

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

**Genotropin® 12 mg
Powder and solvent for reconstitution of solution for subcutaneous injection**

**A Genotropin 12 mg injection pen contains:
somatotropin recombinant 12 mg/ml**

For a list of inactive ingredients and allergens, see section 6 'Further information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar to yours.

WHAT SHOULD I KNOW ABOUT Genotropin?

- Before using this medicine you must be trained by a qualified healthcare professional about preparing the medicine and injecting it.

1. WHAT IS THIS MEDICINE INTENDED FOR?

In children:

- Treatment of growth problems in children due to failed or insufficient secretion of growth hormone by the pituitary.
- Growth problems due to Turner syndrome.
- Retarded growth in children due to renal insufficiency.
- Prader-Willi syndrome.
- Children born small for gestational age (SGA).

In adults:

- Adults who have had growth hormone deficiency since childhood.
- Adults who have growth hormone deficiency due to a problem in their pituitary.

Therapeutic group:
growth hormone.

2. BEFORE USING THIS MEDICINE

Do not use this medicine:

- If you are sensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains (see section 6).
- If you have an active tumor (cancer). Tumors must be inactive and you must have finished your anti-tumor treatment before you start your treatment with Genotropin.
- If 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 medical procedure, or go into hospital for any reason, tell your doctor and all the other doctors you are seeing that you use growth hormone.
- To stimulate growth in children with closed growth plates (epiphyses).

Special warnings about using this medicine

Tell your doctor if any of the following applies 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, closely monitor your blood sugar level during treatment with Genotropin and consult your doctor about adjusting the dose of your diabetes medicines.

- After starting Genotropin treatment some patients may need to start thyroid hormone replacement therapy.
- 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 must 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 medicine without metacresol.
- If you are receiving Genotropin for growth hormone deficiency that is following a previous tumor (cancer), you should be examined regularly for recurrence of the tumor or any other cancer.
- If you experience worsening abdominal pain you should inform your doctor.
- Information about this treatment in patients above 60 years old 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 insufficiency:

Your doctor will check your kidney function and your growth rate before starting treatment with 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 advise you about what diet to follow for weight control.

Your doctor will make an assessment for signs of upper airway obstruction, sleep apnea (where your breathing is interrupted during sleep), or respiratory infection before starting treatment with Genotropin.

During treatment, if there are signs of upper airway obstruction (including starting to snore or worsening of snoring), your child should be examined by the doctor. Treatment with Genotropin may need to be interrupted.

During treatment, your doctor will check you for signs of scoliosis, a type of spinal deformity.

During treatment, if a lung infection develops, tell your doctor so that he/she can treat the infection.

Children born small for gestational age:

In children born small for gestational age (in length or weight) and are aged 9-12 years, ask your doctor for advice about treatment with this product during puberty.

Your doctor will check blood sugar and insulin levels before the start of treatment and every year during treatment.

Treatment should be continued until growth is complete.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- medicines to treat diabetes
- thyroid hormones
- corticosteroids
- estrogen taken orally or other sex hormones
- cyclosporine (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.

Warnings:

- If you are taking glucocorticoid replacement therapy, please consult your doctor regularly because your glucocorticoid dose may need to be adjusted.

Pregnancy and breastfeeding

Do 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 breastfeeding.

Important information about some of this medicine's ingredients

This medicine contains less than 1 mmol sodium (23 mg) per dose, so is considered 'sodium-free'.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by your doctor only.

This medicine is intended for subcutaneous use.

Before first using this medicine, you must be trained by a qualified healthcare professional about preparing the medicine and injecting it.

Most patients inject into the thigh or bottom. You should inject where your doctor or nurse have told you.

For detailed instructions for use see the section 'Genotropin GoQuick 12 mg Instructions for Use'.

Inject the medicine in a different place in the body each time.

Complete the course of treatment as recommended by your doctor.

Do not exceed the recommended dose.

If you have accidentally taken a higher dosage

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. 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 take the medicine

If you forget to take this medicine at the scheduled time, do not take a double dose; take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor or pharmacist. If you stop taking this medicine, your treatment will not work well.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Genotropin, may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

The very common and common side effects in adults may arise during the first few months of treatment and may subside spontaneously or with dose-reduction.

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

In adults:

- joint pain.
- water retention (which shows as puffy fingers or swollen ankles).

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

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 (carpal tunnel syndrome).
- stiffness in the arms and legs, muscle pain.

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

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).

Side effects of unknown 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 interfere with the effect of the growth hormone.

