

GENOTROPIN®

Somatropin (5.3 mg, 12 mg)

What is in this leaflet

1. What GENOTROPIN is used for
2. How GENOTROPIN works.
3. Before you use GENOTROPIN.
4. How to use GENOTROPIN.
5. While you are using it.
6. Side effects.
7. Storage and Disposal of GENOTROPIN.
8. Product Description.
9. Manufacturer and Product Registration Holder.
10. Date of Revision.
11. Serial Number.

What GENOTROPIN is used for

In children, GENOTROPIN is used to treat the following growth disturbances:

- If you are not growing properly and you do not have enough of your own growth hormone.
- If you have Turner syndrome (chromosomal error in girls that can affect growth).
- If you have chronic renal (kidney) insufficiency. As kidneys lose their ability to function normally, this can affect growth.
- If you have Prader-Willi syndrome (a chromosomal disorder). Growth hormone will help you grow taller if you are still growing, and will also improve your body composition.
- If you were small or too light at birth. Growth hormone can help you grow taller if you have not been able to catch up or maintain normal growth by four years of age or later.

In adults, GENOTROPIN is used to treat persons with pronounced growth hormone deficiency. This can start during adult life, or it can continue from childhood.

If you have been treated with GENOTROPIN for growth hormone deficiency during childhood, your growth hormone status will be retested after completion of growth.

How GENOTROPIN works

GENOTROPIN is a recombinant human growth hormone (also called somatropin). It has the same structure as natural human growth hormone, which is needed for bones and muscles to grow. It also helps your fat and muscle tissues to develop in the right amounts. It is a recombinant DNA-derived protein, meaning it is not made from human or animal tissue.

Before you use GENOTROPIN**- When you must not use it**

Do not take GENOTROPIN if

- You are allergic (hypersensitive) to somatropin or any of the other ingredients of GENOTROPIN (listed under Product Description).
- You have an active tumour (cancer). Tumours must be inactive and you must have finished your anti-tumour treatment before you start your treatment with GENOTROPIN.
- You are seriously ill (for example, complications following open heart surgery, abdominal surgery, acute respiratory failure, multiple accidental injury or similar conditions).
- Children who have already stopped growing (closed epiphyses).

Pregnancy and lactation

You should not use GENOTROPIN if you are pregnant, or if you have childbearing potential but are not using contraception.

Ask your doctor for advice before using this medicine while breast-feeding.

- Before you start to use it

Talk to your doctor before taking GENOTROPIN:

- If you are receiving GENOTROPIN and thyroid hormone replacement therapy concurrently, your doctor will need to monitor your thyroid function closely.
- If you are diabetic and are receiving insulin therapy, GENOTROPIN may reduce your insulin sensitivity, tell your doctor. Your dose of insulin may need to be adjusted after GENOTROPIN is initiated.
- If you have severe or reoccurring headache, eye problems, vomiting and nausea, your doctor may examine your eyes to assess if you have increased pressure around your skull. Based on this examination, your doctor will determine whether or not to continue treatment with GENOTROPIN.
- If you are receiving GENOTROPIN therapy, you may be at risk of reduced cortisol levels (stress hormone) in your blood due to underactivity of your adrenal glands and may require steroids. If you were previously diagnosed with underactive adrenal gland, your doctor may need to adjust your steroid dose.
- If you are taking GENOTROPIN and oral oestrogen therapy concurrently, your doctor may need to adjust the dose of GENOTROPIN.
- If you had cancer in childhood, there is an increased chance of getting tumours again after treatment with GENOTROPIN.
- Experience in people above 80 years of age is limited. Elderly persons may be more sensitive to the action of GENOTROPIN and therefore may be more prone to develop side effects.

GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

- If you are suffering from any other critical illness, your doctor will decide on whether this medicine is suitable for you or not by weighing the possible benefit against the potential risk involved.

Children with Prader-Willi syndrome:

- Your doctor will give you diet restrictions to follow to ensure effective weight control before and during treatment with GENOTROPIN.
- Your doctor will assess you for signs of upper airway obstruction, sleep apnoea (where your breathing is interrupted during sleep), or respiratory infection before you start treatment with GENOTROPIN.
- During treatment, if you show signs of upper airway obstruction (including starting to snore or worsening of snoring), your doctor will refer you to an Ear, Nose and Throat (ENT) specialist for an assessment and your treatment with GENOTROPIN may be interrupted.
- During treatment, your doctor will check you for signs of scoliosis, a type of spinal deformity that might happen during rapid growth.
- During treatment, if you develop a lung infection, tell your doctor so that he can treat the infection.

Children with chronic renal (kidney) insufficiency:

- Your doctor should examine your kidney function and verify your growth disturbance by following your growth for a year before starting GENOTROPIN. Medical treatment for your kidney condition should be maintained throughout. GENOTROPIN treatment should be stopped at kidney transplantation.

Children born small or too light at birth:

- Your doctor will check your blood sugar and insulin levels before the start of treatment and every year during treatment.
- Treatment should be continued until you have stopped growing.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Some medicines when taken with GENOTROPIN may cause GENOTROPIN to be less effective and *vice versa*.

You should inform your doctor if you are taking:

- Medicines to treat diabetes,
- Thyroid hormones,
- Steroids to reduce inflammation (corticosteroids),
- Sex hormones (for example, oestrogens),
- Ciclosporin (a medicine that weakens the immune system after transplantation),
- Medicines to control epilepsy (anticonvulsants).

Genotropin contains sodium

- This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

How to use GENOTROPIN

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Recommended dosage

The dose depends on your size, the condition for which you are being

treated and how well growth hormone works for you. Everyone is different. Your doctor will advise you about your individualized dose of GENOTROPIN in milligrams (mg) from either your body weight in kilograms (kg) or your body surface area calculated from your height and weight in square metres (m²), as well as your treatment schedule. Do not change the dosage and treatment schedule without consulting your doctor.

Children with growth hormone deficiency:

0.025-0.035 mg/kg body weight per day or 0.7-1.0 mg/m² body surface area per day. Higher doses can be used. When growth hormone deficiency continues into adolescence, GENOTROPIN should be continued until completion of physical development.

