

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using BEMFOLA?

Bemfola contains the active ingredient follitropin alfa. In women, Bemfola is used to bring about the development of follicles in women who are not ovulating and who have not responded to treatment with clomiphene citrate. Bemfola is also used to stimulate the development of several follicles in women undergoing assisted reproductive technologies (ART) such as in vitro fertilisation. Bemfola can be used together with another hormone called Luteinising Hormone (LH) to stimulate development of follicles in women who have been shown to produce very low levels of some of the hormones involved in the natural reproductive cycle. In men, Bemfola is used in combination with human chorionic gonadotrophin (hCG) to stimulate the production of sperm.

For more information, see Section [1. Why am I using Bemfola?](#) in the full CMI.

2. What should I know before I use BEMFOLA?

Do not use if you have ever had an allergic reaction to Bemfola or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Bemfola?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Bemfola and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use BEMFOLA?

- Your doctor will decide the correct dose of Bemfola for you. Your dose may be adjusted depending on your individual response to treatment.
- Follow all directions given to you by your doctor, nurse or pharmacist carefully, including the Instructions for Use provided in the pack. Do not self-inject until you are sure of how to do it.

More instructions can be found in Section [4. How do I use Bemfola?](#) in the full CMI and in the Instructions for Use leaflet inside the pack.

5. What should I know while using BEMFOLA?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Bemfola.Tell your doctor immediately if you become pregnant while using Bemfola.
Things you should not do	<ul style="list-style-type: none">Do not stop using this medicine or change the dose without telling your doctor.Do not give this medicine to anyone else even if they have the same condition as you.
Looking after your medicine	<ul style="list-style-type: none">Prior to use, store Bemfola in the original package at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. Before opening and within its shelf-life, the medicine may be removed from the refrigerator, without being refrigerated again, for upto 3 months kept at or below 25°C. The product if stored at or below 25°C, must be discarded after 3 months.

For more information, see Section [5. What should I know while using Bemfola?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. Most common side effects include injection site reactions, such as redness, pain and swelling at the site of injection. In women, common side effects may include headache, dizziness, abdominal pain, discomfort, nausea, vomiting and diarrhoea. In men, common side effects may include acne, weight gain and breast development.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Bemfola®

Active ingredient: *follitropin alfa (rch)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Bemfola. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Bemfola.**

Where to find information in this leaflet:

- [1. Why am I using Bemfola?](#)
- [2. What should I know before I use Bemfola?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Bemfola?](#)
- [5. What should I know while using Bemfola?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using BEMFOLA?

Bemfola contains the active ingredient **follitropin alfa (recombinant human follicle stimulating hormone)**. This hormone is similar to follicle stimulating hormone found naturally in humans, but it is made by means of biotechnology. Follicle stimulating hormone belongs to the family of hormones called gonadotrophins and is necessary for the growth and development of egg cells in women and sperm production in men.

Bemfola is an approved biosimilar to the reference product Gonal-f®. Comparability in safety, efficacy and quality between Bemfola and Gonal-f® have been established.

In women, Bemfola is used to bring about the development of follicles in women who are not ovulating and who have not responded to treatment with clomiphene citrate. Bemfola is also used to stimulate the development of several follicles in women undergoing assisted reproductive technologies (ART) such as in vitro fertilisation.

Bemfola can be used together with another hormone called Luteinising Hormone (LH) to stimulate development of follicles in women who have been shown to produce very low levels of some of the hormones involved in the natural reproductive cycle.

In men, Bemfola is used in combination with human chorionic gonadotrophin (hCG) to stimulate the production of sperm.

2. What should I know before I use BEMFOLA

Warnings

Do not use Bemfola if:

- you are allergic to follitropin alfa, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can

use this medicine.

- you have tumours of the hypothalamus or pituitary gland.

In women, do not use Bemfola if:

- you are pregnant
- you are breastfeeding
- your ovaries are enlarged
- you have unexplained ovarian cyst
- you have unexplained vaginal or uterine bleeding
- you have cancer of the ovaries, uterus or breasts
- your ovaries have failed
- you have fibroids in your uterus which would make pregnancy impossible.

In men, do not use Bemfola if:

- you have increased levels of gonadotrophins indicating failure of testes
- your infertility is due to disorders other than hypogonadotropic hypogonadism (low levels of gonadotrophins).