Rough or lumpy skin at the injection site can be prevented by injecting in a different place each time.

Inflammation of the muscles near the injection area is a very rare side effect which can occur due to the preservative metacresol. If your doctor confirms that you have this side effect, you should use a medicine without metacresol.

Rare cases of sudden death have been described in patients with Prader-Willi syndrome; however, no link has been demonstrated between these cases and treatment with Genotropin.

If you feel discomfort or pain in your hip or knee while you are taking Genotropin, your doctor may suspect slipped capital femoral epiphysis or Legg-Calve-Perthes disease.

Other possible side effects that may be related to your treatment with growth hormone are: high blood sugar levels, reduced levels of thyroid hormone. Your doctor may order tests and, if necessary, will prescribe adequate treatment.

Rarely, an inflammation of the pancreas has been reported in patients treated with growth hormone.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage **before** mixing the powder and solvent (reconstitution):

Store in a refrigerator (2°C–8°C) and protect from light.

Before opening: The product may be taken out of the refrigerator, without replacing it there, for a maximum period of one month at a temperature that does not exceed 25°C, but after this it must be discarded in a correct waste container.

Do not freeze! If the product freezes, do not use it.

Storage **after** mixing the powder and solvent (reconstitution):

Store in a refrigerator (2°C–8°C) for up to 28 days; protect from light. Alternatively, it can be stored for up to two hours, once a day, outside the refrigerator at room temperature (up to 25°C), protected from light, for up to 28 days from reconstitution, during the approved shelf life.

Do not freeze! If the product freezes, do not use it.

Do not use the solution if it is cloudy or if you see particles in it.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

Powder:

mannitol, glycine, sodium dihydrogen phosphate anhydrous, disodium phosphate anhydrous.

Solvent:

water for injection, mannitol, metacresol.

What the medicine looks like and contents of the pack:

Each pack contains a pre-filled pen that must be reconstituted once when you start using a new pen.

The Genotropin 12 mg pre-filled pen (GoQuick) has a purple injection button.

Registration holder's name and address: Pfizer Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

Genotropin 12 mg: 121.35.27540.22

Genotropin GoQuick 12 mg Instructions for Use

Please read the instructions completely before using your Genotropin GoQuick Pen. If you have any questions about your dose or your treatment with Genotropin, call your doctor or nurse.

About Genotropin GoQuick

GoQuick is a multidose, disposable injection pen for repeated use 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 reconstituted 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 for every 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** reconstitute the powder with the liquid in your pen unless a needle is attached to 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 the pen. 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 (In section 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 shows the volume of Genotropin left in your pen.

Before you start using GoQuick:

- You must be trained by the healthcare team.
- You must know your dose. You must be familiar with the pen parts.
- You must ensure that you have the pen with the purple injection button.

Storage and Disposal

Storage before mixing the powder and the solvent (reconstitution):

Store in a refrigerator (2°C to 8°C) and protect from light.

Before opening: The product may be taken out of the refrigerator, without replacing it there, for a maximum period of one month at a temperature that does not exceed 25°C, but after this it must be discarded in a correct waste container.

Do not freeze! If the product freezes, do not use it.

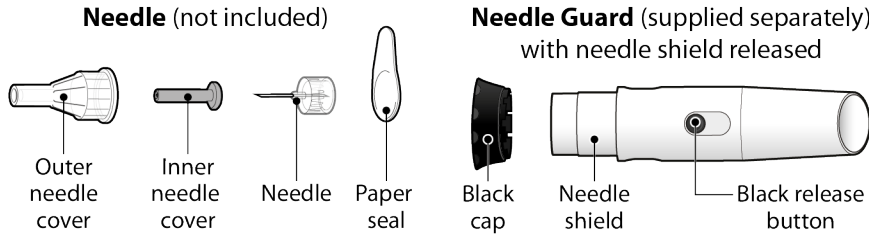
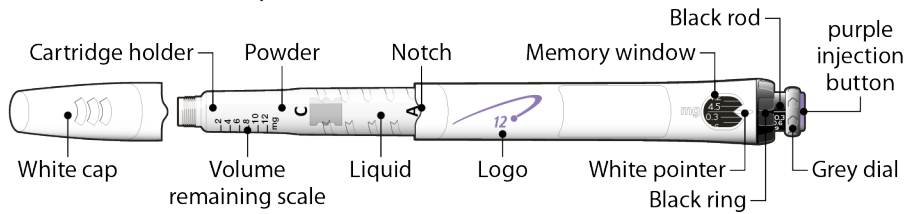
Storage after mixing the powder and the solvent (reconstitution):

Store in a refrigerator (2°C-8°C) for up to 28 days; protect from light. Alternatively, it can be stored for up to two hours, once a day, outside the refrigerator at room temperature (up to 25°C), protected from light, for up to 28 days from reconstitution, during the approved shelf life. Do not freeze! If the product freezes, do not use it.