Children with Turner syndrome:

0.045-0.050 mg/kg body weight per day or 1.4 mg/m² body surface area per day.

Children with chronic renal (kidney) insufficiency:

0.045-0.050 mg/kg body weight per day or 1.4 mg/m² body surface area per day. Higher doses may be necessary if the rate of growth is too low. Dosage adjustment may be necessary after 6 months of treatment.

Children with Prader-Willi syndrome:

0.035 mg/kg body weight per day or 1.0 mg/m² body surface area per day. The daily dosage should not exceed 2.7 mg. Treatment should not be used in children who have almost stopped growing after puberty.

Children born smaller or lighter than expected and with growth disturbance:

GENOTROPIN®

Somatropin (5.3 mg, 12 mg)

0.035 mg/kg body weight per day or 1.0 mg/m² body surface area per day. It is important to continue treatment until final height is reached. Treatment should be discontinued after the first year if you are not responding or if you have reached your final height and stopped growing.

Adults with growth hormone deficiency:

- If you continue GENOTROPIN after treatment during childhood you should start with 0.2-0.5 mg per day.
- If your growth hormone deficiency starts during adult life you should start with 0.15-0.3 mg per day.
- This dosage should be gradually increased according to blood test results as well as clinical response and side effects.

The daily maintenance dose seldom exceeds 1.0 mg per day. Women may require higher doses than men. Dosage should be monitored every 6 months.

Persons above 60 years should start with a dose of 0.1–0.2 mg per day which should be slowly increased according to individual requirements. The minimum effective dose should be used.

The maintenance dose seldom exceeds 0.5 mg per day. Follow the instructions given to you by your doctor.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking GENOTROPIN for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Inject the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not inject a double dose to make up for the missed dose.

- If you use too much (overdose)

If you inject much more than you should, contact your doctor or pharmacist as soon as possible. Your blood sugar level could fall too low and later rise too high. You might feel shaky, sweaty, sleepy or “not yourself”, and you might faint.

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking GENOTROPIN.
- Tell your doctor immediately if you become pregnant while taking this medication.
- If you are receiving GENOTROPIN for growth hormone deficiency following a previous tumour (cancer), you should be examined regularly for recurrence of the tumour.
- If you have diabetes, you should closely monitor your blood sugar level during treatment with GENOTROPIN and discuss the results with your doctor to determine whether you need to change the dose of your medicines to treat diabetes.
- Tell your doctor if you are taking growth hormone to stimulate growth and walk with a limp, or if you start to limp during your growth hormone treatment due to pain in your hip.

- If your doctor confirms that you have developed muscle pain or disproportionate pain near the injection site because of the preservative metacresol, you should use a GENOTROPIN product without metacresol.
- Tell your doctor if you develop stomach pain during the treatment with GENOTROPIN. It may be due to inflammation of the pancreas.

Injecting GENOTROPIN:

Refer to appendix 1 to find instructions for use.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not inject GENOTROPIN to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

When you are mixing GENOTROPIN, do not shake the solution. Mix it gently. Shaking the solution could make the growth hormone foam and damage the active substance.

Driving and using machines

No effects on the ability to drive and use machines have been observed.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

GENOTROPIN®

Somatropin (5.3 mg, 12 mg)

Very common side effects (may affect more than 1 in 10 people) include:

In Adults:

- Joint pain.
- Water retention (which shows as puffy fingers or swollen ankles).

Common side effects (may affect up to 1 in 10 people) include:

In children:

- Joint pain.
- Temporary reddening, itchiness or pain at the injection site.

In adults:

- Numbness/tingling.
- Pain or burning sensation in the hands or underarms (known as Carpal Tunnel Syndrome).
- Stiffness in the arms and legs.
- Muscle pain.

Formation of antibodies to the injected growth hormone but these do not seem to stop the growth hormone from working.

The skin around the injection area can get uneven or lumpy, but this should not happen if you inject in a different place each time.

A very rare side effect that can occur because of the preservative metacresol is inflammation of the muscles near the injection site. If your doctor confirms that you have developed this, you should use a GENOTROPIN product without metacresol.

There have been rare cases of sudden death in patients with Prader-Willi syndrome. However, no link has been made between these cases and treatment with GENOTROPIN.

Slipped capital femoral epiphysis and Legg-Calve-Perthes disease may be considered by your doctor if discomfort or pain in the hip or knee

is experienced whilst being treated with GENOTROPIN.

Other possible side effects related to the treatment with growth hormone may include high blood sugar or reduced levels of thyroid hormone. This can be tested by your doctor and if necessary, your doctor will prescribe the adequate treatment. Rarely, an inflammation of the pancreas has been reported in patients treated with growth hormone.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of GENOTROPIN

- Storage

Before reconstitution:

Store in a refrigerator (2°C – 8°C), or for a maximum of 1 month at or below 25°C. Keep the pre-filled pen in the outer carton in order to protect from light.

After reconstitution:

Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the pre-filled pen in the outer carton in order to protect from light.

From a microbiological point of view, once reconstituted, the product may be stored for 28 days at 2°C - 8°C. Other in-use storage times and conditions are the responsibility of the user.

Keep out of the sight and reach of children.

- Disposal

Any unused product or waste material should be disposed of in accordance with local requirements. Empty GoQuick pre-filled pens should never be refilled and must be properly discarded.

Product Description

- What it looks like

Two-chamber cartridge: Powder and solvent for solution for injection. In the two-chamber cartridge there is a white powder in the front compartment and a clear solution in the rear compartment. The two-chamber cartridge is supplied for use in a sealed disposable multidose pre-filled pen (GoQuick).

Powder and 1 ml solvent in a two-chamber glass cartridge (type I glass) separated by a rubber plunger (bromobutyl). The cartridge is sealed at one end with a rubber disc (bromobutyl) and an aluminium cap and at the other end by a rubber stopper (bromobutyl). The two-chamber cartridge is supplied for use in a sealed disposable multidose pre-filled pen, GoQuick.

The 5.3 mg pre-filled pen GoQuick is colour coded blue. The 12 mg pre-filled pen GoQuick is colour coded purple.

