

PACKAGE LEAFLET: INFORMATION FOR THE USER

GENOTROPIN® 5.3 mg and 12 mg powder and solvent for solution for injection

somatropin

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

What is in this leaflet:

1. What Genotropin is and what it is used for
2. What you need to know before you use Genotropin
3. How to use Genotropin
4. Possible side effects
5. How to store Genotropin
6. Contents of the pack and other information

1. What Genotropin is and what it is used for

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 recombinant meaning it is not made from human or animal tissue.

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. Turner syndrome is a chromosomal error in girls that can affect growth - your doctor will have told you if you have this.
- 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. Your excessive fat will decrease and your reduced muscle mass will improve.
- 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. If severe growth hormone deficiency is confirmed, your doctor will propose continuation of Genotropin treatment.

You should only be given this medicine by a doctor who has experience with growth hormone treatment and who has confirmed your diagnosis.

2 What you need to know before you use Genotropin

Do not use Genotropin and tell your doctor if

- You are allergic (hypersensitive) to somatropin or any of the other ingredients of Genotropin.
- 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, accidental trauma or similar conditions). If you are about to have, or have had, a major operation, or go into hospital for any reason, tell your doctor and remind the other doctors you are seeing that you use growth hormone.
- Genotropin has been prescribed to stimulate growth but you have already stopped growing (closed epiphyses).

Take special care with Genotropin and tell your doctor if any of the following statements apply to you

- If you are at risk of developing diabetes, your doctor will need to monitor your blood sugar level during treatment with Genotropin.
- 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.
- After starting Genotropin treatment some patients may need to start thyroid hormone replacement.
- If you are receiving treatment with thyroid hormones it may be necessary to adjust your thyroid hormone dose.
- 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, you should inform your doctor.
- If you develop raised intracranial pressure (with symptoms such as strong headache, visual disturbances or vomiting) you should inform your doctor about it.
- If your doctor confirms that you have developed inflammation of the muscles near the injection site because of the preservative metacresol, you should use a Genotropin product without metacresol.
- If you are receiving Genotropin for growth hormone deficiency following a previous tumour (cancer), you should be examined regularly for recurrence of the tumour or any other cancer.
- If you experience worsening abdominal pain you should inform your doctor.
- Experience in patients 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.

Children with chronic renal (kidney) insufficiency:

- Your doctor should examine your kidney function and your growth rate before starting Genotropin. Medical treatment for your kidney condition should be continued. Genotropin treatment should be stopped at kidney transplantation.

Children with Prader-Willi syndrome:

- Your doctor will give you diet restrictions to follow to control your weight.
- 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 need to examine you and may interrupt your treatment with Genotropin.
- During treatment, your doctor will check you for signs of scoliosis, a type of spinal deformity.
- During treatment, if you develop a lung infection, tell your doctor so that he can treat the infection.

Children born small or too light at birth:

- If you were small or too light at birth and are aged between 9 and 12 years, ask your doctor for specific advice relating to puberty and treatment with this product.

- 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.

Using other medicines

Tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription.

Warnings and precautions

Talk to your doctor or pharmacist before using Genotropin.

If you have a replacement therapy with glucocorticoids, you should consult your doctor regularly, as you may need adjustment of your glucocorticoid dose.

You should tell your doctor if you are using:

- medicines to treat diabetes,
- thyroid hormones,
- synthetic adrenal hormones (corticosteroids),
- oestrogen taken orally or other sex hormones,
- ciclosporin (a medicine that weakens the immune system after transplantation),
- medicines to control epilepsy (anticonvulsants).

Your doctor may need to adjust the dose of these medicines or the dose of Genotropin.

Pregnancy and breast-feeding

You should not use Genotropin if you are pregnant, think you may be pregnant or are trying to become pregnant.

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

Ask your doctor or pharmacist for advice before taking any medicine.

Genotropin contains sodium

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

3. How to use Genotropin

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 individualised 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:

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. This dosage should be gradually increased or decreased according to blood test results as well as clinical response and side effects.

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.

