

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

This medicine is dispensed with a doctor's prescription only

GENOTROPIN® 5.3 mg

Powder and solvent for reconstitution of solution for subcutaneous injection

**A GENOTROPIN® 5.3 mg injection pen contains:
somatotropin recombinant 5.3 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 5.3 mg Instructions for Reconstitution and 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:

- temporary reddening, itchiness, or pain at the injection site.
- joint pain.
- rash.
- raised itchy bumps on the skin.

In adults:

- numbness/tingling.
- stiffness in the arms and legs, muscle pain.
- pain or burning sensation in the hands or underarms (carpal tunnel syndrome).

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

In children:

- water retention (which shows as puffy fingers or swollen ankles, for a short time at the start of treatment).
- itching.
- breast enlargement (gynaecomastia).

In adults:

- breast enlargement (gynaecomastia).

Rare side effects (may affect up to 1 in 1,000 patients):

In children:

- numbness/tingling.
- leukemia (reported in a small number of growth hormone deficiency patients, some of whom have been treated with somatropin). However, there is no evidence that leukemia incidence is increased in growth hormone recipients without predisposition factors).
- increased intracranial pressure (which causes symptoms such as strong headache, visual disturbances or vomiting).
- muscle pain.

Side effects of unknown frequency (cannot be estimated from the available data):

- type 2 diabetes.
- a decrease in the levels of the hormone cortisol in your blood.
- facial swelling.

In children:

- stiffness in the arms and legs.

In adults:

- increased intracranial pressure (which causes symptoms such as strong headache, visual disturbances or vomiting).
- reddening, itchiness, or pain at the injection site.
- rash.
- itching.
- raised itchy bumps on the skin.

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 not clear 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 diluted once when you start using a new pen. The GENOTROPIN® 5.3 mg pre-filled pen (GoQuick) has a blue 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® 5.3 mg: 111.08.26780.22

GENOTROPIN® GoQuick 5.3 mg Instructions for Reconstitution and Use

Important information

Read these instructions completely before using GENOTROPIN® GoQuick.

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

About GoQuick

GoQuick is a prefilled, multidose, disposable injection pen that holds 5.3 mg of somatropin.

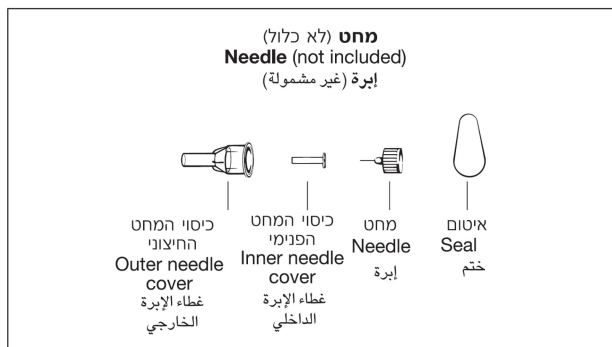
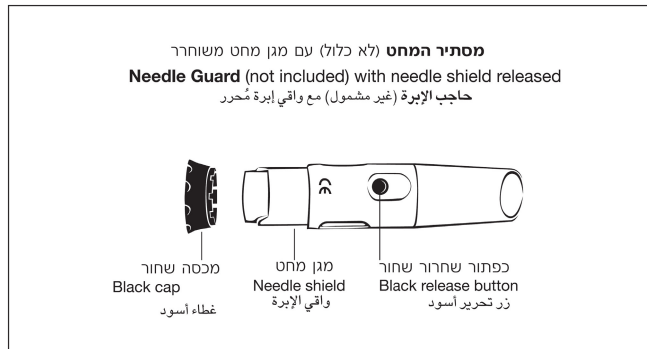
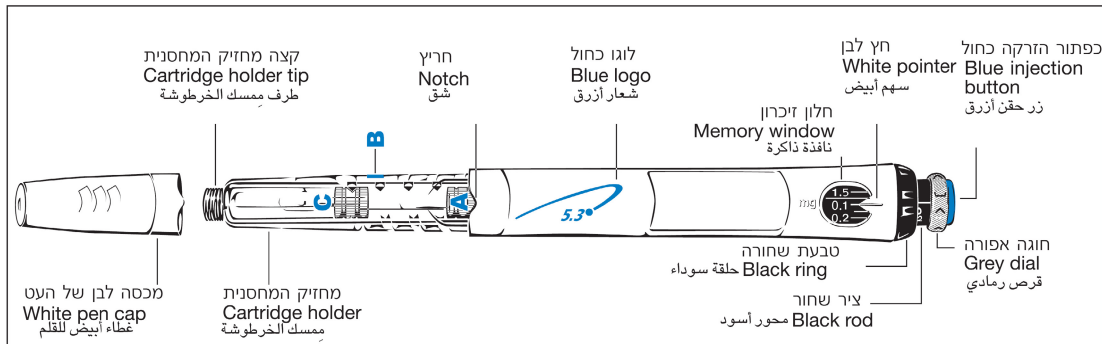
The GENOTROPIN® in the pen is diluted once, when you start using a new pen.