- Ingredients

- Active ingredient:
Somatropin

- Inactive ingredients:

Front compartment (powder):

Glycine
Mannitol
Sodium dihydrogen phosphate, monohydrate
Disodium phosphate,

GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

dodecahydrate

Rear compartment (solvent):

Water for injections

Metacresol

Mannitol

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.

Level 10 & 11

Wisma Averis, Tower 2

Avenue 5, Bangsar South

No. 8, Jalan Kerinchi

59200 Kuala Lumpur, Malaysia

- MAL number(s)

GENOTROPIN 5.3 mg powder and
solvent for solution for injection-
MAL20081840AZ

GENOTROPIN 12 mg powder and
solvent for solution for injection-
MAL20081841AZ

Date of Revision

21/01/2025

Serial Number:

NPRA(R3/01)13012025/0342

PLD-GENOTROPIN-0125

Manufacturer

Pfizer Manufacturing Belgium N.V.

Rijksweg 12

Puurs-Sint-Amands, 2870

Belgium

GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

APPENDIX 1

GOQUICK[®] INSTRUCTIONS FOR USE: 5.3 mg

Please read these instructions completely before using your GoQuick Pen.

If you have any questions about your dose or your treatment with GENOTROPIN, call your doctor or nurse.

About GoQuick

GoQuick is a pre-filled, multidose, disposable injection pen that holds 5.3 mg of somatropin. Your pen can deliver doses from 0.1 mg to 1.5 mg of GENOTROPIN. Each click of the black ring changes the dose by 0.05 mg. The GENOTROPIN in your pen is mixed only once, when you start a new pen. You never have to change cartridges. When your pen is empty, you just start a new pen.

Your pen has dose memory. The dose is set once on a new pen. Your pen then allows you to draw up the same set dose for each injection. This will prevent you from drawing more than your set dose.

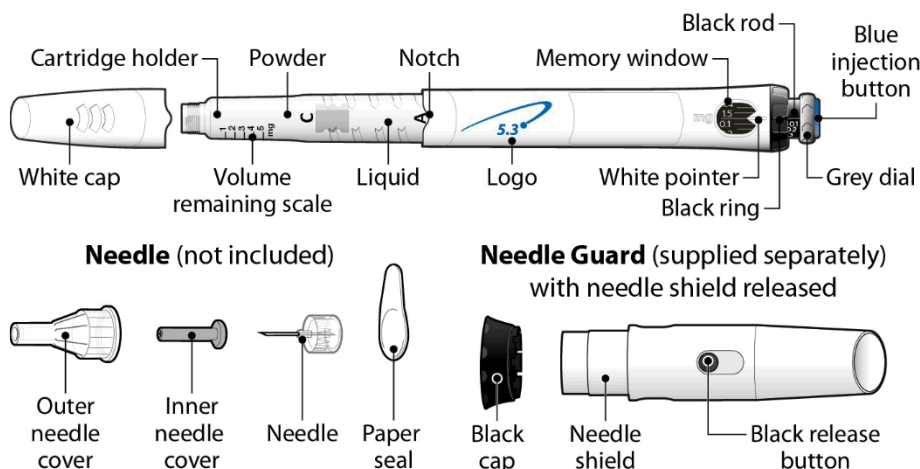
Important Information

- **Do not** mix the powder and liquid of your pen unless a needle is on your pen.
- **Do not** store your pen with the needle attached. The Genotropin may leak from your pen and air bubbles may form in the cartridge. Always remove the needle and attach your pen cap or needle guard cap before storing.
- Take care not to drop your pen. If you drop your pen and any part of it appears broken or damaged, **do not** use it. Contact your doctor or nurse for another pen. If you drop your pen and it is not damaged or broken, you must perform another prime as described in Step 6 (Setting up and using a new GoQuick Pen).
- Clean your pen with a damp cloth. **Do not** put your pen in water.
- Always use a new needle for each injection. **Do not** share your pen needles.
- The volume remaining scale along the side of the cartridge holder is a guide to show the volume of Genotropin left in your pen.

Storage and Disposal

- Store your pen in the refrigerator (2°C to 8°C) in the outer carton to protect from light. **Do not** freeze or expose it to frost.
- **Do not** use your pen after its expiry date.
- 28 days after mixing, throw away (dispose of) your pen even if there is some medicine left.
- See **Storage and Disposal of GENOTROPIN** for how to store your GoQuick Pen.
- Follow your local health and safety laws to throw away (dispose of) your pen. Ask your doctor or nurse if you are not sure what to do.

Parts of Your GoQuick Pen



GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

Pen needles are **not included** with your GoQuick Pen. You will need to get pen needles up to a length of 8 mm from your pharmacy.

- Needles to use with your GoQuick Pen:
 - o 31G or 32G (Becton Dickinson and Company)
 - o 31G or 32G (Novo Nordisk[®])
 - o 32.5G or 34G (Terumo)

Setting up and using a new GoQuick Pen

Step 1 Preparation



- **Wash and dry** your hands.
- **Gather** the following supplies on a clean flat surface:
 - o A new GoQuick Pen
 - o A new needle (not included)
 - o Suitable sharps container (not included).
- **Check** the expiry date on your pen label. **Do not** use your pen if the pen has passed its expiry date.

Step 2 Choose Injection Site

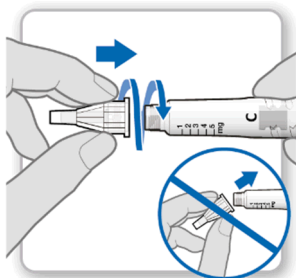


- **Choose and clean** an injection site as recommended by your doctor or nurse. Choose a different site each time you give yourself an injection. Each new injection should be given at least 2 cm from the site you used before.
- Avoid areas that are bony, bruised, red, sore or hard, and areas of the skin that have scars or skin conditions.