Injecting Genotropin

Genotropin is intended for subcutaneous use. This means that it is injected through a short injection needle into the fatty tissue just under your skin. Your doctor should have already shown you how to use Genotropin. Always inject Genotropin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The instructions for using the GoQuick® pre-filled pen are provided in the carton with the pre-filled pen.

The instructions for using the Genotropin two-chamber cartridge with the Genotropin Pen are provided with your device.

Refer to the instructions for use before using your medicine.

When using a pre-filled pen a pen injection device, the needle must be screwed on before mixing. A new needle must be used for each injection. Needles must not be re-used.

- **Preparing the injection:**

You can take your Genotropin out of the refrigerator half an hour before your injection. This lets it warm up slightly and can make your injections more comfortable.

The GoQuick pre-filled pen contains the two-chamber cartridge that has both the growth hormone and the dissolving liquid in it. The growth hormone and the dissolving liquid are mixed together by twisting the cartridge holder (see the detailed steps in the Instructions for Use). A separate device is not needed.

Genotropin in a two-chamber cartridge contains both the growth hormone and the dissolving liquid and it is to be used in a Genotropin device. The growth hormone and the dissolving liquid in the two-chamber cartridge can be mixed together by screwing the Genotropin Pen device together.

For both the GoQuick pre-filled pen and the two-chamber cartridge, dissolve the powder by gently tipping it back and forth until the powder is completely dissolved.

When you are mixing your Genotropin, **DO NOT SHAKE** the solution. Mix it gently. Shaking the solution could make your growth hormone foam and damage the active substance. Check the solution and do not inject if the solution is cloudy or has particles in it.

- **Injecting Genotropin:**
Remember to wash your hands and clean your skin first.

Inject your growth hormone at about the same time every day. Bedtime is a good time because it is easy to remember. It is also natural to have a higher level of growth hormone at night.

Most people do their injections into their thigh or their bottom. Do your injection in the place you have been shown by your doctor. Fatty tissue of the skin can shrink at the site of injection. To avoid this, use a different place for your injection each time. This gives your skin and the area under your skin time to recover from one injection before it gets another one in the same place.

Remember to put your Genotropin back in the refrigerator straight after your injection.

If you use more Genotropin than you should

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.

If you forget to use Genotropin

Do not use a double dose to make up for a forgotten dose.

It is best to use your growth hormone regularly. If you forget to use a dose, have your next injection at the usual time the next day. Keep a note of any missed injections and tell your doctor at your next check-up.

If you stop using Genotropin

Ask for advice from your doctor before you stop using Genotropin.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

The very common and common side effects in adults may start within the first months of treatment and may either stop spontaneously or if your dose is reduced.

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.

Uncommon side effects (may affect up to 1 in 100 people) include:

In children:

- Leukaemia (This has been reported in a small number of growth hormone deficiency patients, some of whom have been treated with somatropin. However, there is no evidence that leukaemia incidence is increased in growth hormone recipients without predisposing factors).
- Increased intracranial pressure (which causes symptoms such as strong headache, visual disturbances or vomiting).
- Numbness / tingling.
- Rash.
- Itching.
- Raised itchy bumps on the skin.
- Muscle pain.
- Breast enlargement (gynaecomastia).
- Water retention (which shows as puffy fingers or swollen ankles, for a short time at the start of treatment).

In adults:

- Breast enlargement (gynaecomastia).

Not known: frequency cannot be estimated from the available data

- Type 2 diabetes.
- Facial swelling.
- Headache.
- A decrease in the levels of the hormone Cortisol in your blood.

In children:

- Stiffness in the arms and legs.

In adults:

- Increased intracranial pressure (which causes symptoms such as strong headache, visual disturbances or vomiting).
- Rash.
- Itching.
- Raised itchy bumps on the skin.
- Reddening, itchiness or pain at the injection site.

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 your treatment with growth hormone may include the following. You (or your child) may experience a 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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Genotropin

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton as MM/YYYY. The expiry date refers to the last day of that month.