The pen can be used for up to 28 days from the day of dilution. There is no need to change cartridges. When the pen is empty, throw it away and start using a new pen.

The pen has dose memory. The dose is set once for each new pen. The pen then shows the same dose each time. You can use the pen with or without the needle guard.

Before You Start Using GoQuick:

- Get training from your doctor or nurse.
- Know your dose. Know the pen parts.
- Make sure you have the pen with the blue injection button.
- Wash your hands.



Priming and Using a New GoQuick Pen

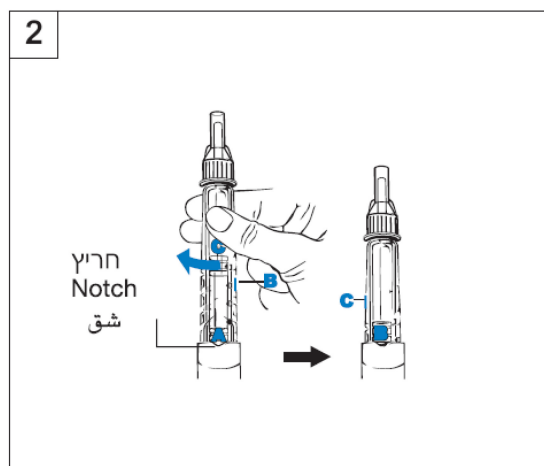
Step 1. Attach the Needle

- a. Pull the white pen cap straight off the pen.
- b. Peel the seal from a new needle.
- c. Firmly grasp the cartridge holder (Figure 1).
- d. Push the needle onto the cartridge holder tip.
- e. Gently screw the needle onto the pen. Do not overtighten.
- f. Leave both needle covers on the needle.



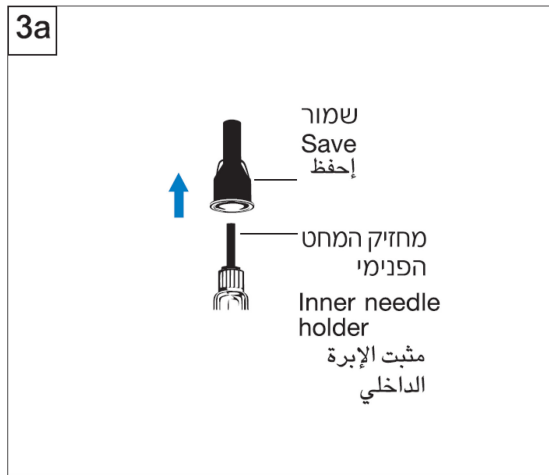
Step 2. Dilute the GENOTROPIN®

- a. Hold the pen with the needle-end pointing up and the **A** facing you (Figure 2).
- b. Firmly twist the cartridge holder into the pen until the **B** clicks into the notch.
 - Gently tilt the pen from side to side. Do not shake the pen. Shaking may damage the growth hormone.
- c. Check that the liquid in the cartridge is clear. All the powder should be dissolved.
 - If not, gently tilt the pen from side to side a few more times.
- d. Check the liquid again. Make sure it is clear.
 - If the liquid is clear, go to Step 3.
 - If the liquid is still cloudy or you see any powder, use a new pen.

