

Patient leaflet in accordance with the Pharmacists' Regulations (Medicinal Products) 1986

This medicine can be sold with a physician's prescription only

GATTEX 5mg
Powder for solution for subcutaneous injection

Active ingredient:

Each vial contains 5 mg Teduglutide.

For the list of excipients in the medicinal product, please see section 6: "Additional information".

Read the entire leaflet carefully before you start using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, contact the physician or the pharmacist.

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

In addition to the leaflet, a Patient Safety Information Card is available for Gattex. This card contains important safety information which you must know prior to starting treatment and during the treatment with Gattex and follow it. Read the Patient Safety Information Card and the Patient Leaflet prior to starting treatment with the medicinal product. Keep the card for further reading if required.

1. What is the medicine intended for?

Gattex contains the active substance teduglutide. It improves the absorption of nutrients and fluid from your remaining gastrointestinal tract (gut).

Gattex is used to treat adults, children and adolescents (aged 1 year and above) with Short Bowel Syndrome. Short Bowel Syndrome is a disorder arising from an inability to absorb food nutrients and fluid across the gut. It is often caused by surgical removal of all or part of the small intestine.

No safety and efficacy data is available for children below the age of 1 year.

Therapeutic group: alimentary tract and metabolism products.

2. Before using this medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient or any of the other ingredients that this medicine contains or to tetracyclines.
- If you have or are suspected to have cancer.
- If you have had cancer in the gastrointestinal tract, including liver, gallbladder or bile ducts, and pancreas within the last five years.

Special warnings regarding the use of this medicine

Before taking Gattex, tell your doctor if:

- you have severely decreased liver function. Your doctor will consider this when prescribing this medicine.

- you suffer from certain cardiovascular diseases (affecting the heart and/or blood vessels), such as high blood pressure (hypertension) or cardiac insufficiency. The signs and symptoms include sudden weight gain, face swelling, swollen ankles and/or shortness of breath.
- you have other severe diseases that are not well controlled. Your doctor will consider this when prescribing this medicine.
- you have decreased kidney function. Your doctor may need to give you a lower dose of this medicine.

When starting and while getting treated with Gattex, your doctor may adjust the amount of intravenous fluids or nutrition you receive.

Tests and follow-up:

Before you start treatment with this medicine, your doctor will need to perform a colonoscopy (a procedure to see inside your colon and rectum) to check for the presence of polyps (small abnormal growths) in the intestine and remove them. It is recommended that your doctor performs these examinations once a year during the first 2 years after starting treatment, and then at a minimum of five-year intervals. If polyps are found either before or during your treatment with Gattex, your doctor will decide whether you should continue using this medicine.

Gattex should not be used if a cancer is detected during your colonoscopy.

The doctor will monitor your body fluids and electrolytes as an imbalance may cause fluid overload or dehydration.

Your doctor will take special care and monitor your small bowel function and monitor for signs and symptoms indicating problems with your gallbladder, bile ducts and pancreas.

Children and adolescents

Tests and follow-up:

Before you start treatment with this medicine, if you are at least 12 years of age, you will need to have undergone a recent (within 1 year) colonoscopy (a procedure to see inside your colon and rectum) to check for the presence of polyps (small abnormal growths) and have them removed. This procedure will also be performed if you are under 12 years of age and have unexplained blood in your bowel movements (stools). If polyps are found before your treatment with Gattex, your doctor will decide whether you should use this medicine. Gattex should not be used if a cancer is detected during your colonoscopy. Your doctor will perform further colonoscopies if you continue treatment with Gattex.

The doctor will monitor your body fluids and electrolytes as an imbalance may cause fluid overload or dehydration.

Children below 1 year of age

This medicine should not be used in children under 1 year of age, because there is no experience with Gattex in this age group.

Drug interactions: If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist.

Gattex may affect how other medicines are absorbed from the gut and therefore how well they work. Your doctor may have to change your dose of other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, the use of Gattex is not recommended. If you are pregnant or breast-feeding, think you may be pregnant or are planning to get pregnant ask your doctor, pharmacist or nurse for advice before using this medicine.