Before reconstitution

Store in a refrigerator (2°C – 8°C). Keep the two-chamber cartridge in the outer carton in order to protect from light.

Before opening, the product may be taken out of the refrigerator, without being replaced, for a maximum period of 1 month at a temperature not above 25°C but after this it must be discarded.

After reconstitution

Store in a refrigerator (2°C – 8°C) for up to 28 days. Do not freeze. Keep the GoQuick pre-filled pen in the GoQuick outer carton, or the two-chamber cartridge in the Pen box in order to protect from light.

Do not use this medicine if you notice particles or if the solution is cloudy.

Do not freeze or expose Genotropin to frost. If it freezes, do not use it.

Never throw away needles or partly used or empty cartridges with your ordinary rubbish. When you have finished with a needle, you must discard it carefully in a suitable sharps container so that no-one will be able to use it or prick themselves on it.

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

6. Contents of the pack and other information

What Genotropin contains

- The active substance is somatropin*.
- One cartridge contains 5.3 mg or 12 mg of somatropin*.
- After reconstitution the concentration of somatropin* is 5.3 mg or 12 mg per ml.
- The other ingredients in the powder are: glycine (E640), mannitol (E421), sodium dihydrogen phosphate anhydrous (E339), and disodium phosphate anhydrous (E339) (see section 2 “Genotropin contains sodium”).
- The ingredients in the solvent are: water for injections, mannitol (E421) and metacresol.

* Produced in *Escherichia coli* cells by recombinant DNA technology

What Genotropin looks like and contents of the pack

Genotropin is a powder and solvent for solution for injection, in a two-chamber cartridge containing the powder in one section and the solvent in the other (5.3 mg/ml or 12 mg/ml). The cartridge may be contained in a pre-filled pen. Pack size of 1 or 5 pre-filled pen(s), or 1 or 5 or 20 cartridge(s).

Not all strengths and pack sizes may be marketed.

The powder is white and the solvent is clear.

You can use the cartridges in a specific pen injection device for Genotropin. Genotropin cartridges are colour coded and must be used with the matching colour coded Genotropin Pen to give the correct dose: The Genotropin 5.3 mg cartridge (blue) must be used with the Genotropin Pen 5.3 (blue). The Genotropin 12 mg cartridge (purple) must be used with the Genotropin Pen 12 (purple).

The instructions for use of the device are enclosed in the device package. You should ask your doctor for an injection device if you do not already have one.

Marketing Authorisation Holder

Pfizer Healthcare Ireland,
9 Riverwalk, National Digital Park,
Citywest Business Campus,
Dublin 24, Ireland

Manufacturer

Pfizer Manufacturing Belgium NV
Rijksweg 12
2870 Puurs-Sint-Amands
Belgium

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Genotropin: Austria, Denmark, Finland, Germany, Greece, Ireland, Italy, Netherlands, Portugal, Sweden, United Kingdom (Northern Ireland)

Genotonorm: Belgium, France, Luxembourg

Genotonorm Kabipen: Spain

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Ref: 41_0

GENOTROPIN GOQUICK® INSTRUCTIONS FOR USE

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 somatotropin. 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.

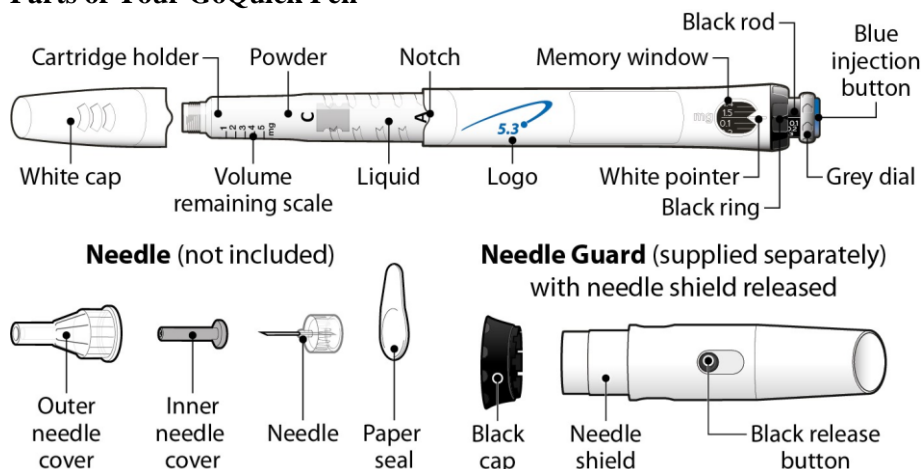
Important Information

- **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 the **other side of this** leaflet 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



