol swab packages (x4) 	<b>G</b> Sharps container (1; not supplied) 

\*Some product vials in their carton to protect from light until use. This medicine may be removed from the refrigerator for a maximum period of 30 days at room temperature (up to 25°C). Your healthcare provider may recommend a different needle for injection.

NOTE: These images are for reference only.

# YOUR PREPARATION AREA

## STEP 1: SET UP MATERIALS FOR AN INJECTION

Once your workspace is clean and ready, take the Nplate<sup>®</sup> self-injection kit out of the refrigerator.

Look closely at the powder in the Nplate<sup>®</sup> vial, to see if it's frozen. **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<sup>®</sup> dose requires more than one injection of Nplate<sup>®</sup>, you will need to use more than one self-injection kit. Follow the steps as described in this *Step-by-step guide* and use as many self-injection kits as necessary to complete your prescribed dose of Nplate<sup>®</sup>.

Make sure you have the following items. These are the items you will need to prepare and administer Nplate®. These items are organised the same way they are on your *Nplate® preparation mat*, which you should use whenever you prepare your Nplate® injection. Note: Do not open items until directed to do so in the instructions. Do not use components that have evidence of tampering or damage. Do not re-use items. The Sharps container is not included in your self-administration pack, and should be obtained before initiating self-administration.

**A** Product vial (1)



**B1** Plunger rod (1)



**B2** Prefilled water syringe (1)



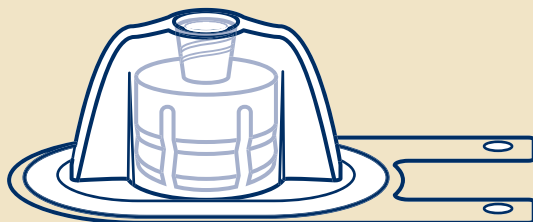
**C** Disposable 1 ml syringe with Luer lock



**D** Safety needle: 27 G, 13 mm (1)



**E** Vial adapter (1)



**F** Alcohol swabs (x4)



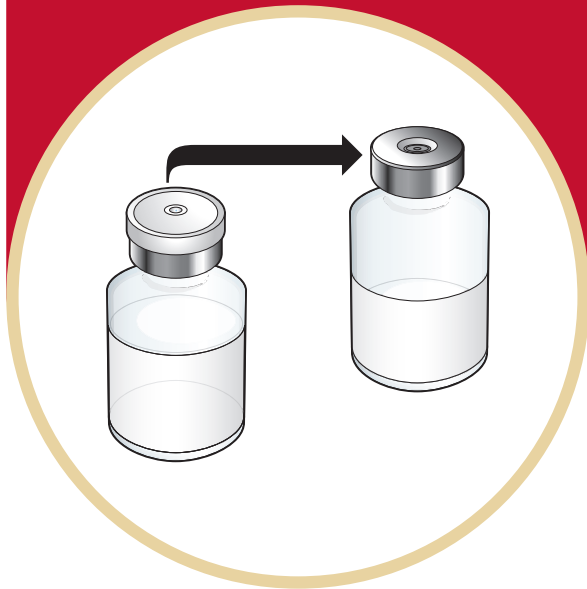
**G** Sharps container (1; not supplied)



## STEP 2: PREPARE VIAL FOR USE, ATTACH VIAL ADAPTER

This step uses 1 alcohol swab (item F), 1 Nplate<sup>®</sup> vial (item A), and 1 vial adapter (item E)

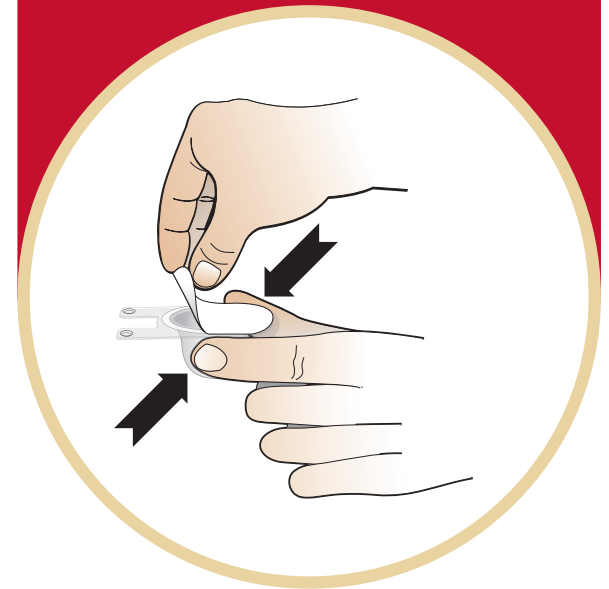
- Remove red (250 micrograms) or blue (500 micrograms) plastic cap from vial



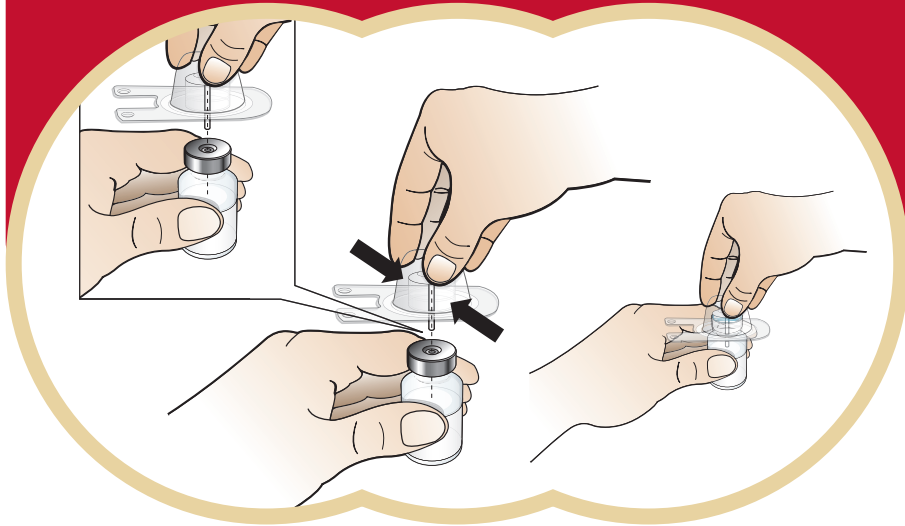
- Using a new alcohol swab clean vial stopper
- Do not touch vial stopper after cleaning it