Step 3 Attach New Needle

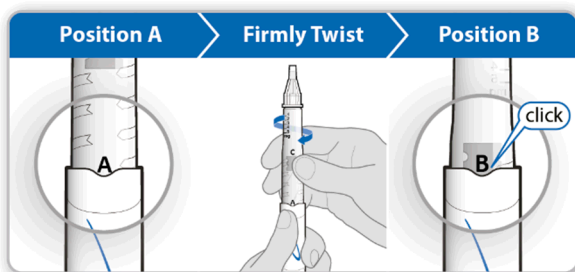
GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)



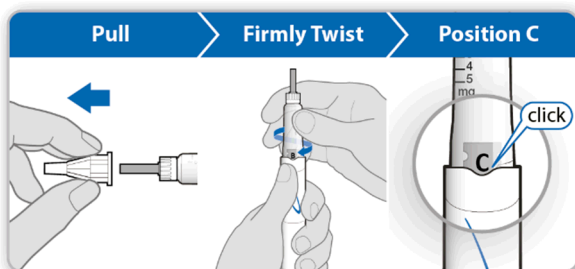
- **Pull** the white cap straight off your pen.
- Take a new needle and peel off the paper seal.
- **Gently push and then screw** the needle onto your pen. **Do not** overtighten.
Note: Be careful not to attach the needle at an angle. This may cause your pen to leak.
- Leave both needle covers on the needle.

Step 4 Mix the Genotropin



- **Hold** your pen with the needle-end pointing up and the “A” facing you.
- **Firmly twist** the cartridge holder into your pen until “B” clicks into the notch.
- **Gently tilt** your pen from side to side to help dissolve the powder completely. **Do not** shake. Shaking can damage the growth hormone.
- **Check** that the liquid in the cartridge is clear and all the powder is dissolved.
 - If the liquid is cloudy or you see any powder, gently tilt your pen from side to side a few more times.
 - If the liquid is still cloudy or you see any powder, **do not** use the pen and try again with a new pen.

Step 5 Remove the Air from Your Pen



- **Pull** the outer needle cover off. Keep it to remove the needle after your injection.
- Leave the inner needle cover on.

Note: You should see an inner needle cover after you have removed the outer cover. If you do not see this, try to attach the needle again.

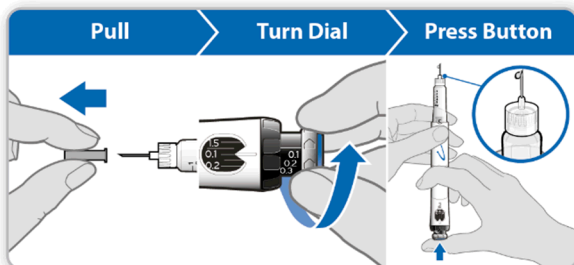
- **Hold** your pen with the needle-end pointing up.
- **Gently tap** the cartridge holder to help any trapped air move to the top.

GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

- **Firmly twist** the cartridge holder into your pen until “C” clicks into the notch.
- Some liquid may appear around the inner needle cover. This is normal.

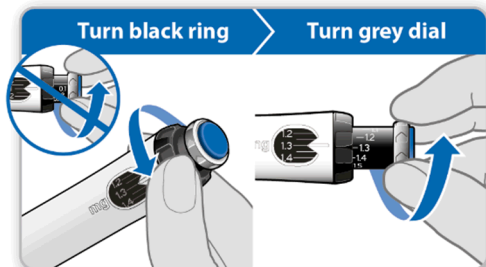
Step 6 Prime Your Pen



Priming removes any remaining air by pushing a small amount of liquid out of your pen. The priming dose is 0.1 mg and is different from the dose your doctor or nurse has prescribed. **Only prime your pen the first time you use it.**

- **Pull** the inner needle cover off and throw it away.
- Caution: Do not touch the needle to avoid a needle stick.**
- **Check** that 0.1 mg is set in the memory window.
- **Turn** the **grey dial** in the direction of the arrows until it stops clicking.
- **Hold** your pen with the needle pointing **straight up**.
- **Push** the blue injection button all the way in.
- **Check** for liquid at the needle tip. If liquid appears, your pen is primed.
 - If liquid does not appear, repeat the priming steps up to two additional times.
 - If liquid still does not appear, do not use your pen. Contact your doctor or nurse for advice.

Step 7 Set and Draw Up Your Dose



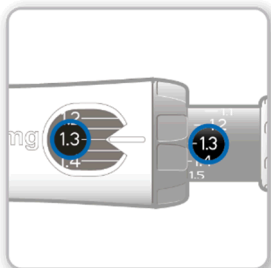
The first time you use your pen you will set the dose that your doctor or nurse has prescribed. You do not need to set the dose again until you start a new pen or your doctor or nurse tells you.

- **Turn the black ring counterclockwise** until your dose is lined up with the white pointer in the memory window. **Be careful not to turn the grey dial.**
 - If you turn your dose past the white pointer, turn the black ring back to set your correct dose.
- Note:** If you cannot turn the black ring, press the blue injection button until it stops clicking. Then try and set your dose again. Note that liquid will come out of the needle.
- **Turn the grey dial** in the direction of the arrows until it stops clicking.

GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

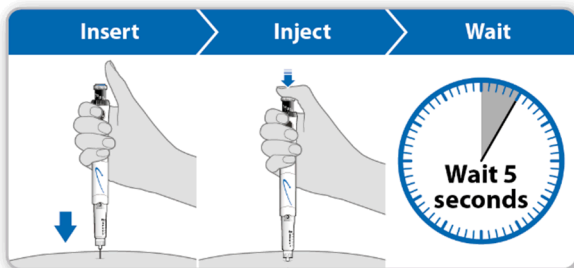
Step 8 Check Your Dose



Your dose on the black rod should **line up** with the white pointer.

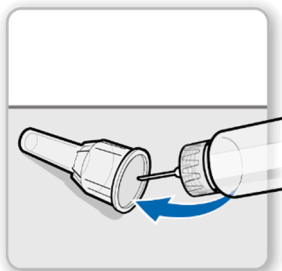
- **Check** that the dose you drew up on the black rod is the same as the dose you set in the memory window.
 - If the doses match, your pen is ready to give your injection.
 - If the doses do not match, make sure you have turned the grey dial in the direction of the arrows until it does not click anymore.