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:

- 31G or 32G (Becton Dickinson and Company)
- 31G or 32G (Novo Nordisk®)
- 32.5G or 34G (Terumo)

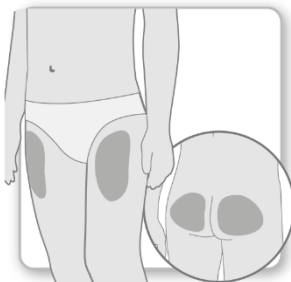
Setting up and using a new GoQuick Pen

Step 1 Preparation



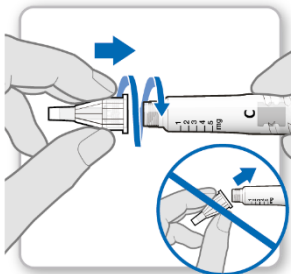
- **Wash and dry** your hands.
- **Gather** the following supplies on a clean flat surface:
 - A new GoQuick Pen
 - A new needle (not included)
 - Suitable sharps container (not included).
- **Check** the expiry date on your pen label. **Do not** use your pen if the pen has passed its expiry date.

Step 2 Choose Injection Site



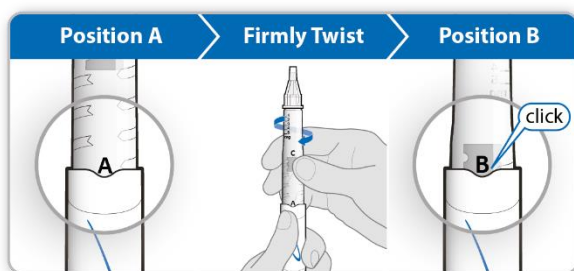
- **Choose and clean** an injection site as recommended by your doctor or nurse. Choose a different site each time you give yourself an injection. Each new injection should be given at least 2 cm from the site you used before.
- Avoid areas that are bony, bruised, red, sore or hard, and areas of the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

Step 3 Attach New Needle



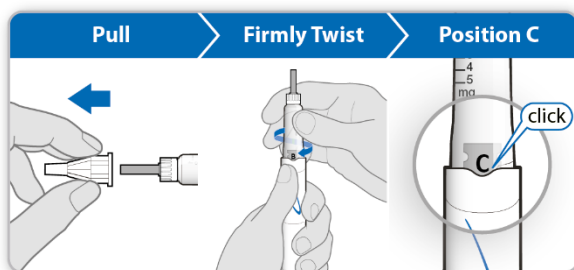
- **Pull** the white cap straight off your pen.
- Take a new needle and peel off the paper seal.
- **Gently push and then screw** the needle onto your pen. **Do not** overtighten.
Note: Be careful not to attach the needle at an angle. This may cause your pen to leak.
- Leave both needle covers on the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

Step 4 Mix the Genotropin



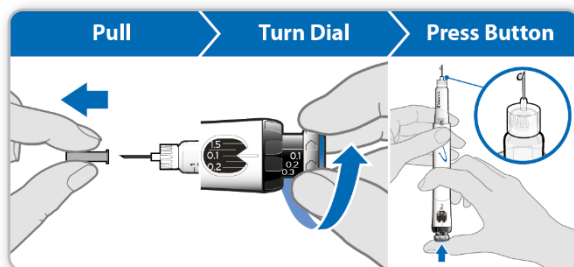
- **Hold** your pen with the needle-end pointing up and the “A” facing you.
- **Firmly twist** the cartridge holder into the pen until “B” clicks into the notch.
- **Gently tilt** your pen from side to side to help dissolve the powder completely. **Do not** shake. Shaking can damage the growth hormone.
- **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