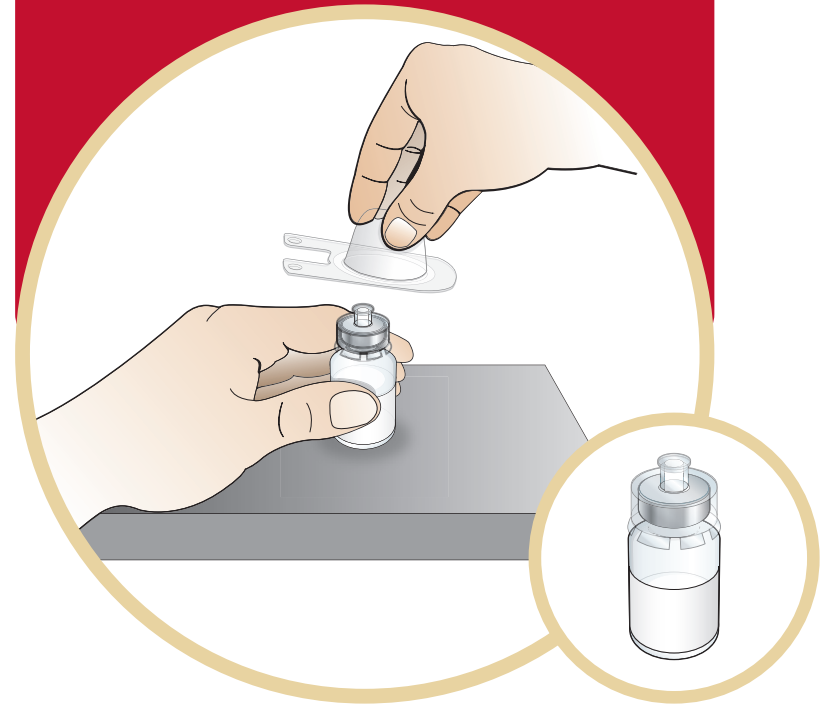
- Peel off paper backing slowly from vial adapter while keeping vial adapter in the plastic package
- Do not touch vial stopper or spike of vial adapter



- 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 syringe connector

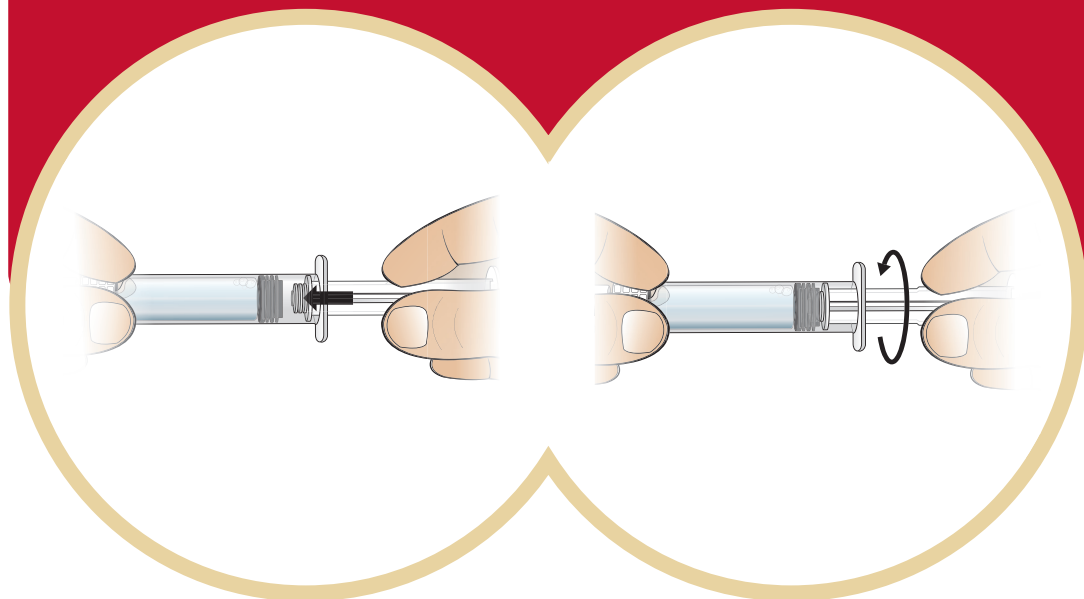


## STEP 3: PREPARE STERILE WATER SYRINGE

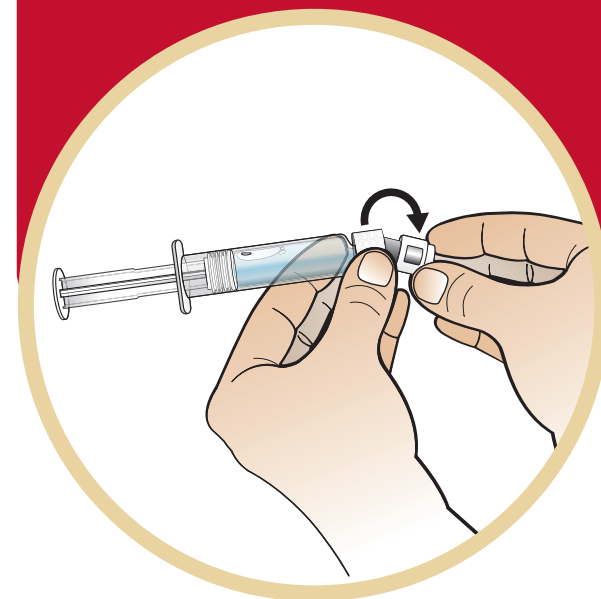
**This step uses 1 plunger rod (item B1) and 1 pre-filled water syringe (item B2)**

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.

- **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



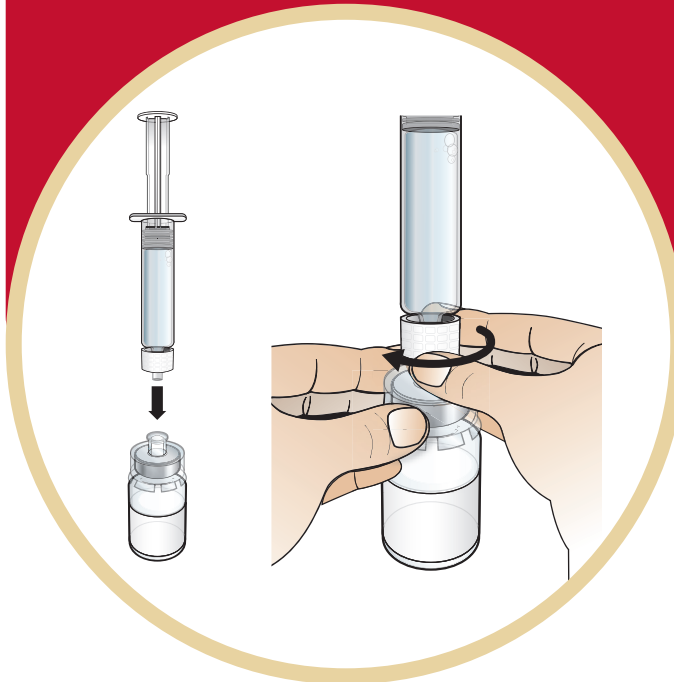


## STEP 4: DISSOLVING NPLATE<sup>®</sup> BY INJECTING WATER INTO VIAL

**This step uses the syringe you just assembled in step 3, plus the vial and adapter assembly from step 2**

Before you begin step 4 please note the following: Do dissolve Nplate<sup>®</sup> powder slowly and carefully. This is a protein product and proteins can be easily damaged by improper mixing and excessive shaking.