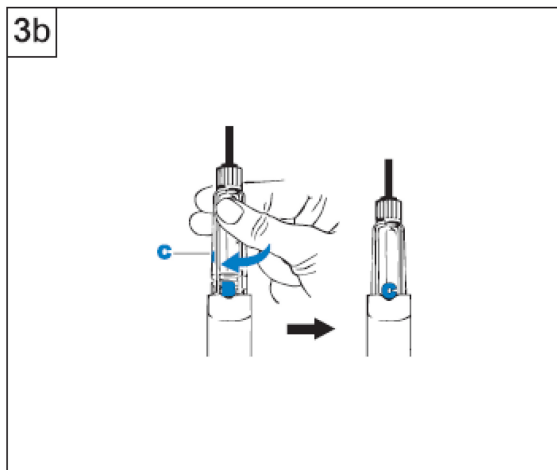


Step 3. Remove the Air

- a. Pull the outer needle cover off. Save it to cover the needle again later (Figure 3a).
- b. Leave the inner needle cover in place.

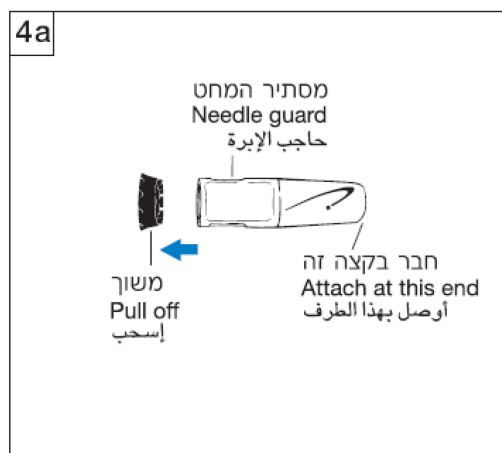


- c. Hold the pen with the needle-end pointing up (Figure 3b).
 - d. Tap the cartridge holder gently to release any trapped air bubbles move to the top.
 - e. Firmly, twist the cartridge holder into the pen until **C** clicks into the notch.
- Some liquid may appear around the inner needle cover.

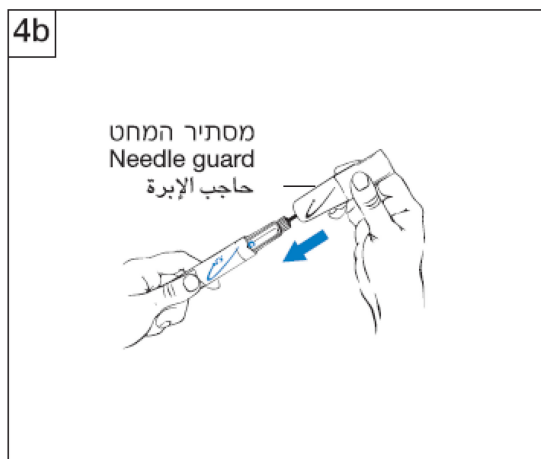


Step 4. Attach the Needle Guard (Optional)

- a. Pull the black cap off the needle guard. (Figure 4a)
- If the needle shield slides out, push it back into the needle guard until it slides into place.