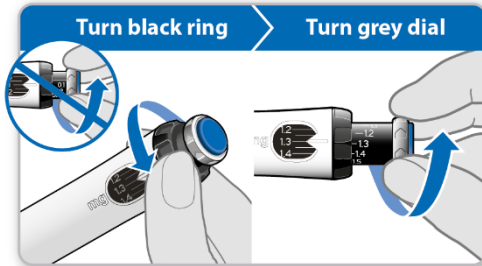


Priming removes any remaining air by pushing a small amount of liquid out of your pen. The priming dose is 0.1 mg and is different from the dose your doctor or nurse has prescribed. **Only prime your pen the first time you use it.**

- **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.

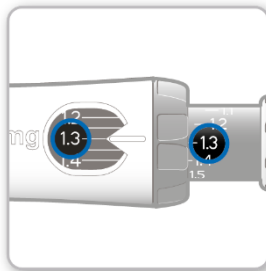
Step 7 Set and Draw Up Your Dose



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.

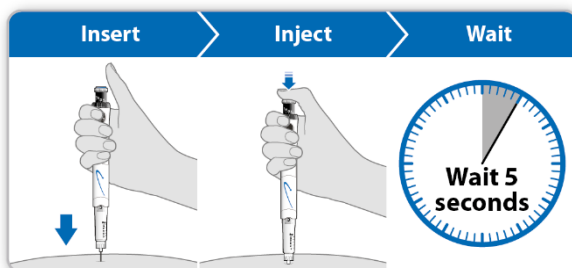
Step 8 Check Your Dose



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.

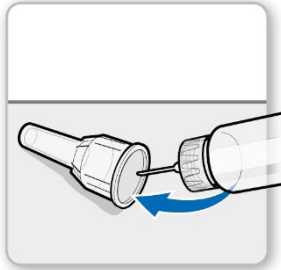
Step 9 Give Your Injection of Genotropin



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

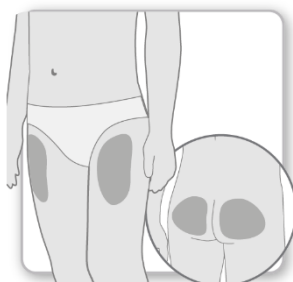
Routine (daily) use of GoQuick Pen

Step 1 Preparation



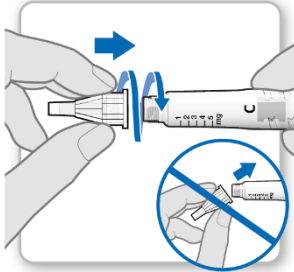
- **Wash and dry** your hands.
- **Gather** the following supplies on a clean flat surface:
 - An already mixed GoQuick Pen
 - A new needle (not included)
 - Suitable sharps container (not included).
- **Check** the expiry date on your pen label. **Do not** use your pen if the pen has passed its expiry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

Step 2 Choose Injection Site



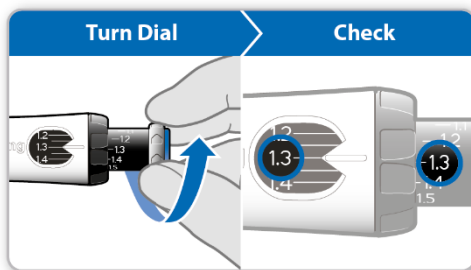
- **Choose and clean** an injection site as recommended by your doctor or nurse. Choose a different site each time you give yourself an injection. Each new injection should be given at least 2 cm from the site you used before.
- Avoid areas that are bony, bruised, red, sore or hard, and areas of the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