- **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



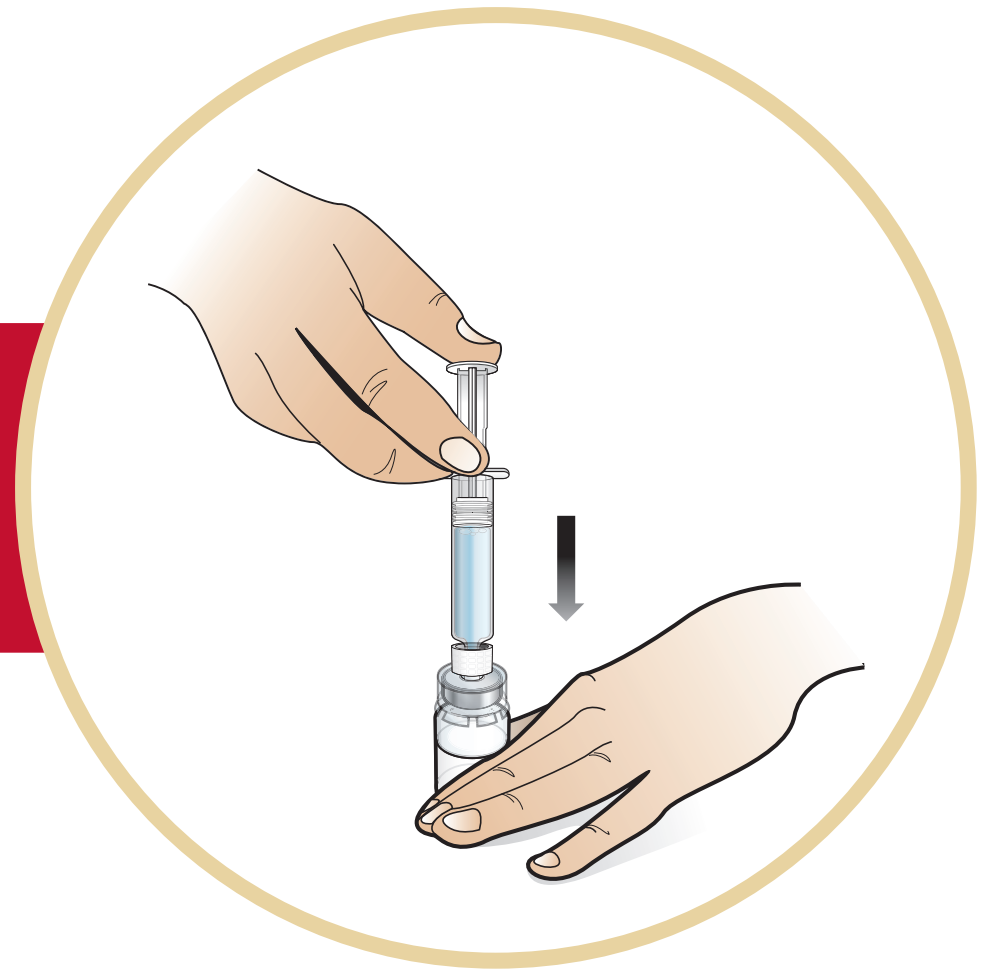
STEP 3

STEP 4

## STEP 4: DISSOLVE NPLATE® BY INJECTING WATER INTO VIAL

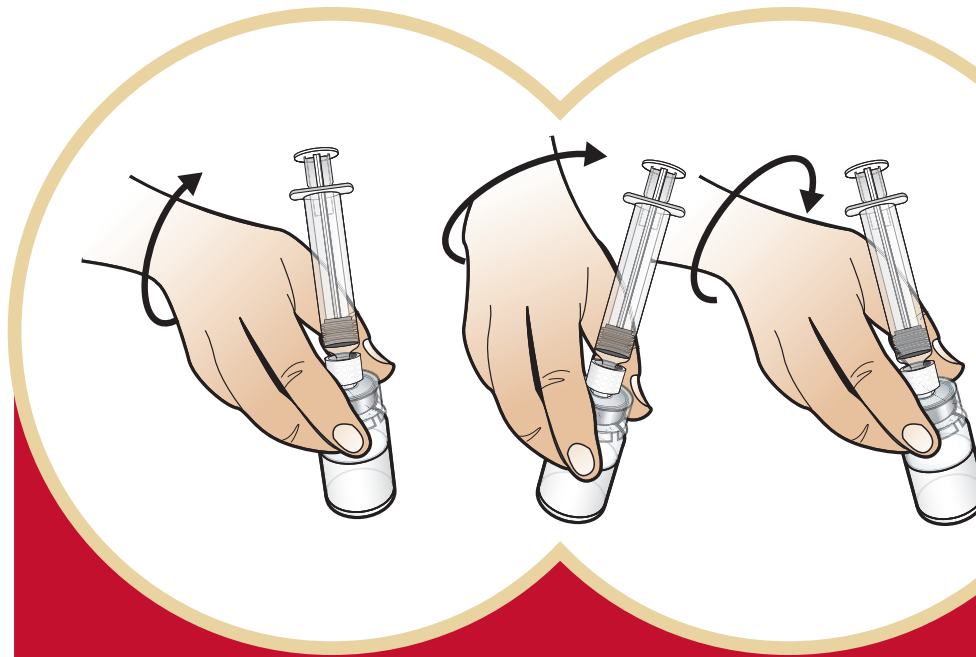
- **Very slowly and gently push down on plunger rod to inject all water in the syringe into the vial.** Water must flow slowly onto powder
- **Do not** force the water into the vial

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.