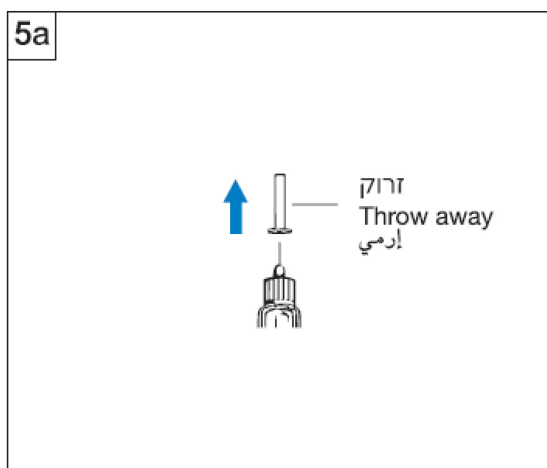


- b. Hold the pen in one hand below the blue logo. With the other hand, hold the needle guard below the needle shield (Figure 4b).
- c. Line up the black logo on the needle guard with the blue logo on the pen. Carefully push the needle guard onto the pen until it snaps into place.

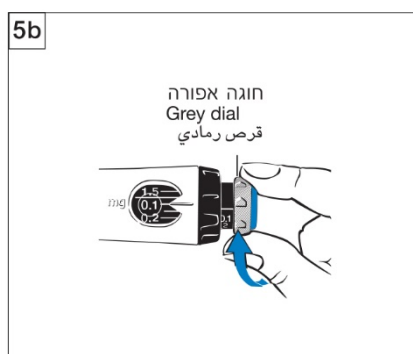


Step 5. Prepare the pen

- a. Pull the inner needle cover off. Throw it away. (Figure 5a)

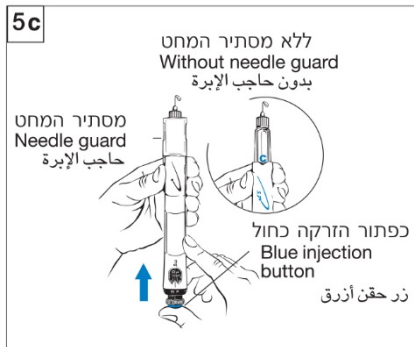


- b. Check that 0.1 mg is set in the memory window.
- c. Turn the grey dial in the direction of the arrows until it stops clicking (Figure 5b).

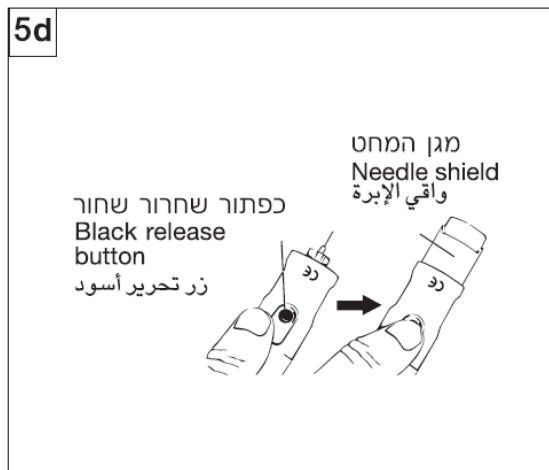


- d. Hold the pen with the needle pointing up (Figure 5c with and without needle guard).
- e. Push the blue injection button until liquid appears.

- f. If liquid does not appear at Step “e”, repeat Steps “b-e” in this section up to two more times.
- g. If liquid still does not appear, do not use the pen.
- See the ‘Questions and Answers’ section below for more information.

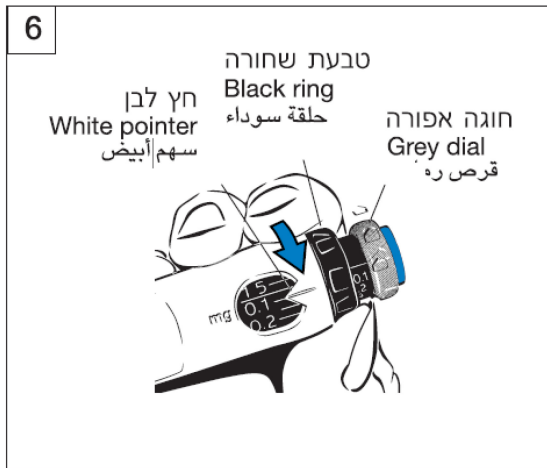


- h. If you use the needle guard, press the black button to release the needle shield (Figure 5d).