Step 4 Draw Up Your Dose

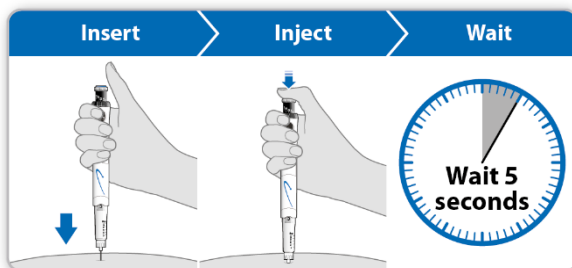


- **Turn** the **grey dial** in the direction of the arrows until it stops clicking.
- Your dose on the black rod should **line up** with the white pointer.
- **Check** that the dose you drew up on the black rod is the same as the dose you set in the memory window.
 - If the doses match, your pen is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

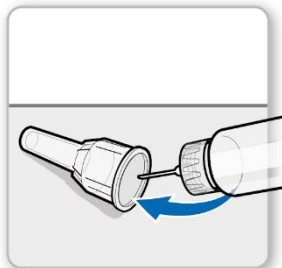
Step 5 Give Your Injection of Genotropin



- **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



- **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.

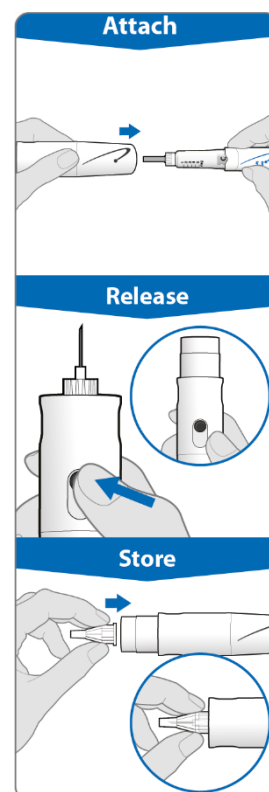
- Pull the black cap off the needle guard.
 - If the needle shield slides out, push it back into the needle guard until it clicks into place.
- Line up the black logo on the needle guard with the blue logo on your pen. Carefully push the needle guard onto your pen until it snaps into place.
- After Step 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 GOQUICK® INSTRUCTIONS FOR USE

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.

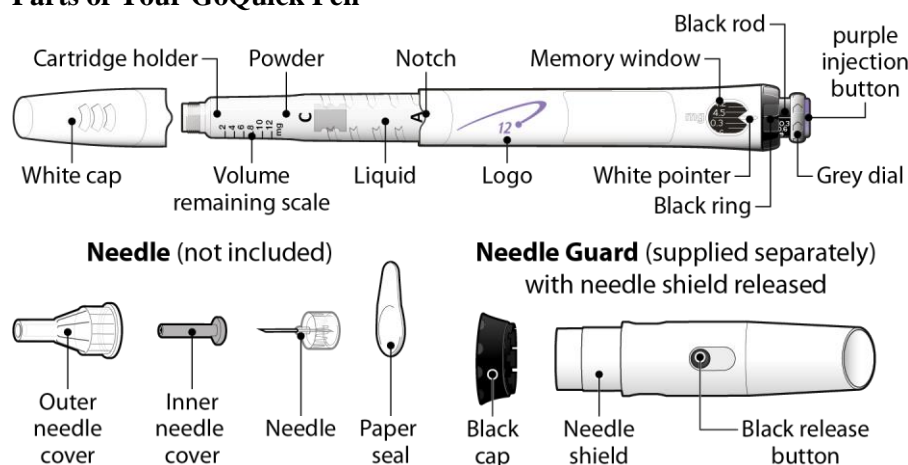
Important Information

- **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 the **other side of this** leaflet 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



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:
 - 31G or 32G (Becton Dickinson and Company)

- 31G or 32G (Novo Nordisk®)
- 32.5G or 34G (Terumo)

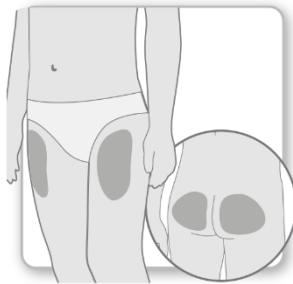
Setting up and using a new GoQuick Pen

Step 1 Preparation



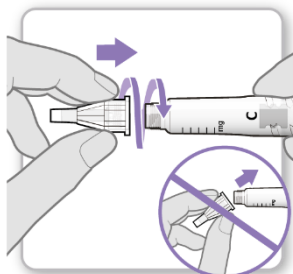
- **Wash and dry** your hands.
- **Gather** the following supplies on a clean flat surface:
 - A new GoQuick Pen
 - A new needle (not included)
 - Suitable sharps container (not included).
- **Check** the expiry date on your pen label. **Do not** use your pen if the pen has passed its expiry date.