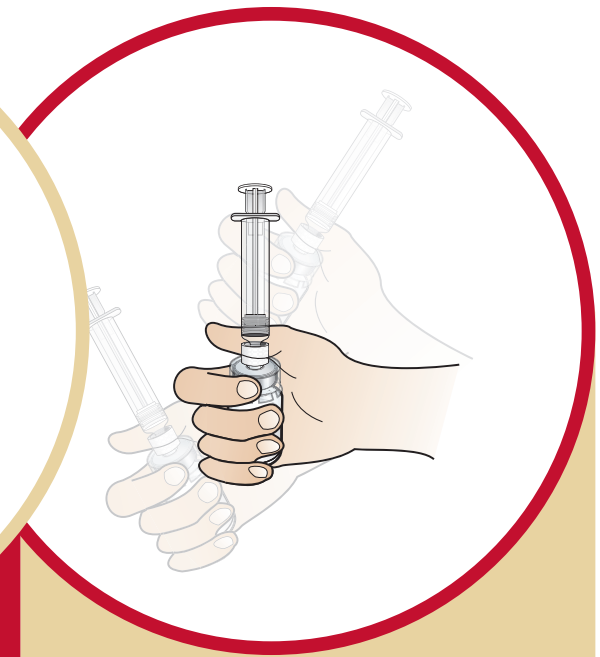
Before continuing: Do ensure that all water is injected from the syringe into the vial before dissolving.

### Correct



- 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

### Incorrect

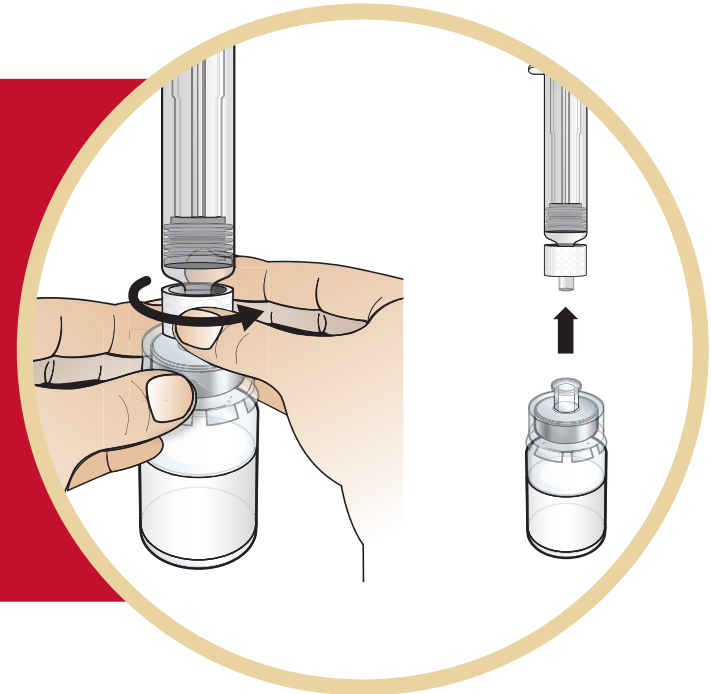


- **Do not** shake the vial
- **Do not** roll vial between palms

**Note:** It may take up to 2 minutes for the powder to completely dissolve

## STEP 4: DISSOLVE NPLATE® BY INJECTING WATER INTO VIAL

- 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®

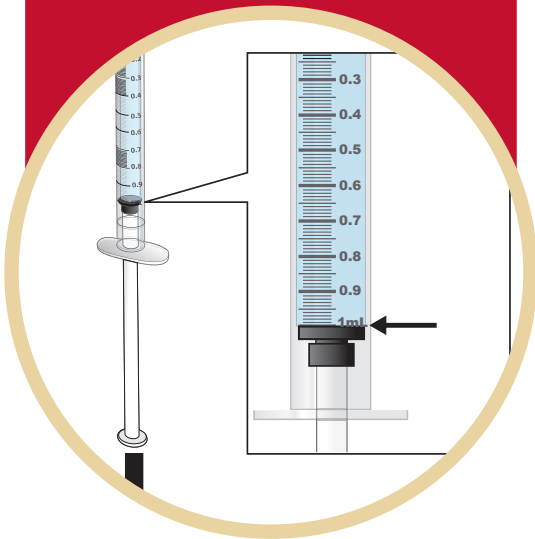


## STEP 5: PREPARE NEW SYRINGE FOR INJECTION

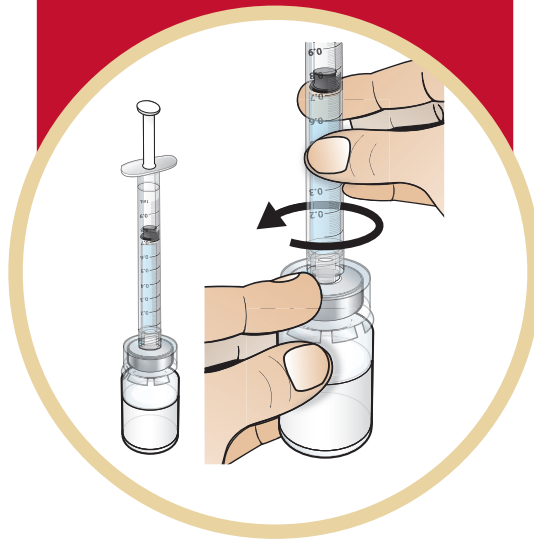
This step uses the vial of clear, dissolved Nplate<sup>®</sup> plus the vial adapter from step 4, and the 1 ml syringe (item C)

Before continuing: Do check your dose before starting this step. Note: The Nplate<sup>®</sup> liquid is highly potent which is why accuracy and dose measurement are important. Do make sure that all air bubbles are removed before injection.