Driving and using machines

This medicine may cause you to feel dizzy. Do not drive or use any dangerous machines while using this medicine. As for children, they should be warned about riding bicycles or playing close to the road and the like.

Important information regarding some of the ingredients of the medicine:

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

Caution is needed if you are hypersensitive to tetracycline (see "**Do not use the medicine**" section).

3. How to use the medicine?

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

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

The commonly recommended daily dose is 0.05 mg per kg body weight. The dose will be given in millilitres (ml) of solution.

Your doctor will choose the dose that is right for you depending on your body weight. Your doctor will tell you which dose to inject. If you are not sure, ask your doctor, pharmacist or nurse.

Do not exceed the recommended dose.

Use in children and adolescents

Gattex can be used in children and adolescents (aged 1 year and above). Use this medicine exactly as your doctor has told you.

How to use Gattex

Gattex is injected under the skin (subcutaneously) once daily. The injection can be self-administered or given by another person, for example your doctor, his assistant or your home nurse. **If you, or your carer, are injecting the medicine, you or your carer must receive adequate training by your doctor or nurse.** You will find detailed instructions for injection at the end of this leaflet.

It is strongly recommended that every time you or your child receive a dose of Gattex, the name and lot number of the product are recorded in order to maintain a record of the lots used.

If you have accidentally taken a higher dosage

If you have taken more Gattex than you should, consult your doctor, pharmacist or nurse. If accidentally a child swallows the medicine or self-injects it, immediately contact a doctor or an emergency room and bring the medicine with you.

If you forget to take the medicine

If you forget to inject this medicine (or cannot inject it at your usual time), use it as soon as possible on that day. Never use more than one injection in the same day. Do not inject a double dose to make up for a forgotten dose.

You should continue the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

If you stop taking the medicine

Keep using this medicine for as long as your doctor prescribes it for you. Do not stop using this medicine without consulting your doctor, as a sudden stop can cause changes in your fluid balance.

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

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

4. Side effects

As with any medicine, Gattex can cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Seek immediate medical attention if any of the following side effects occur:

Common side effects (may affect 1-10 people from 100):

- Congestive heart failure. Contact your doctor if you experience tiredness, shortness of breath or swelling of ankles or legs or face swelling.
- Inflammation of the pancreas (pancreatitis). Contact your doctor or the emergency unit if you experience severe stomach ache and fever.
- Intestinal obstruction (blockage of the bowel). Contact your doctor or the emergency unit if you experience severe stomach ache, vomiting and constipation.
- Reduced flow of bile from the gallbladder and/or inflammation of the gallbladder. Contact your doctor or the emergency unit if you experience yellowing of the skin and the whites in the eyes, itching, dark urine and light-coloured stools or pain in the upper right side or middle of the stomach area.

Uncommon side effects (may affect 1-10 people from 1000):

- Fainting. If heart rate and breathing is normal and you awaken fast, speak to your doctor. In other cases, seek help as soon as possible.

Other side effects include:

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

- Respiratory tract infection (any infection of the sinuses, throat, airways or lungs)
- Headache
- Stomach pain
- Bloating stomach
- Feeling sick (nausea)
- Swelling of stoma (an artificial opening for waste removal)
- Vomiting
- Injection site reactions (e.g.: reddening, pain or swelling)

Common side effects (may affect 1-10 people from 100):

- Flu (influenza) or flu-like symptoms
- Decreased appetite
- Swelling of hands and/or feet
- Problems sleeping, anxiety
- Cough, shortness of breath
- Polyps (small abnormal growths) in your large bowel
- Passing gases (flatulence)
- Narrowing or blockage of your pancreatic duct, which may cause inflammation of the pancreas
- Inflammation of the gallbladder

Uncommon side effects (may affect 1-10 people from 1000)

- Polyps (small abnormal growths) in your small bowel

Not known side effects (frequency cannot be estimated from the available data)

- Allergic reaction (hypersensitivity)
- Fluid retention
- Polyps (small abnormal growths) in your stomach

Use in children and adolescents

In general, the side effects in children and adolescents are similar to those seen in adults. The following side effects were seen more frequently in children and adolescents in the clinical study: Fatigue (very common), painful bowel movements (very common), and feeling dizzy or lightheaded (common).