Check with your doctor if you:

- have or have had any other medical conditions, such as:
 - thyroid problems
 - adrenal problems
 - high prolactin levels in the blood
 - porphyria or a family history of porphyria.
- take any medicines for any other condition.

Tell your doctor if you or a family members have or have had signs of blood clots (e.g. pain, warmth, redness, numbness or tingling in the arm or leg). Treatment with Bemfola and hCG may increase the risk of blood clots forming in your blood vessels.

Your doctor will assess you and your partner's infertility. This may include tests for other medical conditions, which may interfere with your ability to become pregnant. If necessary, other medical conditions may be treated before starting infertility treatments with Bemfola.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant while using Bemfola.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Multiple pregnancies carry risks for mothers and babies. Compared to natural conception, the frequency of multiple pregnancies and births is higher in patients receiving treatments that stimulate follicle growth for ovulation induction. Your doctor will monitor your

response to minimise the chance of multiple pregnancies.

Compared to natural conception, the frequency of pregnancy loss is higher in patients undergoing fertility treatments.

There may be a slightly increased risk of birth defects in women using assisted reproductive technologies. This may be due to increased maternal age, genetic factors, multiple pregnancies or the procedure.

For men

- Elevated follicle stimulating hormone blood levels are indicative of testicular failure. Your doctor may ask you for a semen analysis to assess your response to treatment.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Bemfola and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Bemfola.

4. How do I use BEMFOLA?

Treatment with Bemfola should be started under the supervision of a specialist doctor experienced in the treatment of infertility.

How much to use

- Always use Bemfola exactly as your doctor has told you. You should check with your doctor if you are unsure.
- Your doctor will decide the correct dose of Bemfola for you depending on your condition.
- For women who are not ovulating, the common dose usually starts at 75 IU daily. The dose may be adjusted as your treatment progresses. The maximum daily dose is usually not higher than 225 IU.
- For women undergoing assisted reproductive technologies, the common dose usually starts at 150 IU daily. The dose may be adjusted as your treatment progresses. The maximum daily dose is usually not higher than 450 IU.
- For women who are not ovulating and have been diagnosed with very low levels of FSH and LH hormones, the common dose usually starts at 75 IU to 150 IU BEMFOLA together with 75IU lutropin alfa daily.
- For men, the common dose usually starts at 150 IU three times a week.
- Your dose may be adjusted depending on your individual response to treatment.
- Follow the instructions provided by your doctor or nurse carefully.

When to use Bemfola

- Your doctor will tell you when to use Bemfola. The length of your treatment will be determined by your doctor depending on your condition.

How to use Bemfola

- Bemfola is given as a subcutaneous (under your skin) injection in the lower abdominal area or thigh.
- The injection site should be changed daily to lessen possible injection site reactions.
- Before using Bemfola, your doctor or nurse can teach you the injection technique. Your partner may be trained to give the injection at home.
- Read the Instructions for Use provided in the pack before commencing injections. Do not self-inject until you are sure of how to do it.

If you forget to use Bemfola

If you forget an injection or are not sure what to do, contact your doctor or nurse immediately for advice.

Do not inject double dose to make up for the dose you missed.

If you use too much Bemfola

If you think that you have used too much Bemfola, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using BEMFOLA?

Things you should do

See your doctor regularly. Your doctor will monitor you closely throughout your treatment.

Tell your doctor immediately if you become pregnant while using Bemfola.

If you plan to have surgery, tell your doctor or dentist that you are using Bemfola.

Remind any doctor, dentist or pharmacist you visit that you are using Bemfola.

Things you should not do

- Do not stop using this medicine suddenly without telling your doctor.
- Do not change the dose unless your doctor tells you to.
- Do not give this medicine to anyone else even if they have the same condition as you.

Ovarian Hyperstimulation Syndrome (OHSS)

Treatment with Bemfola may increase your risk of developing a condition called ovarian hyperstimulation syndrome (OHSS). This is when the ovaries overreact to the hormonal treatment and become larger.

The most common symptom is lower abdominal pain. During stimulation your doctor will monitor your treatment by using ultrasound and/or blood tests to help determine if you are likely to develop OHSS. If necessary, your doctor will delay or cancel your Bemfola injection. You may also be advised to refrain from sexual intercourse until the end of the cycle if this occurs.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Bemfola affects you.