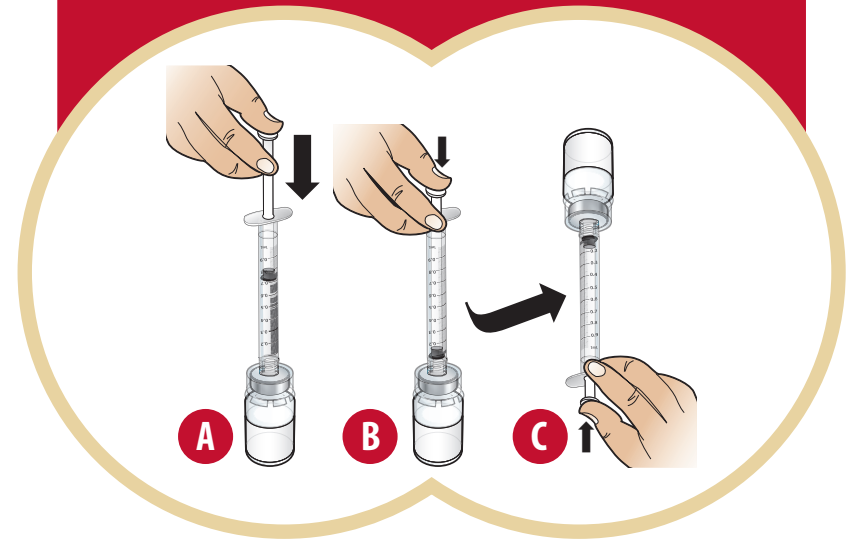
- Remove 1 ml syringe from package
- Draw air into syringe to 1 ml marking
- Do not pull plunger back to more than 1 ml



- **Attach 1 ml syringe to vial adapter** of the dissolved Nplate<sup>®</sup> by twisting the syringe tip clockwise onto the vial adapter until you feel a slight resistance

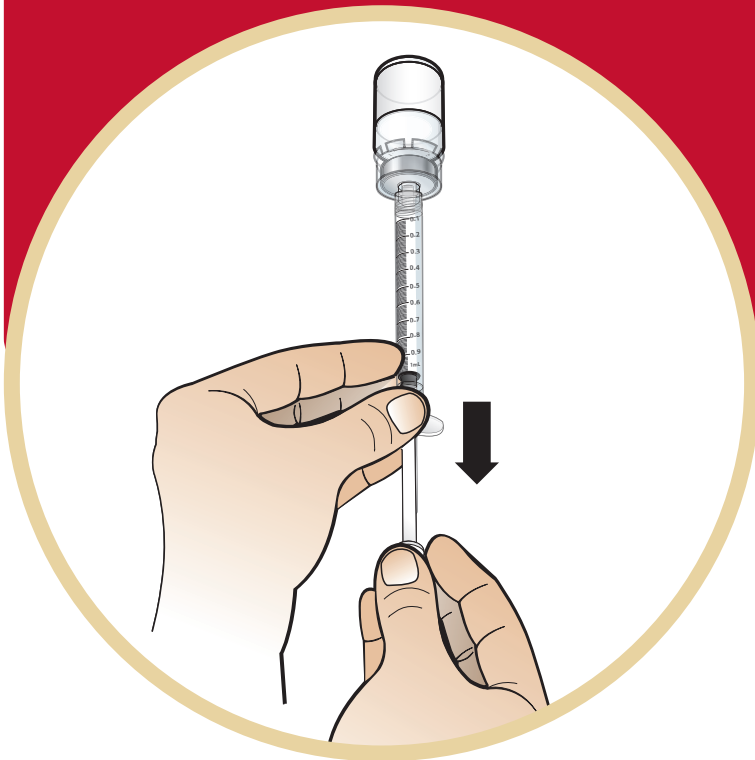


- A. Push air into vial
- B. Maintain pressure on plunger
- C. Turn vial assembly and syringe upside down, so the vial is directly above the syringe

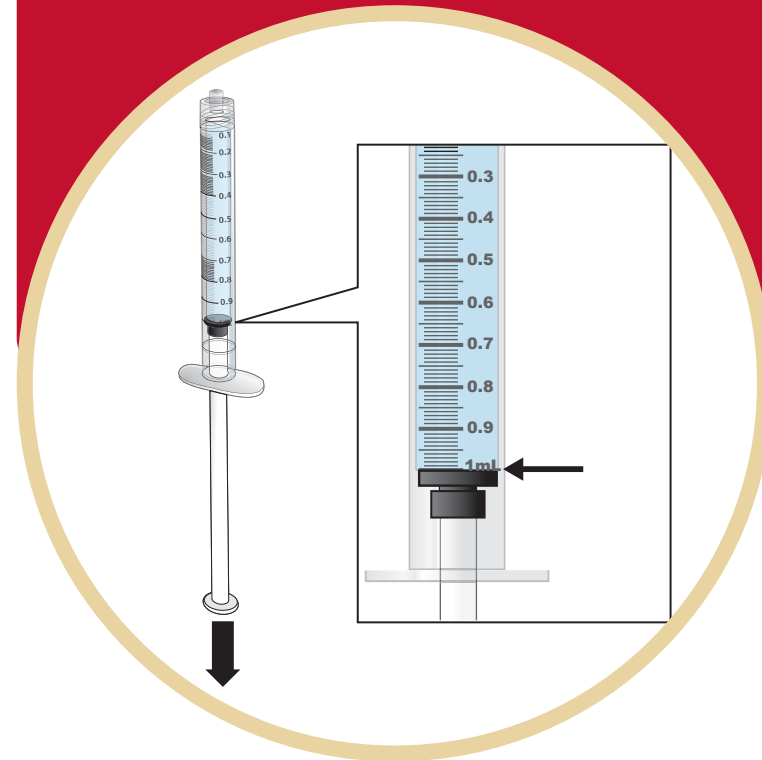


## STEP 5: PREPARE NEW SYRINGE FOR INJECTION

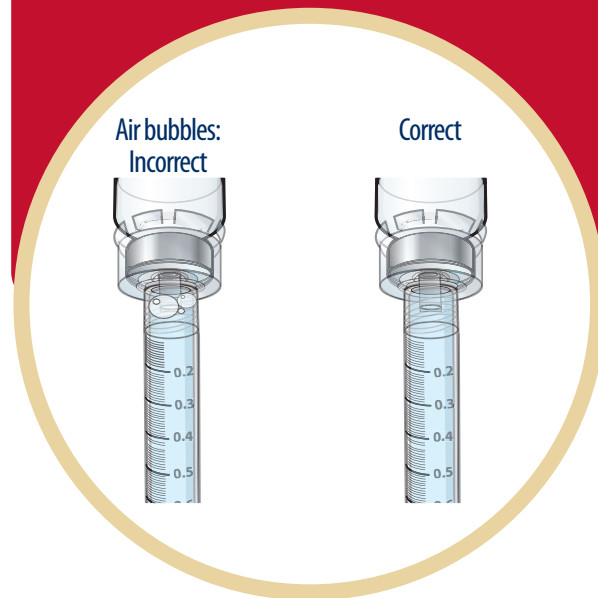
- Withdraw the full amount of liquid into the syringe
  - The maximum deliverable volume for the 250 mcg vial is 0.5 ml and for the 500 mcg vial is 1 ml
- Do not pull the plunger out of the back of the syringe