There is no experience in children under 1 year of age.

If a side effect appears, if any side effect gets worse or if you suffer from a side effect not mentioned in the leaflet, you should consult the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” that appears on the homepage of the Ministry of Health’s website (www.health.gov.il) which links to an online form for reporting side effects, or by the following link: <https://sideeffects.health.gov.il/> and by emailing the Registration Holder’s Patient Safety Unit at: drugsafety@neopharmgroup.com

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants to avoid poisoning. Do not induce vomiting without specific instruction from the doctor.
- Do not use the medicine after the expiration date (exp. date) appearing on the packaging. The expiry date refers to the last day of that month.

- **Storage conditions:** store refrigerated 2-8°C. Do not freeze.
- It is possible to store the product below 25°C outside of a refrigerator for up to 3 month period of time (do not exceed expiration date as mentioned on the package).
- Use immediately after reconstitution.
- Prior to use, inspect the solution. Do not use if the solution is cloudy or contains particulate matter.

6. Additional information

• **In addition to the active ingredient, the medicine also contains:**
Mannitol, L-histidine, dibasic sodium phosphate heptahydrate, monobasic sodium phosphate monohydrate.

• **What does the medicine look like and the content of the package:**

The package consists of vials containing white powder.

• **Registration holder name and address:**

Neopharm Ltd., Hashiloach 6, P.O.B 7641, Petach Tikva 49170.



• **Manufacturer name and address:** Shire NPS Pharmaceuticals Inc., 300 Shire Way, Lexington, MA 02421, USA.

Gattex® is a registered trademark of Shire NPS Pharmaceuticals Inc.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 152-48-33962-00

Revised in May 2023 according to MOHs guidelines.

Gattex pow for sol for inj PIL vs 01A

Instructions for preparing and injecting Gattex

Important information:

- Read the Package Leaflet before using Gattex.
- Gattex is for injection under the skin (subcutaneous injection).
- Do not inject Gattex into a vein (intravenously) or muscle (intramuscularly).
- Keep Gattex out of the sight and reach of children.
- Do not use Gattex after the expiry date which is stated on the carton and the vial. The expiry date refers to the last day of that month.
- Store between 2°C to 8°C.
- Do not freeze.
- After reconstitution, the solution should be used immediately.
- Do not use Gattex if you notice that the solution is cloudy or contains particulate matter.
- 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.
- Dispose of all needles and syringes in a sharps disposal container.

Materials provided in the pack:

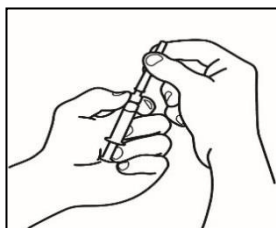
- 1, 5, 6, 10, 30 or 60 vials with 5 mg teduglutide powder.

Materials needed but not included in the pack:

- Water for Injection (WFI)
- Reconstitution needles [size 22G, length 1½" (0.7 x 40 mm)]
- Reconstitution syringe
- 0.5 or 1 ml injection syringes (with scale intervals of 0.02 ml or smaller). **For children, a 0.5 ml (or smaller) injection syringe may be used.**
- Thin injection needles for subcutaneous injection [e.g., size 26G, length 5/8" (0.45 x 16 mm)] or smaller needles for children, as appropriate
- Alcohol wipes
- Alcohol swabs
- A puncture-proof container for safe disposal of the used syringes and needles

NOTE: Before you start, make sure you have a clean work surface and that you have washed your hands before proceeding.