- **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.

- Follow your local health and safety laws to throw away (dispose of) your pen. Ask your doctor or nurse if you are not sure about how to discard your pen.

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



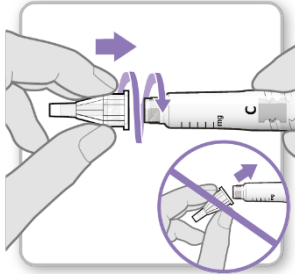
- **Wash and dry** your hands.
- **Gather** the following supplies on a clean flat surface:
 - A new GoQuick Pen
 - A new needle (not included)
 - Suitable sharps container (not included).
- **Check** the expiry date on your pen label. **Do not** use your pen if the pen has passed its expiry date.

Step 2 Choose Injection Site



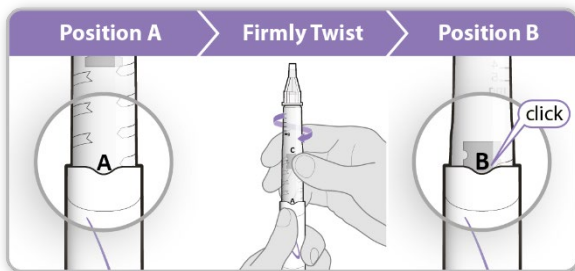
- **Choose and clean** an injection site as recommended by your doctor or nurse. Choose a different site each time you give yourself an injection. Each new injection should be given at least 2 cm from the site you used before.
- Avoid areas that are bony, bruised, red, sore or hard, and areas of the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

Step 3 Attach New Needle



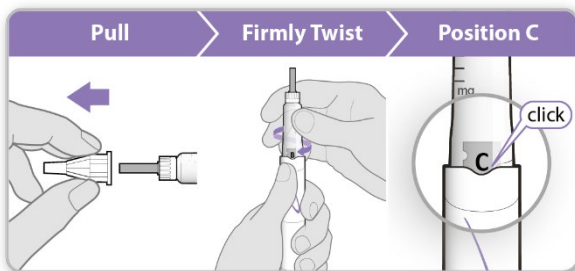
- **Pull** the white cap straight off your pen.
- Take a new needle and peel off the paper seal.
- **Gently push and then screw** the needle onto your pen. **Do not** overtighten. **Note:** Be careful not to attach the needle at an angle. This may cause your pen to leak.
- Leave both needle covers on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

Step 4 Reconstitute 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 the pen. 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

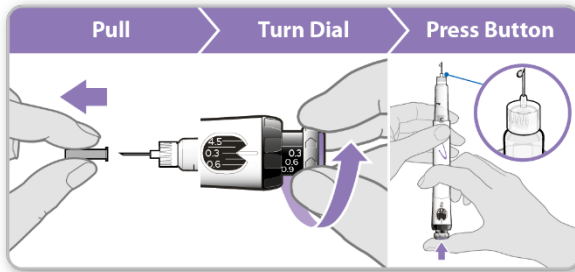


- **Pull** the outer needle cover off. Keep it to remove the needle after your injection.
- Leave the inner needle cover on.

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.

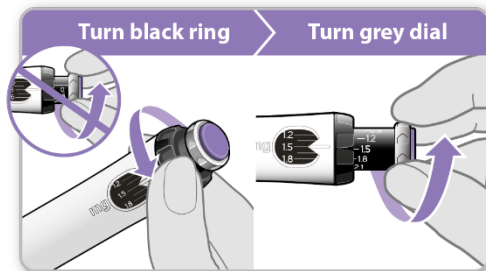
Step 6 Prime Your Pen



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

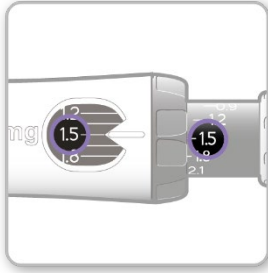


The first time you use your pen, you will set the dose that your doctor or nurse has prescribed.

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 continue setting 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.