Bemfola may cause dizziness in some people.

Looking after your medicine

- Prior to use, store Bemfola in the original package at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light.
- Before opening and within its shelf-life, the medicine may be removed from the refrigerator, without being refrigerated again, for up to 3 months kept at or below 25 °C.
- The product if stored at or below 25 °C, must be discarded if it has not been used after 3 months.

Discard used pen and needle immediately after injection.

Follow the instructions in the carton on how to take care of your medicine properly.

Do not use Bemfola if the solution contains particle or is not clear.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Injection site related:</p> <ul style="list-style-type: none">• pain, numbness, redness or swelling at the injection site. <p>Gastrointestinal system related:</p> <ul style="list-style-type: none">• stomach pain, abdominal pain or discomfort• nausea, vomiting, diarrhoea. <p>Nervous system related:</p> <p>headache, dizziness.</p> <p>Reproductive system related:</p> <ul style="list-style-type: none">• vaginal bleeding• ovarian cyst• ovarian enlargement• ovarian hyperstimulation syndrome (OHSS).	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Symptoms of allergic reactions:</p> <ul style="list-style-type: none">• shortness of breath• wheezing or difficulty breathing• swelling of the face, lips, tongue or other parts of the body• rash, itching or hives on the skin. <p>Respiratory system related:</p> <ul style="list-style-type: none">• signs of aggravation of asthma, such as coughing, wheezing, chest tightness and shortness of breath. <p>Vascular related:</p> <ul style="list-style-type: none">• signs of blood clots such as pain, warmth, redness, numbness or tingling in your arm or leg. <p>Reproductive system related:</p> <ul style="list-style-type: none">• signs of severe ovarian hyperstimulation syndrome such as severe lower abdominal pain, severe pelvic pain, nausea, vomiting, diarrhoea followed by rapid weight gain, reduced amount of urine and shortness of breath.	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

In New Zealand, you can report side effects to Medsafe online at <https://pophealth.my.site.com/carmreportnz/s/>.

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

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Bemfola contains

Active ingredient (main ingredient)	Follitropin alfa (rch)
Other ingredients (inactive ingredients)	Sucrose Dibasic sodium phosphate dihydrate Monobasic sodium phosphate monohydrate Phosphoric acid Poloxamer Methionine Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What Bemfola looks like

Bemfola contains sterile solution for injection in a cartridge, pre-assembled in a pen.

Bemfola Pen Injector is pre-filled with a clear, colourless solution of 0.125 mL (75 IU), 0.25 mL (150 IU), 0.375 mL (225 IU), 0.5 mL (300 IU) or 0.75 mL (450 IU).

Bemfola Pen Injector is available in five strengths:

- 75 IU/0.125 mL (5.5 micrograms/0.125 mL) (AUST R 231039);
- 150 IU/0.25 mL (11 micrograms/0.25 mL) (AUST R 231046);
- 225 IU/0.375 mL (16.5 micrograms/0.375 mL) (AUST R 231051);
- 300 IU/0.50 mL (22 micrograms/0.5 mL) (AUSTR 231052); and
- 450 IU/0.75 mL (33 micrograms/0.75 mL) (AUSTR 231 053).

Pack sizes of 1, 5 and 10 pre-filled pens. Not all pack sizes may be marketed. Each pack also contains the corresponding number of needles to be used with the pen for administration.

Bemfola Pens are not designed to allow the cartridge to be removed.

Who distributes Bemfola is supplied in Australia by:

Gedeon Richter Australia Pty Ltd
Suite 902, 15 Blue Street
North Sydney NSW 2060
Australia

Phone number: 1300 GEDEON (1300 433 366)

Bemfola is supplied in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks Mangere
AUCKLAND

Phone: 0800 GEDEON (0800 433 366)

This leaflet was prepared in June 2024.

Instructions for Use

CONTENTS

1. How to use the Bemfola pre-filled pen
2. Before you start using your pre-filled pen
3. Getting your pre-filled pen ready for injection
4. Setting the dose
5. Injecting the dose
6. After the injection

1. How to use the Bemfola pre-filled pen

- Before starting to use your pre-filled pen, please read these instructions the whole way through first.
- Only use this pen for you – do not let anyone else use it.
- The numbers on the dose display are measured in International Units or IU. **Your doctor will have told you how many IU to inject each day.**
- **Your doctor/pharmacist will tell you how many Bemfola pens you need to use for your complete treatment course.**
- Give yourself the injection at the same time each day.