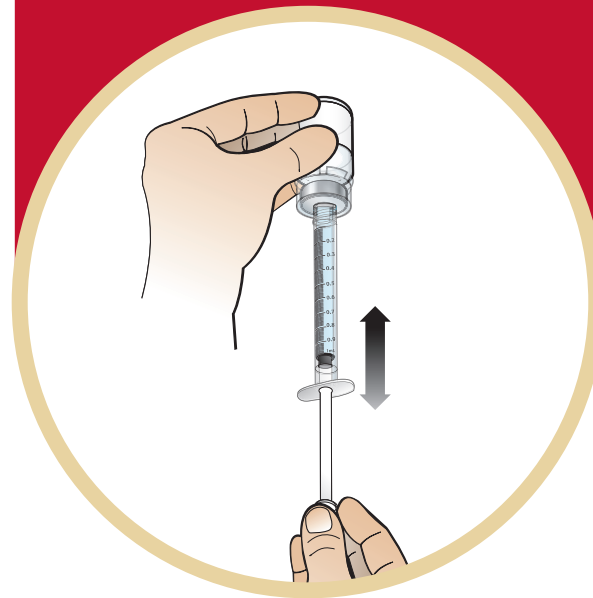
- Do ensure that the plunger remains in the syringe



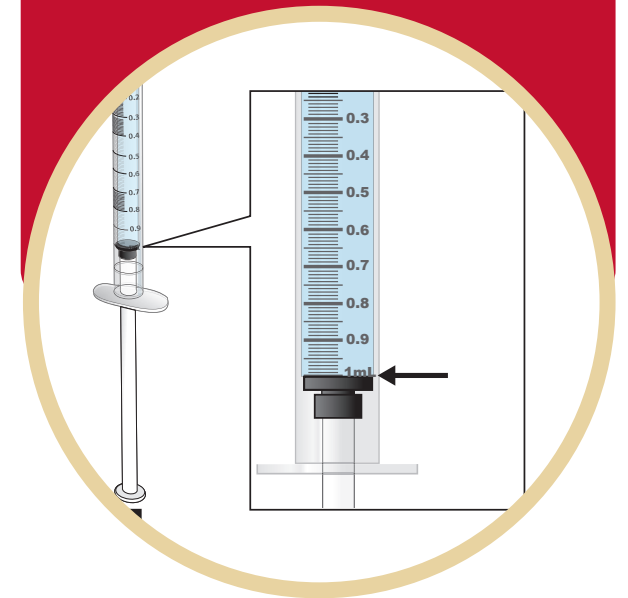
- Check and remove all air bubbles from the syringe
  - Gently tap the syringe with your fingers to separate the bubbles from the liquid
  - Slowly push the plunger up to force the air bubbles out of the syringe



- **Check your dose by looking at your dose card**
- Slowly push back on the plunger to leave only the amount prescribed by your healthcare professional



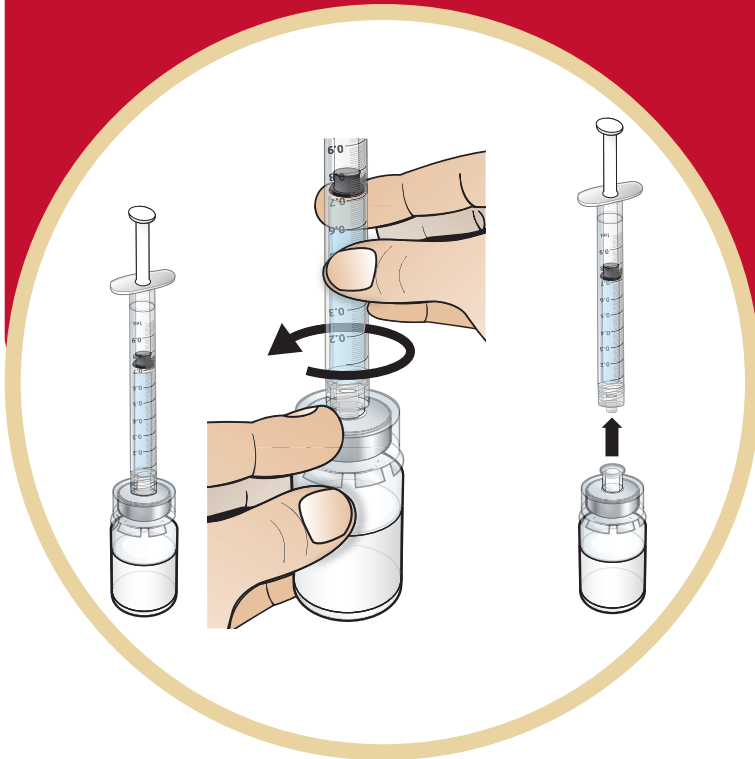
- Make sure the top of the plunger head lines up with the syringe marking that matches your prescribed dose. If necessary push liquid back into the vial to achieve the desired dose
- Do a final check to ensure the correct amount of liquid for your dose is in the syringe and all air bubbles have been removed



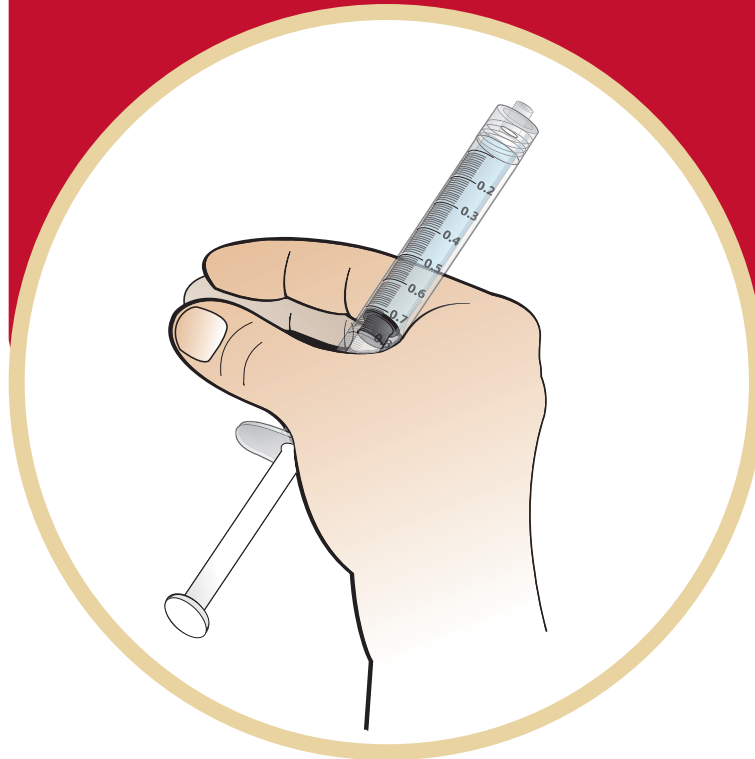
Before continuing: Do make sure the correct amount of liquid for your dose remains in the syringe. Do make sure all air bubbles are removed from the syringe.