Step 9 Give Your Injection of Genotropin



- **Hold** your pen over the injection site.
 - **Insert** the needle straight into the skin.
 - **Push** the blue injection button down until it stops clicking.
 - **Wait** for a full 5 seconds to ensure that your complete dose is injected. Keep lightly pressing on the blue injection button while you count.
 - After 5 seconds, pull the needle straight out of your skin.
- Note:** If you see a drop of liquid at the injection site or needle tip, then with your next injection try pressing the blue injection button for longer before pulling the needle out of your skin.

Step 10 Remove Needle



- **Carefully cover** the needle with the outer needle cover.
- Caution:** Do not touch the needle to avoid a needle stick.
- Use the needle cover to unscrew the needle.
 - **Throw away** (dispose of) the needle in a suitable sharps container.

GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

- **Push** the white cap onto your pen.
- Store your pen in the refrigerator until your next injection.

Routine (daily) use of GoQuick Pen

Step 1 Preparation



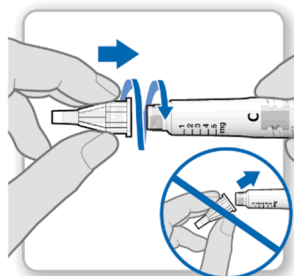
- **Wash and dry** your hands.
- **Gather** the following supplies on a clean flat surface:
 - o An already mixed GoQuick Pen
 - o A new needle (not included)
 - o Suitable sharps container (not included).
- **Check** the expiry date on your pen label. **Do not** use your pen if the pen has passed its expiry date. **Do not** use your pen **28 days after first use**.

Step 2 Choose Injection Site



- **Choose and clean** an injection site as recommended by your doctor or nurse. Choose a different site each time you give yourself an injection. Each new injection should be given at least 2 cm from the site you used before.
- Avoid areas that are bony, bruised, red, sore or hard, and areas of the skin that have scars or skin conditions.

Step 3 Attach New Needle



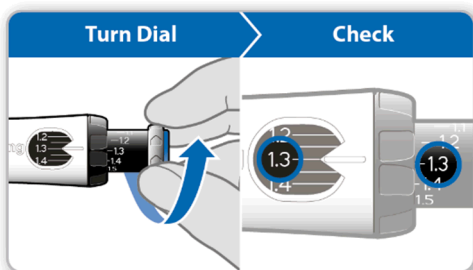
- **Pull** the white cap straight off your pen.

GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

- Take a new needle and peel off the paper seal.
- **Gently push and then screw** the needle onto your pen. **Do not** overtighten.
Note: Be careful not to attach the needle at an angle. This may cause your pen to leak.
- **Remove** both needle covers.
 - Keep the outer needle cover to remove the needle after your injection.

Step 4 Draw Up Your Dose

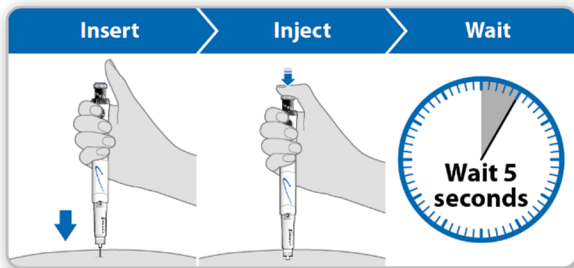


- **Turn** the **grey dial** in the direction of the arrows until it stops clicking.
- Your dose on the black rod should **line up** with the white pointer.
- **Check** that the dose you drew up on the black rod is the same as the dose you set in the memory window.
 - If the doses match, your pen is ready to give your injection.

Note: If the dose you drew up is smaller, your pen does not have a full dose of Genotropin.

Follow what your doctor or nurse told you to do when your pen does not have a full dose . Or contact your doctor or nurse for advice.

Step 5 Give Your Injection of Genotropin



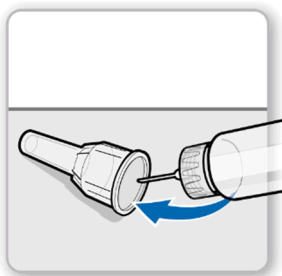
- **Hold** your pen over the injection site.
- **Insert** the needle straight into the skin.
- **Push** the blue injection button down until it stops clicking.
- **Wait** for a full 5 seconds to ensure that your complete dose is injected. Keep lightly pressing on the blue injection button while you count.
- After 5 seconds, pull the needle straight out of your skin.

Note: If you see a drop of liquid at the injection site or needle tip, then with your next injection try pressing the blue injection button for longer before pulling the needle out of your skin.

Step 6 Remove Needle

GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)



- **Carefully cover** the needle with the outer needle cover.
- **Caution: Do not** touch the needle to avoid a needle stick.
- Use the needle cover to unscrew the needle.
- **Throw away** (dispose of) the needle in a suitable sharps container.
- **Push** the white cap onto your pen.
- Store your pen in the refrigerator until your next injection.

Using the Needle Guard (Optional)

The needle guard is an optional feature supplied separately to hide the needle during injection.

Attach the needle guard:

Attach the needle guard after Step 5 (Setting up and using a new GoQuick Pen) to avoid a needle stick.

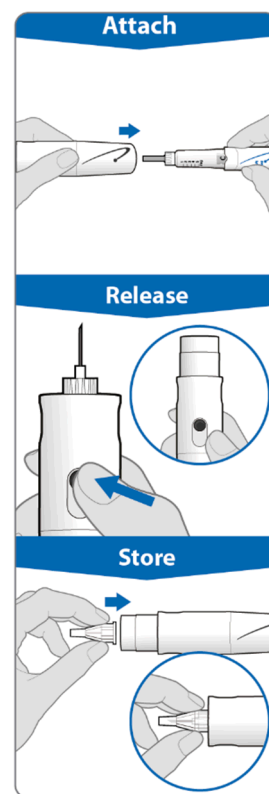
- Pull the black cap off the needle guard.
 - If the needle shield slides out, push it back into the needle guard until it clicks into place.
- Line up the black logo on the needle guard with the blue logo on your pen. Carefully push the needle guard onto your pen until it snaps into place.
- After Step 6 (Setting up and using a new GoQuick Pen), press the black button to release the shield from the needle guard.
- Follow the instructions as described from Step 7 (Setting up and using a new GoQuick Pen).