2. Before you start using your pre-filled pen

2.1. Wash your hands

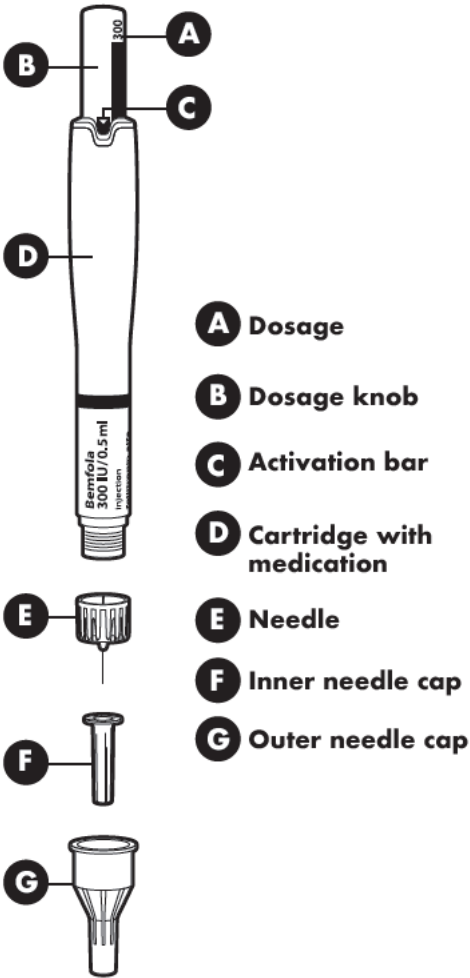
- It is important that your hands and the things you use to get your pen ready are as clean as possible.

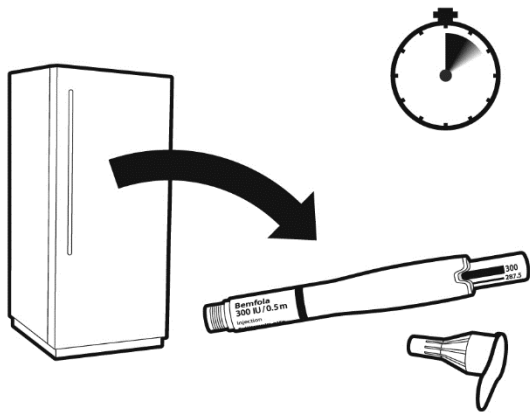
2.2. Find a clean area

- A good place is a clean table or surface.

3. Getting y our pre-filled pen ready for injection

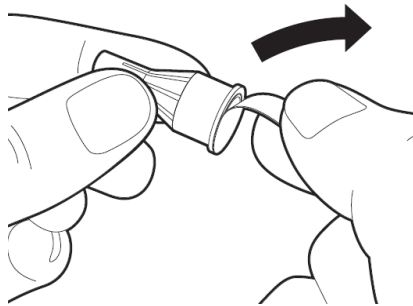
The different parts of your pre-filled pen





Perform the injection every day around the same time. Take the pen out of the fridge 5 to 10 minutes before using it.

Note: Please check that the medicine is not frozen.



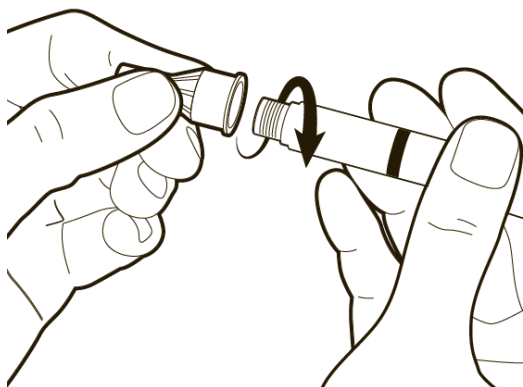
Prepare your needle for injection

Get a new needle - only use the single-use needles supplied in the package. Hold the outer needle cap firmly.

Check in all cases that the peel-off seal on the outer needle cap is not damaged or loose.

Remove the peel-off seal from the injection needle.