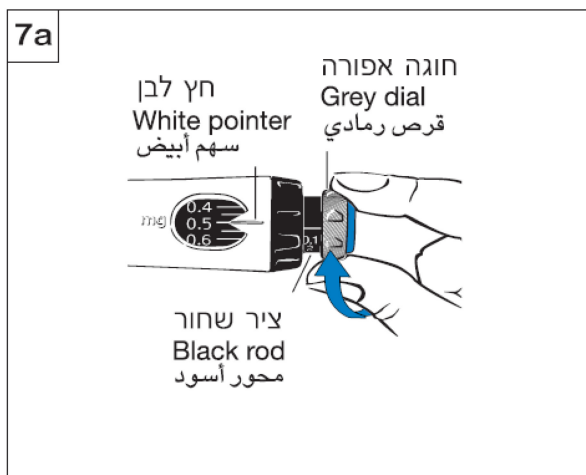
Step 6. Set the Dose

- Use the black ring to set the dose. Be careful not to turn the grey dial while setting the dose.
 - a. Hold the black ring as shown in Figure 6.
 - b. Turn the ring until the white pointer lines up with your prescribed dose. Your doctor or nurse has told you your dose.
 - c. If you turn your dose past the white pointer, just turn the black ring back to the correct dose.
 - d. Once you have set your dose, do not change it unless your doctor or nurse tells you. Note: If you cannot turn the black ring, press the blue injection button until it stops clicking. Then continue to set your dose using the black ring (for more information, see also the ‘Questions and Answers’ section below).

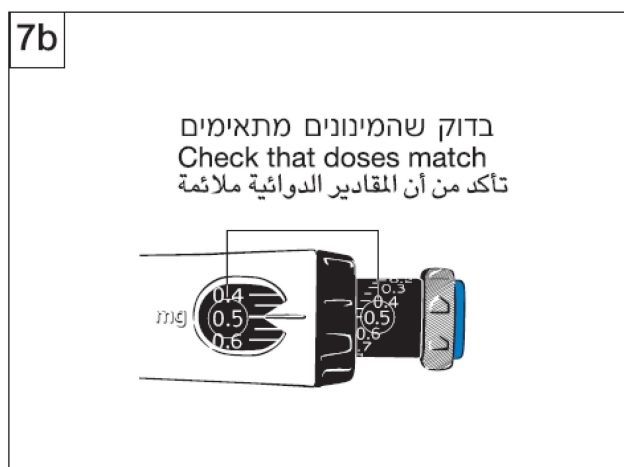


Step 7. Draw Up a Dose

- Turn the grey dial in the direction of the arrow until the clicking stops (Figure 7a).
- Your dose on the black rod (with numbers) should line up with the white pointer.

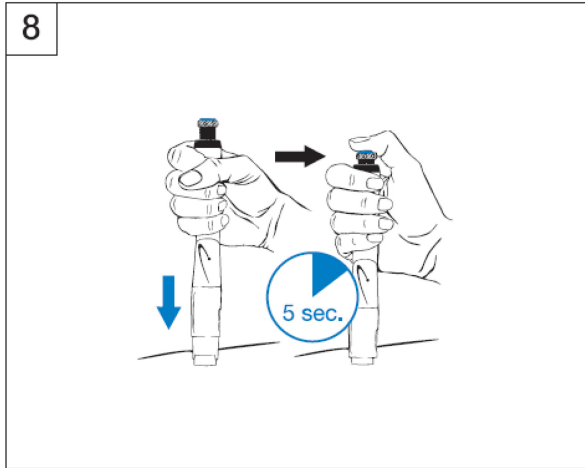


- Check that the dose you set on the black rod (with numbers) is the same as the dose you set in the memory window. Figure 7b shows an example.
- If the doses do not match, make sure you have turned the grey dial in the direction of the arrow until it does not click anymore.