## STEP 5: PREPARE A NEW SYRINGE FOR INJECTION

- 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

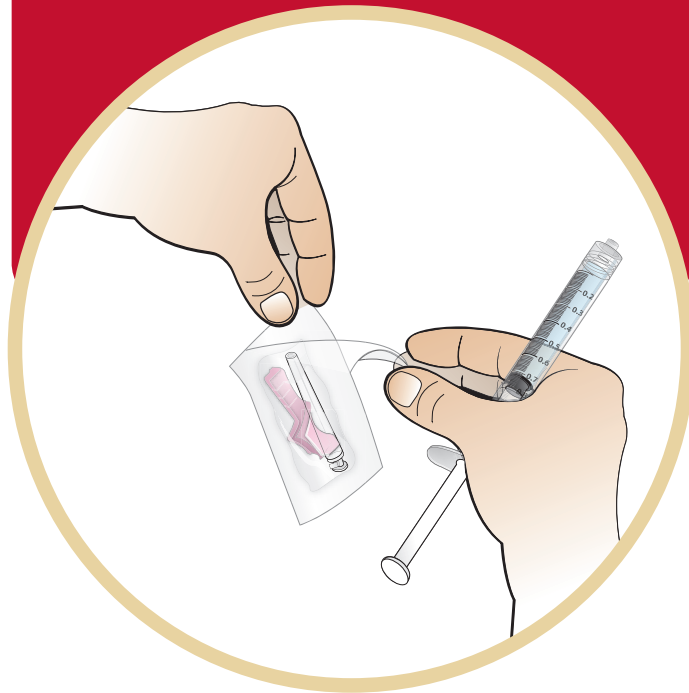




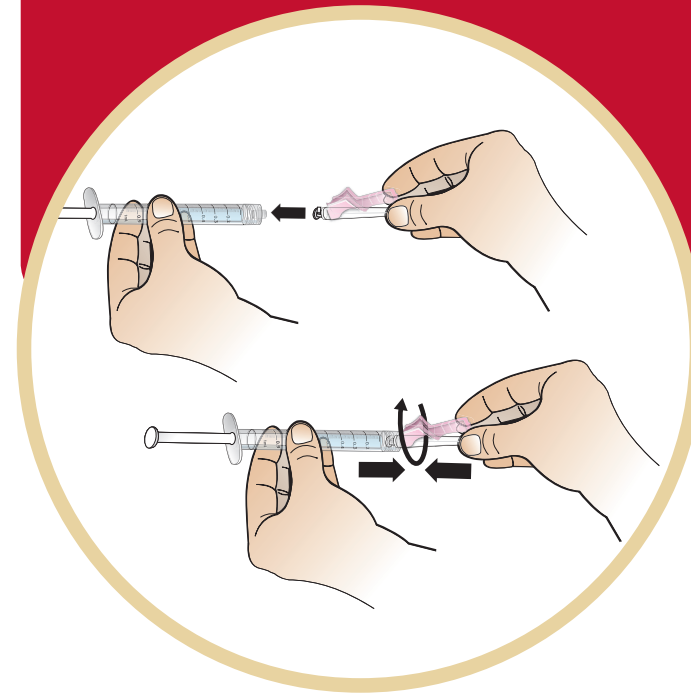
## STEP 6: PREPARE INJECTION NEEDLE

This step uses the syringe filled with measured Nplate<sup>®</sup> dose plus the safety needle (item D)

- 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 the syringe tip (Luer lock)
- The product is now ready for injection. **IMMEDIATELY** continue to Step 7



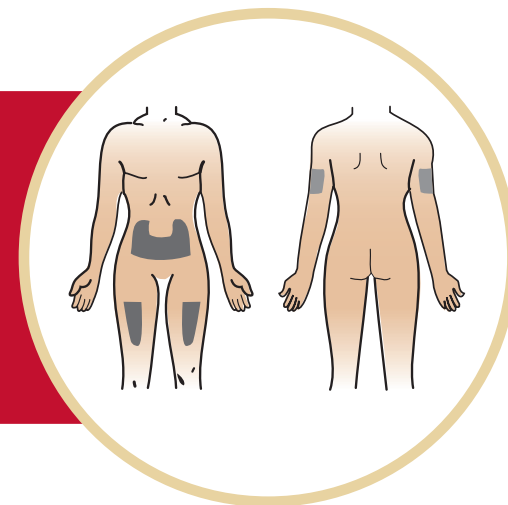
STEP 5

STEP 6

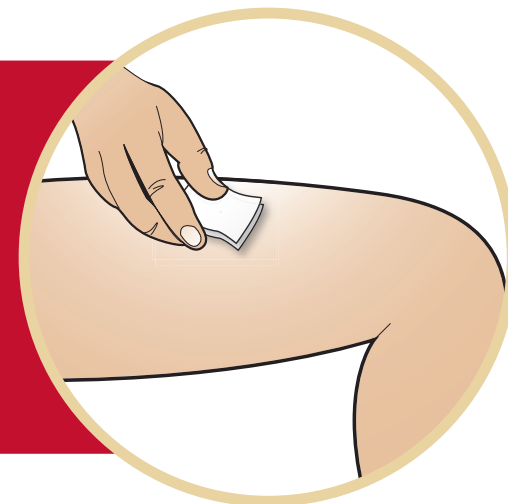
## STEP 7: CHOOSE AND PREPARE AN INJECTION SITE

This step uses a new alcohol swab (item E)

- Select your injection site. Three recommended sites for Nplate<sup>®</sup> are:
  - Front of the middle thighs
  - Abdomen, except for the 5-centimetre area 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