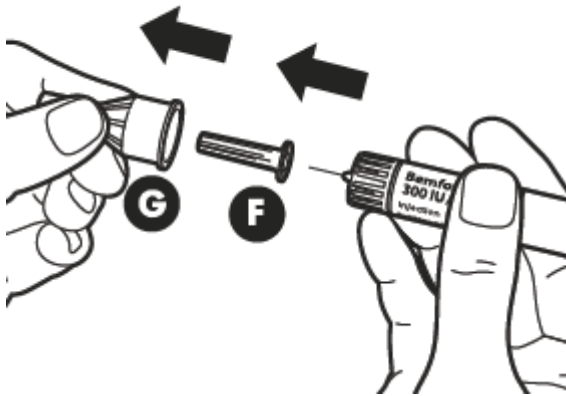
Caution: If the peel-off seal is damaged or loose, do not use the needle. Throw it away in a sharps disposal container. Get a new needle.



Attach the needle.

Hold the pen by its sides and keep the needle in line with it while attaching the needle. Screw the needle clockwise onto the tip of the pen all the way until firmly attached. Make sure that the needle is properly secured on the pen in a straight position.

Caution: Do not overtighten the needle. Do not push the dosage knob in while attaching the needle.

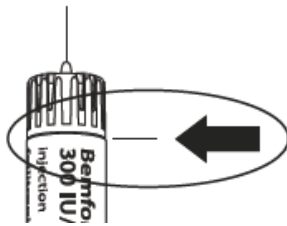


Remove the outer needle cap (G). **Keep it for later. You will need it after the injection to discard the pen.**

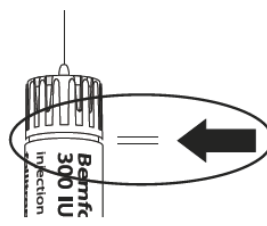
Remove the inner needle cap (F).

Make sure that the needle is in the correct position.

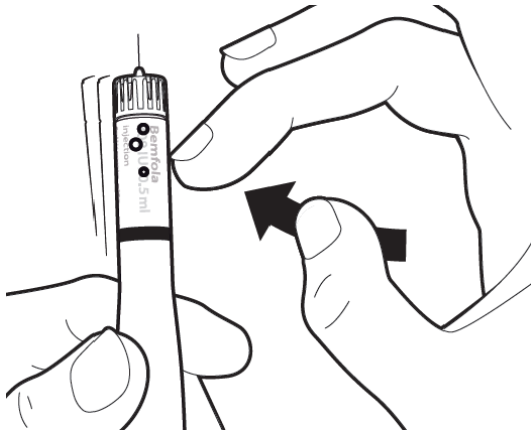
Correct position of the needle



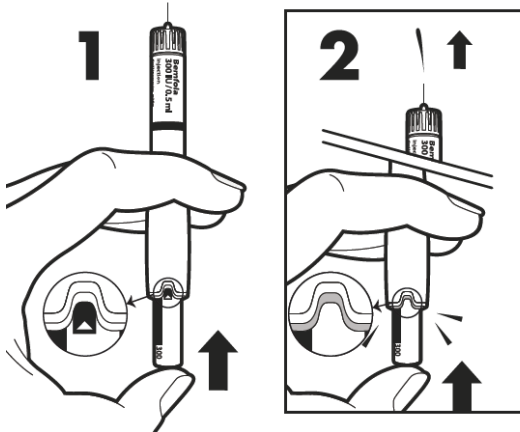
Incorrect position of the needle



4. Setting the dose prescribed by your doctor

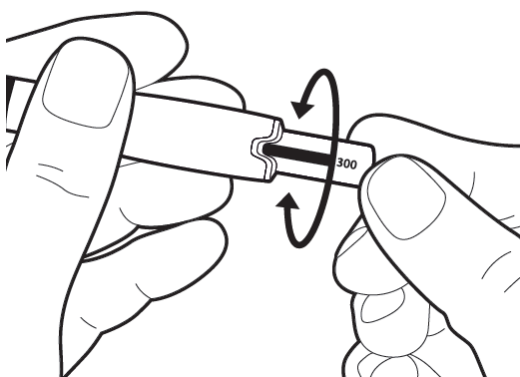


First, hold the pen so that the needle is pointing upwards. To remove the air bubbles from the system, gently tap the side of the pen to make the any existing air bubbles rise to the top.