1. Assemble the syringe

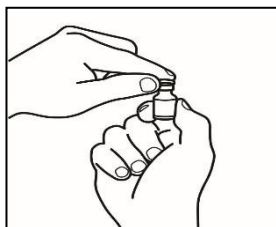


1.1 Attach the reconstitution needle [22G, 1½" (0.7 x 40 mm)] to the reconstitution syringe by screwing it on in a clockwise direction.

1.2 If Water for Injection is taken from a vial, wipe the top with alcohol prior to drawing up the water. Draw up 0.5 ml of Water for Injection into the reconstitution syringe, then re-cap the needle part.

2. Dissolve the powder

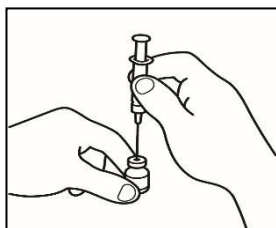
Now you are ready to dissolve the powder with the solvent.



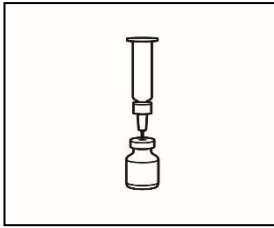
2.1 Remove the green flip-off button from the powder vial, wipe the top with an alcohol wipe and allow to dry. Do not touch the top of the vial.



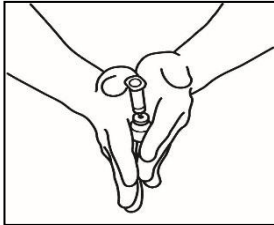
2.2 Uncap the reconstitution needle on the assembled reconstitution syringe (with solvent) without touching the the needle.



2.3 Taking the powder vial, insert the reconstitution needle attached to the assembled reconstitution syringe into the center of the rubber stopper and gently push the plunger all the way down to inject all the solvent into the vial.

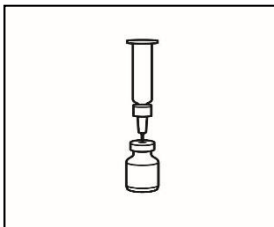


2.4 Leave the reconstitution needle and empty syringe in the vial. Let the vial rest for approximately 30 seconds.



2.5 Gently roll the vial between your palms for about 15 seconds. Then gently turn the vial upside-down once with the reconstitution needle and empty syringe still in the vial.

NOTE: Do not shake the vial. Shaking the vial may produce foam, which makes it difficult to extract the solution from the vial.



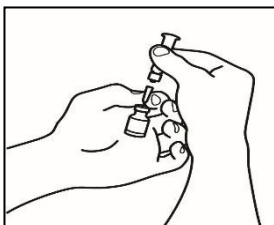
2.6 Let the vial rest for about two minutes.

2.7 Observe the vial for any undissolved powder. If any powder remains, repeat steps 2.5 and 2.6. Do not shake the vial. If there is still some undissolved powder, discard the vial and start the preparation again from the beginning with a new vial.

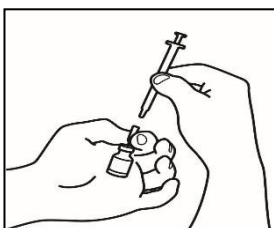
NOTE: The final solution should be clear. If the solution is cloudy or contains particulate matter, do not inject it.

NOTE: Once prepared, the solution should be used immediately.

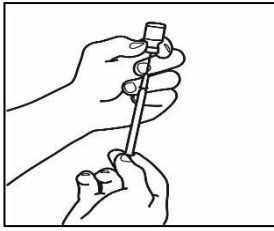
3. Prepare the injection syringe



3.1 Remove the reconstitution syringe from the reconstitution needle which is still in the vial and discard the reconstitution syringe.

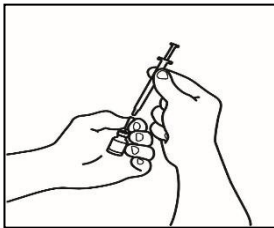


3.2 Take the injection syringe and attach it to the reconstitution needle which is still in the vial.

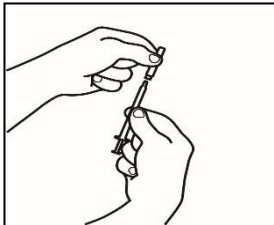


3.3 Turn the vial upside down, slide the tip of the reconstitution needle close to the stopper and allow all the medicine to fill the syringe by pulling the plunger back gently.