To remove the needle with needle guard in place:

- Place the outer needle cover into the end of the needle shield.
- Use the outer needle cover to push in the needle shield until it locks into place.
- Use the needle cover to unscrew the needle and throw away (dispose of) in a suitable sharps container.
- Leave the needle guard on your pen.
- Place the black cap on the needle guard. Store your pen in the refrigerator.

To remove the needle guard:

- Remove the needle first, then gently pull the needle guard off the pen.
- **Do not** throw away the needle guard. It can be used with your next pen.



GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

GOQUICK[®] INSTRUCTIONS FOR USE: 12 mg

Please read these instructions completely before using your GoQuick Pen.

If you have any questions about your dose or your treatment with GENOTROPIN, call your doctor or nurse.

About GoQuick

GoQuick is a pre-filled, multidose, disposable injection pen that holds 12 mg of somatropin. Your pen can deliver doses from 0.3 mg to 4.5 mg of Genotropin. Each click of the black ring changes the dose by 0.15 mg. The Genotropin in your pen is mixed only once, when you start a new pen. You never have to change cartridges. When your pen is empty, you just start a new pen.

Your pen has dose memory. The dose is set once on a new pen. Your pen then allows you to draw up the same set dose for each injection. This will prevent you from drawing more than your set dose.

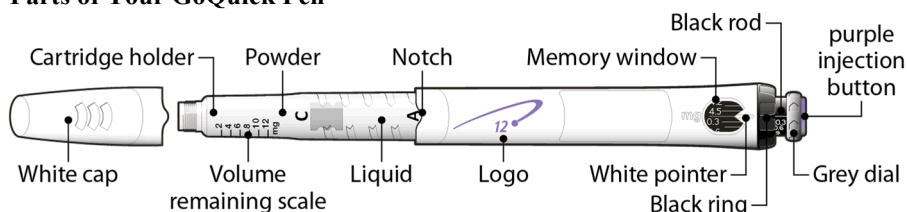
Important Information

- **Do not** mix the powder and liquid of your pen unless a needle is on your pen.
- **Do not** store your pen with the needle attached. The Genotropin may leak from your pen and air bubbles may form in the cartridge. Always remove the needle and attach your pen cap or needle guard cap before storing.
- Take care not to drop your pen. If you drop your pen and any part of it appears broken or damaged, **do not** use it. Contact your doctor or nurse for another pen. If you drop your pen and it is not damaged or broken, you must perform another prime as described in Step 6 (Setting up and using a new GoQuick Pen).
- Clean your pen with a damp cloth. **Do not** put your pen in water.
- Always use a new needle for each injection. **Do not** share your pen needles.
- The volume remaining scale along the side of the cartridge holder is a guide to show the volume of Genotropin left in your pen.

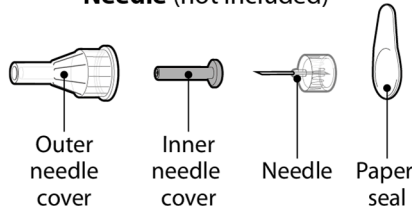
Storage and Disposal

- Store your pen in the refrigerator (2°C to 8°C) in the outer carton to protect from light. **Do not** freeze or expose it to frost.
- **Do not** use your pen after its expiry date.
- 28 days after mixing, throw away (dispose of) your pen even if there is some medicine left.
- See **Storage and Disposal of GENOTROPIN** for how to store your GoQuick Pen.
- Follow your local health and safety laws to throw away (dispose of) your pen. Ask your doctor or nurse if you are not sure what to do.

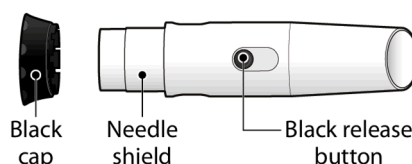
Parts of Your GoQuick Pen



Needle (not included)



Needle Guard (supplied separately) with needle shield released



Pen needles are **not included** with your GoQuick Pen. You will need to get pen needles up to a length of 8 mm from your pharmacy.

GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

- Needles to use with your GoQuick Pen:
 - o 31G or 32G (Becton Dickinson and Company)
 - o 31G or 32G (Novo Nordisk[®])
 - o 32.5G or 34G (Terumo)

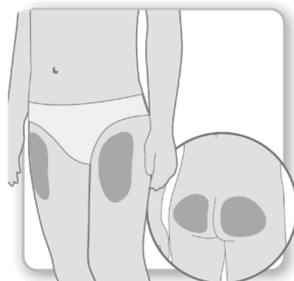
Setting up and using a new GoQuick Pen

Step 1 Preparation



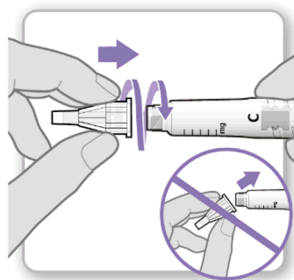
- **Wash and dry** your hands.
- **Gather** the following supplies on a clean flat surface:
 - o A new GoQuick Pen
 - o A new needle (not included)
 - o Suitable sharps container (not included).
- **Check** the expiry date on your pen label. **Do not** use your pen if the pen has passed its expiry date.

Step 2 Choose Injection Site



- **Choose and clean** an injection site as recommended by your doctor or nurse. Choose a different site each time you give yourself an injection. Each new injection should be given at least 2 cm from the site you used before.
- Avoid areas that are bony, bruised, red, sore or hard, and areas of the skin that have scars or skin conditions.

Step 3 Attach New Needle



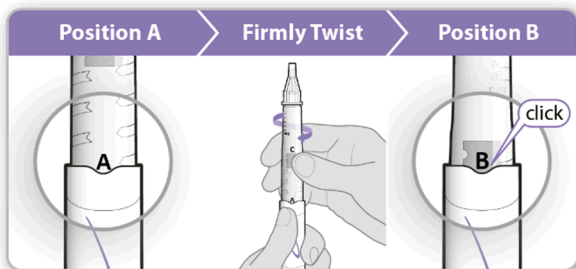
- **Pull** the white cap straight off your pen.
- Take a new needle and peel off the paper seal.

GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

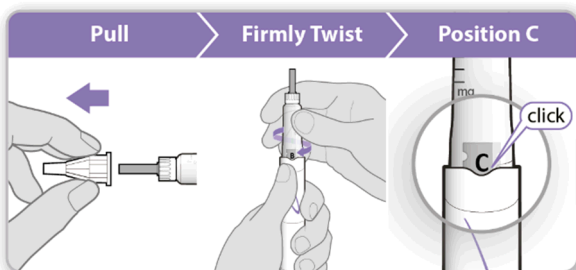
- **Gently push and then screw** the needle onto your pen. **Do not** overtighten.
Note: Be careful not to attach the needle at an angle. This may cause your pen to leak.
- Leave both needle covers on the needle.

Step 4 Mix the Genotropin



- **Hold** your pen with the needle-end pointing up and the “A” facing you.
- **Firmly twist** the cartridge holder into your pen until “B” clicks into the notch.
- **Gently tilt** your pen from side to side to help dissolve the powder completely. **Do not** shake. Shaking can damage the growth hormone.
- **Check** that the liquid in the cartridge is clear and all the powder is dissolved.
 - If the liquid is cloudy or you see any powder, gently tilt your pen from side to side a few more times.
 - If the liquid is still cloudy or you see any powder, **do not** use the pen and try again with a new pen.

Step 5 Remove the Air from Your Pen

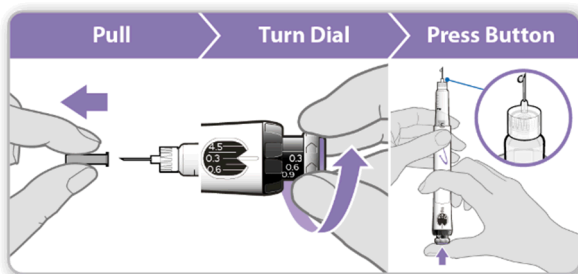


- **Pull** the outer needle cover off. Keep it to remove the needle after your injection.
- Leave the inner needle cover on.
Note: You should see an inner needle cover after you have removed the outer cover. If you do not see this, try to attach the needle again.
- **Hold** your pen with the needle-end pointing up.
- **Gently tap** the cartridge holder to help any trapped air move to the top.
- **Firmly twist** the cartridge holder into your pen until “C” clicks into the notch.
 - Some liquid may appear around the inner needle cover. This is normal.

Step 6 Prime Your Pen

GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

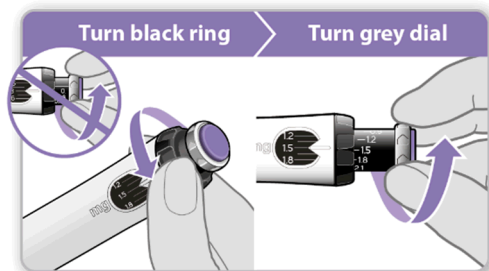


Priming removes any remaining air by pushing a small amount of liquid out of your pen. The priming dose is 0.3 mg and is different from the dose your doctor or nurse has prescribed. **Only prime your pen the first time you use it.**

- **Pull** the inner needle cover off and throw it away.

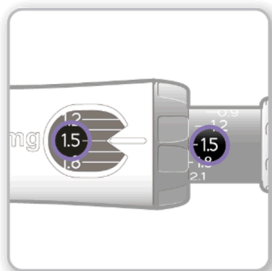
Caution: Do not touch the needle to avoid a needle stick.

- **Check** that 0.3 mg is set in the memory window.
- **Turn** the **grey dial** in the direction of the arrows until it stops clicking.
- **Hold** your pen with the needle pointing **straight up**.
- **Push** the purple injection button all the way in.
- **Check** for liquid at the needle tip. If liquid appears, your pen is primed.
 - If liquid does not appear, repeat the priming steps up to two additional times.
 - If liquid still does not appear, do not use your pen. Contact your doctor or nurse for advice.

Step 7 Set and Draw Up Your Dose

The first time you use your pen you will set the dose that your doctor or nurse has prescribed. You do not need to set the dose again until you start a new pen or your doctor or nurse tells you.

- **Turn** the **black ring counterclockwise** until your dose is lined up with the white pointer in the memory window. **Be careful not to turn the grey dial.**
 - If you turn your dose past the white pointer, turn the black ring back to set your correct dose.
- Note:** If you cannot turn the black ring, press the purple injection button until it stops clicking. Then try and set your dose again. Note that liquid will come out of the needle.
- **Turn** the **grey dial** in the direction of the arrows until it stops clicking.

Step 8 Check Your Dose

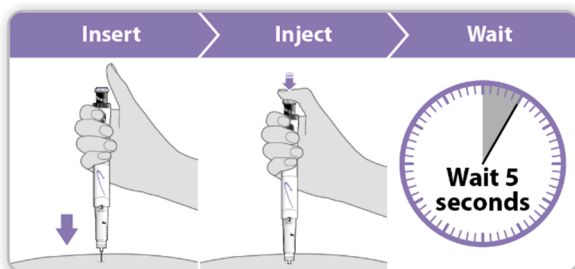
GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

Your dose on the black rod should **line up** with the white pointer.

- **Check** that the dose you drew up on the black rod is the same as the dose you set in the memory window.
 - If the doses match, your pen is ready to give your injection.
 - If the doses do not match, make sure you have turned the grey dial in the direction of the arrows until it does not click anymore.

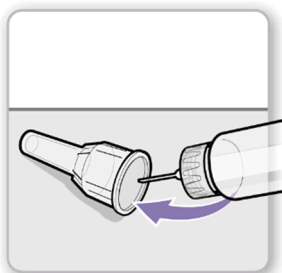
Step 9 Give Your Injection of Genotropin



- **Hold** your pen over the injection site.
- **Insert** the needle straight into the skin.
- **Push** the purple injection button down until it stops clicking.
- **Wait** for a full 5 seconds to ensure that your complete dose is injected. Keep lightly pressing on the purple injection button while you count.
- After 5 seconds, pull the needle straight out of your skin.