Still holding the pen upright, push the **dosage knob** in until the **activation bar** with the small arrow disappears. You should also hear a click, and some liquid will splash out (this is normal). The pen is now ready to set the dose.

Caution: If no liquid splashes out, or liquid leakage is detected at the junction of the needle and the pen, the pen should not be used. Tell your doctor or pharmacist if you notice any problems.



Gently turn the dosage knob until the bar of your prescribed dose is in line with the middle of the indent on the pen.

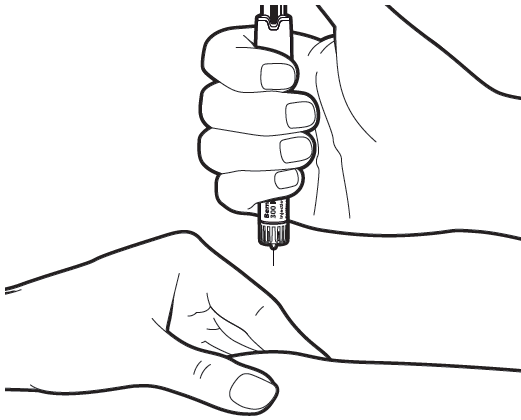
Note: For the Bemfola 75 IU/0.125 mL pre-filled pen, the dosage knob cannot go around completely, but it can still be rotated backwards.

The pen is now ready for injection.

Caution: Do not push the dosage knob in any further, at this point.

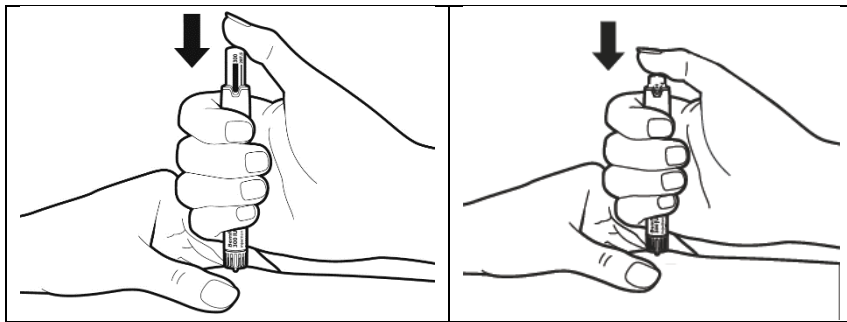
5. Injecting the dose

Now you are ready to immediately give yourself the injection: Your doctor or nurse will have already advised you where to inject (e.g. tummy, front of thigh). To minimise skin irritation, select a different injection site each day.



Check again that the correct dose is displayed on the pen. Lightly pinch the skin of the injection area. Hold the pen at approximately a right angle (90° angle) and insert the needle completely in one steady movement into your skin.

Caution: Do not push the dosage knob, while inserting the needle and do not change the direction of the needle as it goes in.



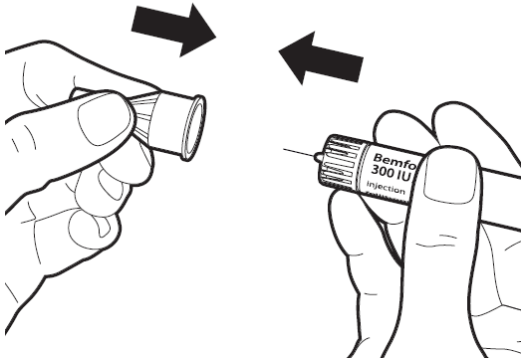
Once the needle is fully inserted in the injection site, push in the dosage knob slowly and continuously until it stops, and the bar of the set dose has disappeared.

Do not remove the needle immediately, wait at least for **5 seconds**, before pulling it out to ensure you have injected the full dose.

Caution: If liquid leakage is detected at the junction of the needle and the pen during injecting, tell your doctor or pharmacist.

6. After the injection

Replace the outer needle cap onto the needle carefully.



You can use the pre-filled injection pen only once and must discard the pen even if any liquid remains in the pen after injection.

Throw away the packaging box, inner needle cap, peel tab and the Instructions for use in the normal household waste. Do not throw away any medicines via your sink, toilet or in your household waste. The used pen needs to be discarded in a sharps container and returned to the pharmacy for a correct disposal. Ask your pharmacist how to dispose of medicines you no longer use.