Step 8. Give the injection

- Prepare an injection site as your doctor or nurse has told you.
- Hold the pen over the injection site.
- Push the pen down to insert the needle into the skin.
- Using your thumb, push the blue injection button down until it stops clicking (Figure 8).
- Count 5 seconds before you pull the needle out of the skin. Keep light pressure on the button with your thumb while you count.
- Pull the pen straight out from the skin.



Step 9. Remove the Needle; Cap and Store Your Pen

Step 9a: With needle guard

- Place the outer needle cover into the end of the needle shield (Figure 9a).
- Use the needle cover to push in the needle shield until it locks into place.
- Use the needle cover to unscrew the needle and put it in a proper container for used needles.
- Leave the needle guard on the pen.
- Place the black cap on the needle guard. Store your pen in the refrigerator.



Step 9b: Without needle guard

- Do not touch the needle.
- Carefully cover the needle with the outer needle cover (Figure 9b).
- Use the needle cover to unscrew the needle and put it in a proper container for used needles.
- Place the white cap on the pen. Store your pen in the refrigerator.



Routine Use of GoQuick

1. Pull the black cap from the needle guard or the white cap from the pen.

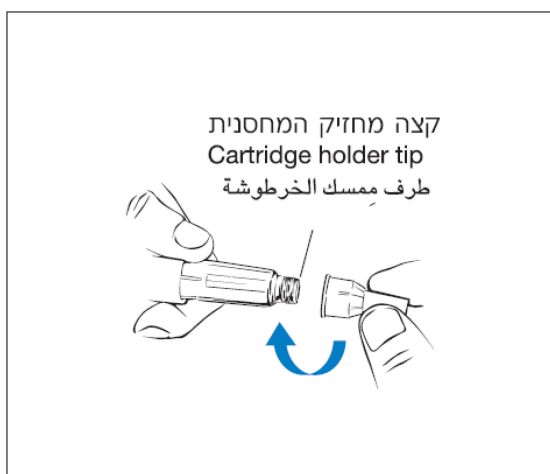


2. **Attach a new needle.**

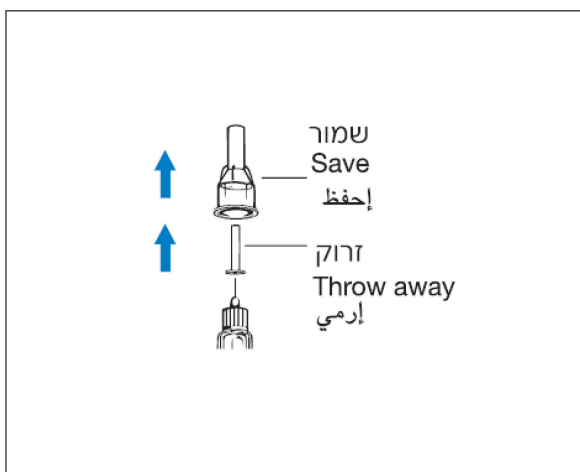
- With needle guard:
 - If the needle shield releases, push it back into place.
 - Attach a new needle to the cartridge holder tip.