Step 2 Choose Injection Site



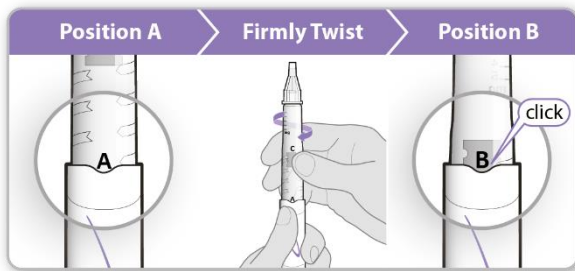
- **Choose and clean** an injection site as recommended by your doctor or nurse. Choose a different site each time you give yourself an injection. Each new injection should be given at least 2 cm from the site you used before.
- Avoid areas that are bony, bruised, red, sore or hard, and areas of the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

Step 3 Attach New Needle



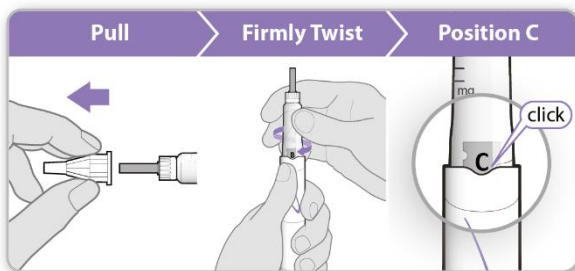
- **Pull** the white cap straight off your pen.
- Take a new needle and peel off the paper seal.
- **Gently push and then screw** the needle onto your pen. **Do not** overtighten.
Note: Be careful not to attach the needle at an angle. This may cause your pen to leak.
- Leave both needle covers on the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

Step 4 Mix the Genotropin



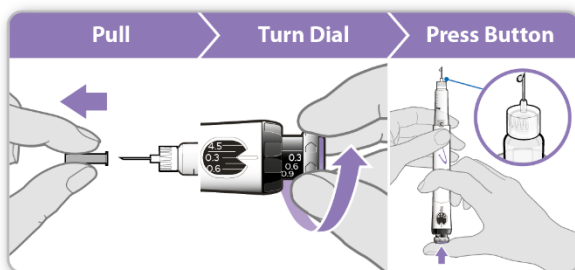
- **Hold** your pen with the needle-end pointing up and the “A” facing you.
- **Firmly** twist the cartridge holder into your pen until “B” clicks into the notch.
- **Gently tilt** your pen from side to side to help dissolve the powder completely. **Do not** shake. Shaking can damage the growth hormone.
- **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

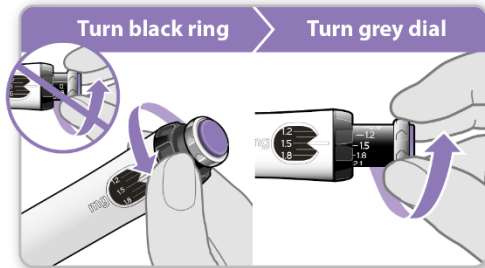


Priming removes any remaining air by pushing a small amount of liquid out of your pen. The priming dose is 0.3 mg and is different from the dose your doctor or nurse has prescribed. **Only prime your pen the first time you use it.**

- **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.

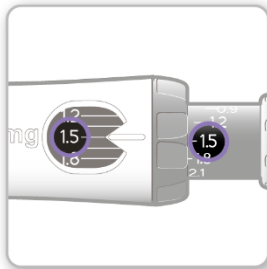
Step 7 Set and Draw Up Your Dose



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.