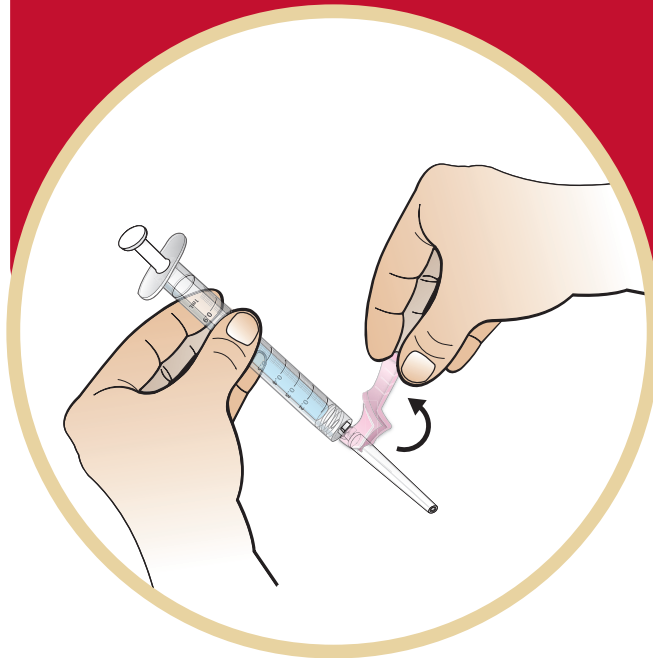
- Do not inject into areas where the skin is tender, bruised and hard
- Do not inject into areas with scars or stretch marks
- Wipe the site where Nplate<sup>®</sup> is to be injected with an alcohol swab, using a circular motion
- Do not touch this area again before giving the injection



## STEP 8: INJECTING THE NPLATE<sup>®</sup> LIQUID

This step uses the filled syringe and needle assembly

- Pull back on the pink needle safety cover (toward the syringe and away from the needle)

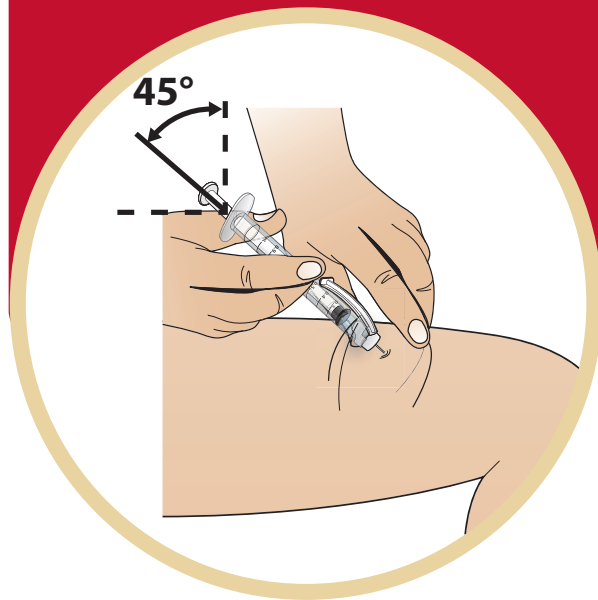


- Remove clear needle shield by holding the syringe in one hand and carefully pulling shield straight off with your other hand
- Do not remove the clear shield before injecting



## STEP 8: INJECTING THE NPLATE<sup>®</sup> LIQUID

- 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

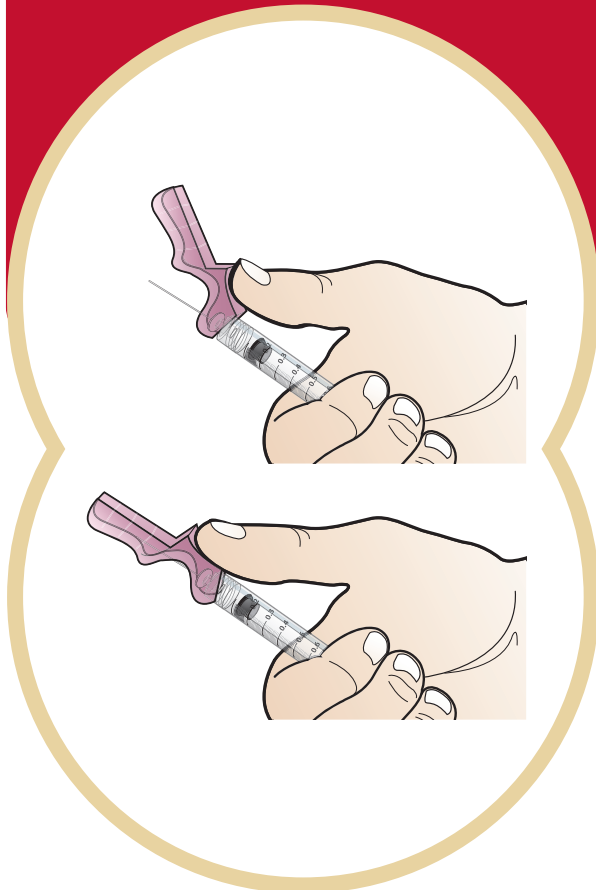


- Inject the prescribed dose subcutaneously as directed by your doctor, nurse or pharmacist

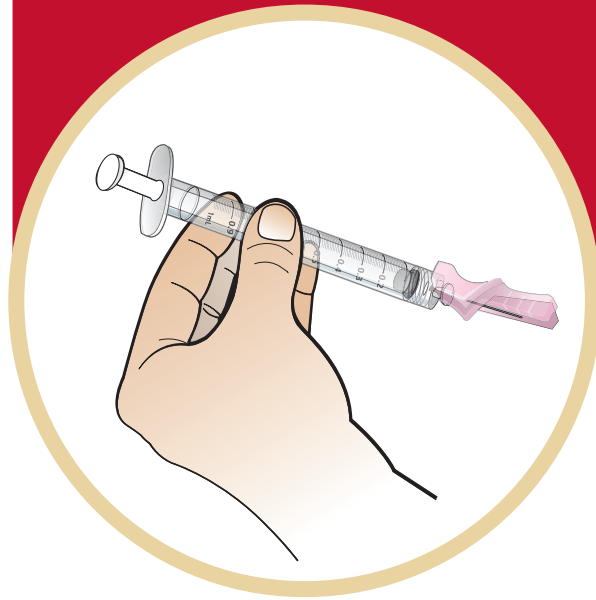


- When the syringe is empty, pull the needle out of the skin, **being careful to keep it at the same angle as inserted**
  - There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site for 10 seconds
  - **Do not rub the injection site.** If needed, 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<sup>®</sup> vial** into an appropriate waste container
- **Make sure all other materials are discarded into proper containers**

### The injection device and Nplate<sup>®</sup> 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<sup>®</sup> in proper waste container. **Left-over Nplate<sup>®</sup> in the vial must NEVER be re-used for another injection**

## IF YOU NEED MORE NPLATE® TO COMPLETE YOUR DOSE...

- Take a new self-administration kit and a new vial of Nplate® product
- Return to the beginning of this *Step-by-step guide* and follow all the preparation and administration steps with a new self-administration kit