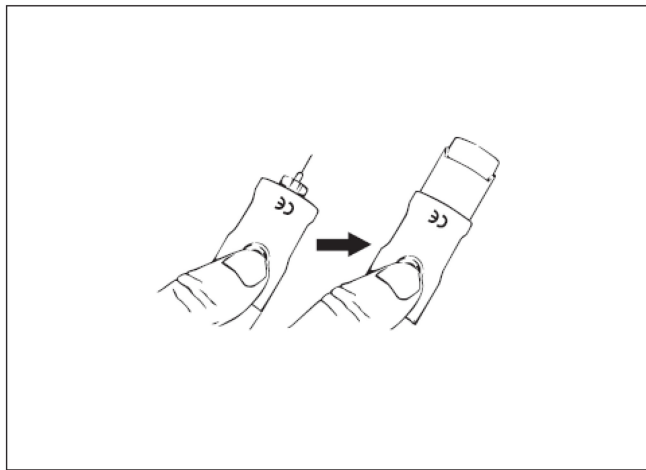
- Without needle guard:
 - Attach a new needle to the cartridge holder tip.



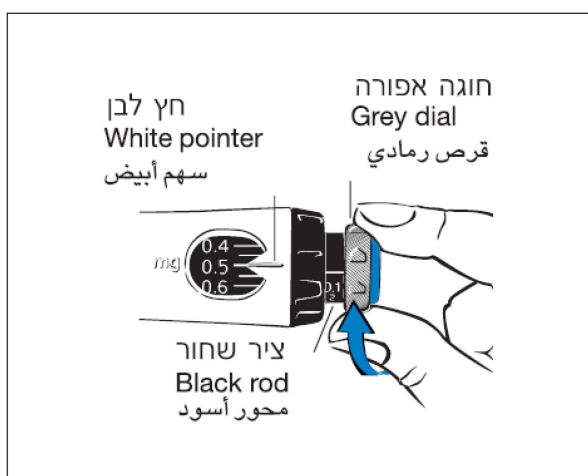
3. Remove both needle covers. Save the outer needle cover.



4. If you use the needle guard, press the black release button to extend the needle shield.

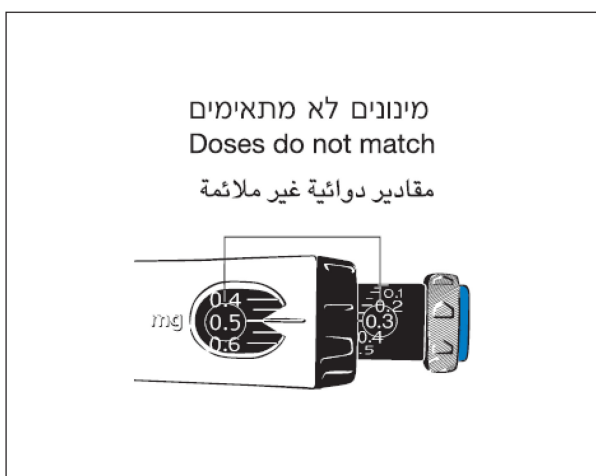


5. To set the dose, turn the grey dial until it stops clicking.



6. Check that the dose you set is the same as the dose in the memory window.

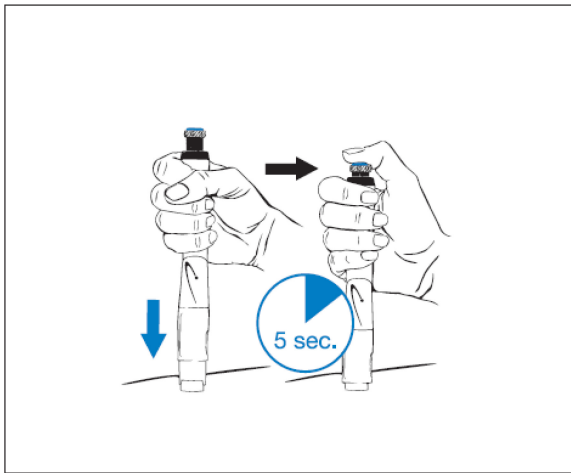
- If you set the dose too low, the pen will not have the full dose of GENOTROPIN®.
- Follow what your doctor or nurse told you to do when the pen does not contain a full dose.