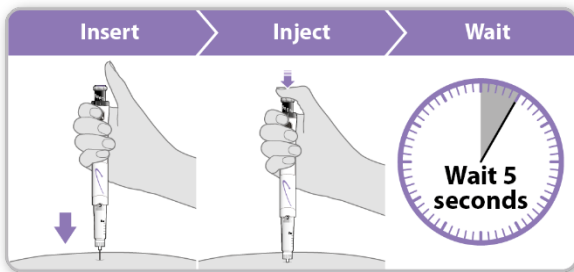
Step 8 Check Your Dose



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

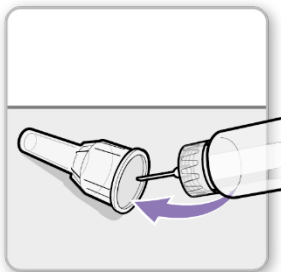
- **Check** that the dose you drew up on the black rod is the same as the dose you set in the memory window.
 - If the doses match, your pen is ready for injection.
 - If the doses do not match, make sure you have turned the grey dial in the direction of the arrows until it stops clicking.

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 5 full 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** the needle in a suitable sharps container.
- **Push** the white cap onto your pen.
- Store your pen in the refrigerator until your next injection.

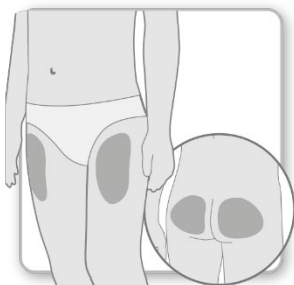
Routine (daily) use of GoQuick Pen

Step 1 Preparation



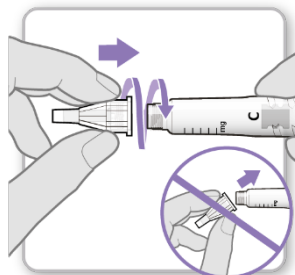
- **Wash and dry** your hands.
- **Gather** the following supplies on a clean flat surface:
 - An already mixed GoQuick Pen
 - A new needle (not included)
 - Suitable sharps container (not included).
- **Check** the expiry date on your pen label. **Do not** use your pen if the pen has passed its expiry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

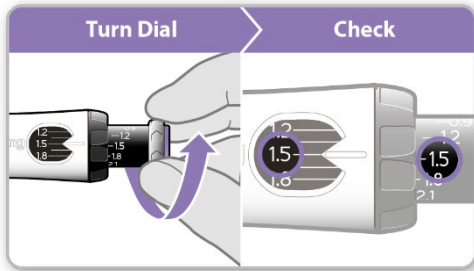
Step 3 Attach New Needle



- **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

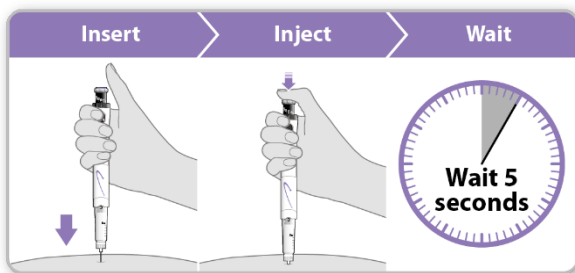


- Turn the **grey dial** in the direction of the arrows until it stops clicking.
- Your dose on the black rod should **line up** with the white pointer.
- **Check** that the dose you drew up on the black rod is the same as the dose you set in the memory window.
 - If the doses match, your pen is ready 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 5 full 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** 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 device supplied separately and used to hide the needle during injection.

Attach the needle guard:

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

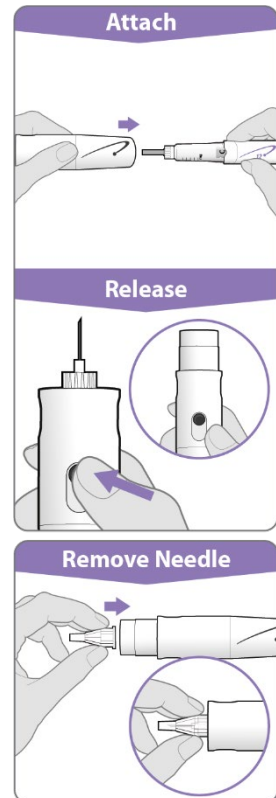
- Pull the black cap off the needle guard.
 - If the needle shield slides out, push it back into the needle guard until it clicks into place.
- Line up the black logo on the needle guard with the purple logo on your pen. Carefully push the needle guard onto your pen until it snaps into place.
- After Step 6 (In section 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 (In section 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.



Revised in 08/2024.