Note: If you see a drop of liquid at the injection site or needle tip, then with your next injection try pressing the purple injection button for longer before pulling the needle out of your skin.

Step 10 Remove Needle



- **Carefully cover** the needle with the outer needle cover.
- Caution:** Do not touch the needle to avoid a needle stick.
- Use the needle cover to unscrew the needle.
 - **Throw away** (dispose of) the needle in a suitable sharps container.
 - **Push** the white cap onto your pen.
 - Store your pen in the refrigerator until your next injection.

Routine (daily) use of GoQuick Pen

Step 1 Preparation

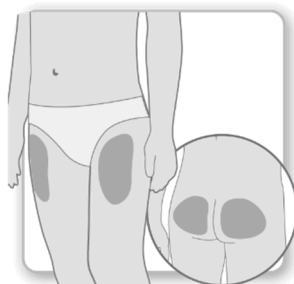
GENOTROPIN®

Somatropin (5.3 mg, 12 mg)



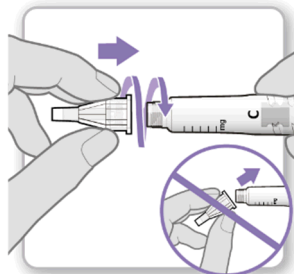
- **Wash and dry** your hands.
 - **Gather** the following supplies on a clean flat surface:
 - o An already mixed GoQuick Pen
 - o A new needle (not included)
 - o Suitable sharps container (not included).
 - **Check** the expiry date on your pen label. **Do not** use your pen if the pen has passed its expiry date.
- Do not** use your pen 28 days after first use.

Step 2 Choose Injection Site



- **Choose and clean** an injection site as recommended by your doctor or nurse. Choose a different site each time you give yourself an injection. Each new injection should be given at least 2 cm from the site you used before.
- Avoid areas that are bony, bruised, red, sore or hard, and areas of the skin that have scars or skin conditions.

Step 3 Attach New Needle



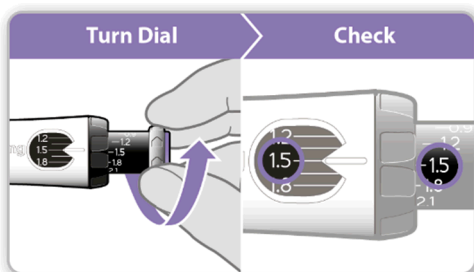
Pull the white cap straight off your pen.

- Take a new needle and peel off the paper seal.
 - **Gently push and then screw** the needle onto your pen. **Do not** overtighten.
- Note:** Be careful not to attach the needle at an angle. This may cause your pen to leak.
- **Remove** both needle covers.
 - o Keep the outer needle cover to remove the needle after your injection.

Step 4 Draw Up Your Dose

GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

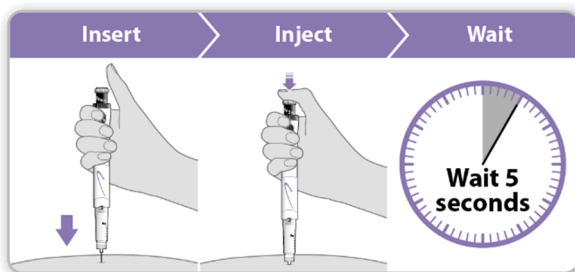


- **Turn the grey dial** in the direction of the arrows until it stops clicking.
- Your dose on the black rod should **line up** with the white pointer.
- **Check** that the dose you drew up on the black rod is the same as the dose you set in the memory window.
 - If the doses match, your pen is ready to give your injection.

Note: If the dose you drew up is smaller, your pen does not have a full dose of Genotropin.

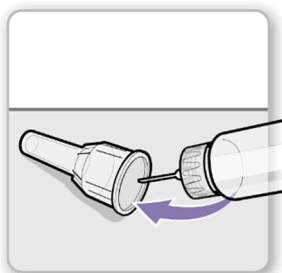
Follow what your doctor or nurse told you to do when your pen does not have a full dose. Or contact your doctor or nurse for advice.

Step 5 Give Your Injection of Genotropin



- **Hold** your pen over the injection site.
 - **Insert** the needle straight into the skin.
 - **Push** the purple injection button down until it stops clicking.
 - **Wait** for a full 5 seconds to ensure that your complete dose is injected. Keep lightly pressing on the purple injection button while you count.
 - After 5 seconds, pull the needle straight out of your skin.
- Note:** If you see a drop of liquid at the injection site or needle tip, then with your next injection try pressing the purple injection button for longer before pulling the needle out of your skin.

Step 6 Remove Needle



- **Carefully cover** the needle with the outer needle cover.
- **Caution:** Do not touch the needle to avoid a needle stick.
- Use the needle cover to unscrew the needle.
- **Throw away** (dispose of) the needle in a suitable sharps container.

GENOTROPIN[®]

Somatropin (5.3 mg, 12 mg)

- **Push** the white cap onto your pen.
- Store your pen in the refrigerator until your next injection.

Using the Needle Guard (Optional)

The needle guard is an optional feature supplied separately to hide the needle during injection.

Attach the needle guard:

Attach the needle guard after Step 5 (Setting up and using a new GoQuick Pen) to avoid a needle stick.

- Pull the black cap off the needle guard.
 - If the needle shield slides out, push it back into the needle guard until it clicks into place.
- Line up the black logo on the needle guard with the purple logo on your pen. Carefully push the needle guard onto your pen until it snaps into place.
- After Step 6 (Setting up and using a new GoQuick Pen), press the black button to release the shield from the needle guard.
- Follow the instructions as described from Step 7 (Setting up and using a new GoQuick Pen).

To remove the needle with needle guard in place:

- Place the outer needle cover into the end of the needle shield.
- Use the outer needle cover to push in the needle shield until it locks into place.
- Use the needle cover to unscrew the needle and throw away (dispose of) in a suitable sharps container.
- Leave the needle guard on your pen.
- Place the black cap on the needle guard. Store your pen in the refrigerator.

To remove the needle guard:

- Remove the needle first, then gently pull the needle guard off the pen.
- **Do not** throw away the needle guard. It can be used with your next pen.