7. Prepare the injection site as your doctor or nurse has told you.

8. Give the injection.

- Push the pen down to insert the needle into the skin.
- Press the blue injection button until it stops clicking.
- Count 5 seconds before you pull the needle out of the skin. Keep light pressure on the button with your thumb while you count.
- Pull the pen straight out from the skin.



9. Remove the needle.

- With needle guard
 - Use the outer needle cover to push in the needle shield until it locks into place.
- Without needle guard
 - Carefully cover the needle with the outer needle cover.
- Use the outer needle cover to unscrew the needle. Throw the needle away in a proper container for used needles.



10. Cap your needle guard or pen and store it in the refrigerator.

FURTHER INFORMATION

Storage

- See the other side of this leaflet for how to store your GoQuick.
- After 4 weeks, throw away the pen even if there is some medicine left.
- Do not freeze GoQuick.
- Do not use your GoQuick after its expiry date.
- Follow your local health and safety laws to throw away your GoQuick pen. Ask your doctor or nurse, if you are not sure.

Handling

- Do not mix the powder and liquid of GoQuick unless a needle is on the pen.
- Do not store your GoQuick with the needle attached. The GENOTROPIN® may leak from the pen and air bubbles may form in the cartridge. Always remove the needle and attach the pen cap or needle guard cap before storing.
- Take care not to drop your GoQuick.
- If you do drop the pen you must perform another prime as described in Step 5 (Priming and Using a New GoQuick Pen). But if any part of your GoQuick is broken or damaged, do not use the pen. Contact your doctor or nurse for another pen.
- Clean the pen and needle guard with a damp cloth. Do not put the pen in water.

Needles

- Use a new needle for each injection.
- Put all used needles in an appropriate “sharps” container in accordance with your local health and safety laws. Ask your doctor or nurse, if you are not sure what to do.
- Do not share your pen or needles.

General

- The numbers and lines on the cartridge holder can help you estimate how much GENOTROPIN® is left in the pen.
- If in Step 6 of routine use the pen does not contain a full dose of GENOTROPIN®, the scale on the black rod (with numbers) indicates the amount of medicine remaining in the pen.
- Patients who are blind or who do not see well should only use GoQuick with the help of someone trained to use the pen.
- Follow your doctor or nurse’s instructions for cleaning your hands and skin when you prepare the medicine and inject it.
- Do not discard your needle guard; to remove it from the pen just twist it off. Save it to use with each new pen.
- If you have questions about how to use GENOTROPIN® GoQuick, ask your doctor or nurse.

Questions and answers

Question

What should I do if I see more than a small drop of liquid on the needle after giving my injection?

Is it a problem if I see air bubbles in the cartridge?

What should I do if I see GENOTROPIN® leaking from the pen?

What should I do if the pen that I am using was not stored in the refrigerator overnight?

What should I do if I can't turn the black ring?

Answer

Next time you give an injection, wait the full 5 seconds before taking out the needle from the skin. If you still see some drops of liquid after you take out the needle, hold it in for a little longer next time.

No, small amounts of air may be present in the cartridge during normal use.

Make sure that the needle has been attached correctly.

Discard the pen and use a new GoQuick pen.

You have probably accidentally turned the grey dial. If you have turned the grey dial, the pen will prevent you from turning the black ring so that your dose does not change during your injection. To release the black ring, press in the blue injection button until

What if my doctor changes my dose when I've already started a pen?

What should I do if I inject the wrong dose?

What if my pen will not prime (for example, if liquid did not appear in step 5g)?

What doses can my pen deliver?

it stops. Note that liquid will come out of the needle. Then continue to set your dose using the black ring.

Set the new dose by turning the black ring.

Call your doctor or nurse immediately and follow their instructions.

Call your doctor or nurse and follow their instructions.

The pen can deliver doses from 0.10 mg to 1.5 mg of GENOTROPIN®. Each click of the black ring changes the dose by 0.05 mg.

Revised in 01/2022 according to MOH guidelines.