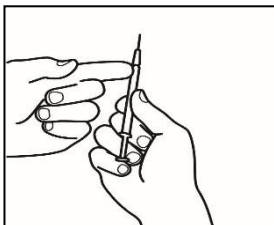
NOTE: If your doctor has told you that you need two vials, prepare a second reconstitution syringe with solvent and a second powder vial as shown in the main steps 1 and 2. Withdraw the solution from the second vial into the same injection syringe by repeating step 3.



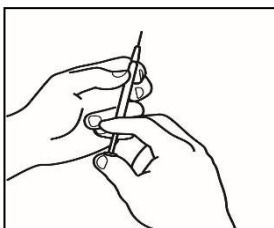
3.4 Remove the injection syringe from reconstitution needle leaving the needle in the vial. Discard the vial and reconstitution needle together into the sharps disposal container.



3.5 Attach the injection needle to the injection syringe without removing the plastic needle.

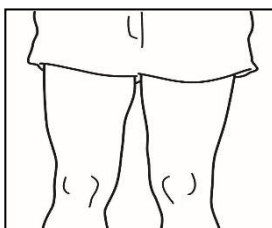
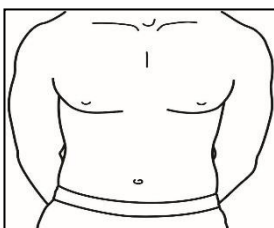


3.6 Check for air bubbles. If air bubbles are present, gently tap the syringe until they rise to the top. Then gently push up the plunger to expel the air.



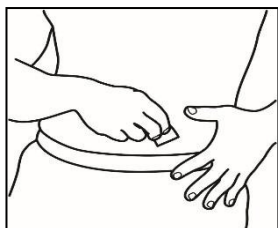
3.7 Your dose in ml has been calculated by your doctor. Expel any excessive volume from the syringe with the needle cap still on until your dose is reached.

4. Inject the solution

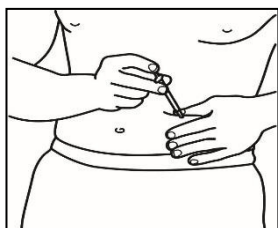


4.1 Find an area on your belly, or if you have pain or hardening of the tissue on your belly, on your thigh where it is easy for you to give the injection (see the diagram).

NOTE: Do not use the same injection area each day - rotate sites (use upper, lower, and left and right side of your belly) to avoid discomfort. Avoid areas that are inflamed, swollen, scarred or covered by a mole, birthmark or other lesion.



4.2 Clean the intended site of injection on your skin with an alcohol swab, using a circular motion. Allow the area to air-dry.



4.3 Remove the plastic cap from the needle of the prepared injection syringe. Gently grasp the cleaned skin at the injection site with one hand. With the other hand, hold the syringe as you would with a pencil. Bend your wrist back and quickly insert the needle at a 45° angle.

4.4 Pull back the plunger slightly. If you see any blood in the syringe, withdraw the needle and replace the needle on the injection syringe with a clean one of the same size. You can still use the medicine that is already in the syringe. Try to inject in another place in the cleaned skin area.

4.5 Inject the medicine slowly by pushing steadily on the plunger until all the medicine is injected and the syringe is empty.

4.6 Pull the needle straight out of the skin and discard the needle and syringe together into the sharps disposal container. A small amount of bleeding may occur. If necessary, press gently on the injection site with an alcohol swab or 2*2 gauze until any bleeding has stopped.

4.7 Dispose all needles and syringes in a sharps disposal container or hard-walled container (for example, a detergent bottle with a lid). This container must be puncture proof (top and sides). If you need a sharps disposal container, please contact your doctor.