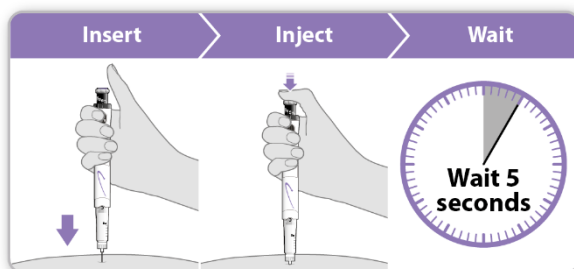
Step 8 Check Your Dose



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.

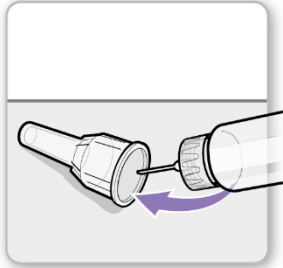
Step 9 Give Your Injection of Genotropin



- **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.

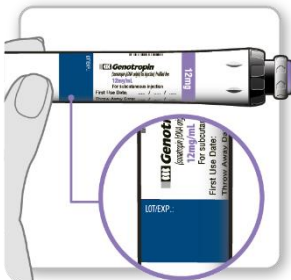
Step 10 Remove Needle



- **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.

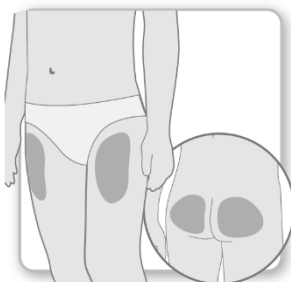
Routine (daily) use of GoQuick Pen

Step 1 Preparation



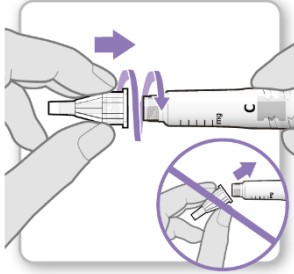
- **Wash and dry** your hands.
- **Gather** the following supplies on a clean flat surface:
 - An already mixed GoQuick Pen
 - A new needle (not included)
 - Suitable sharps container (not included).
- **Check** the expiry date on your pen label. **Do not** use your pen if the pen has passed its expiry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

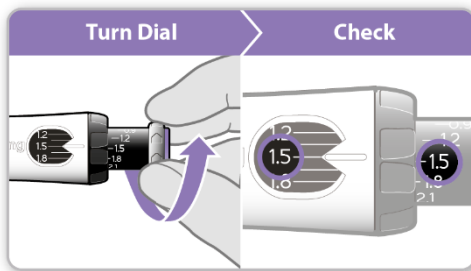
Step 3 Attach New Needle



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.
 - Keep the outer needle cover to remove the needle after your injection.

Step 4 Draw Up Your Dose

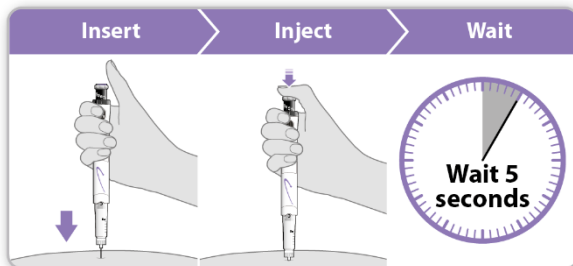


- **Turn** the **grey dial** in the direction of the arrows until it stops clicking.
- Your dose on the black rod should **line up** with the white pointer.
- **Check** that the dose you drew up on the black rod is the same as the dose you set in the memory window.
 - If the doses match, your pen is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

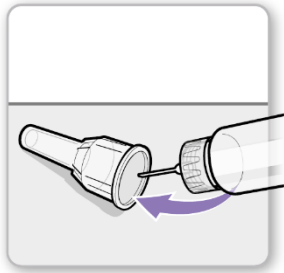
Step 5 Give Your Injection of Genotropin



- **Hold** your pen over the injection site.
- **Insert** the needle straight into the skin.
- **Push** the 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.
- **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.

