**Package leaflet: Information for the user**

**BYANNLI 700 mg prolonged-release suspension for injection in pre-filled syringe**
**BYANNLI 1000 mg prolonged-release suspension for injection in pre-filled syringe**
paliperidone

**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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

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


## 1. What BYANNLI is and what it is used for

BYANNLI contains the active substance paliperidone which belongs to the class of antipsychotic medicines.

BYANNLI is used as a maintenance treatment for the symptoms of schizophrenia in adult patients.

If you have responded well to treatment with paliperidone palmitate injection given once a month or once every three months, your doctor may start treatment with BYANNLI.

Schizophrenia is a disease with “positive” and “negative” symptoms. Positive means an excess of symptoms that are not normally present. For example, a person with schizophrenia may hear voices or see things that are not there (called hallucinations), believe things that are not true (called delusions), or feel unusually suspicious of others. Negative means a lack of behaviours or feelings that are normally present. For example, a person with schizophrenia may appear withdrawn and may not respond at all emotionally or may have trouble speaking in a clear and logical way. People with this disease may also feel depressed, anxious, guilty, or tense.

BYANNLI can help alleviate the symptoms of your disease and reduce the risk of your symptoms coming back.

## 2. What you need to know before you use BYANNLI

**Do not use BYANNLI**
- if you are allergic to paliperidone or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to risperidone.

**Warnings and precautions**
Talk to your doctor, pharmacist or nurse before using BYANNLI.

This medicine has not been studied in elderly patients with dementia. However, elderly patients with dementia, who are treated with other similar types of medicine, may have an increased risk of stroke or death (see section 4).

All medicines have side effects and some of the side effects of this medicine can worsen the symptoms of other medical conditions. For that reason, it is important to discuss with your doctor any of the following conditions which can potentially worsen during treatment with this medicine:

- if you have Parkinson's disease
- if you have a type of dementia called "Lewy body dementia"
- if you have ever been diagnosed with a condition whose symptoms include high temperature and muscle stiffness (also known as Neuroleptic Malignant Syndrome)
- if you have ever experienced twitching or jerking movements that you cannot control in your face, tongue, or other parts of your body (Tardive Dyskinesia)
- if you know that you have had low levels of white blood cells in the past (which may or may not have been caused by other medicines)
- if you are diabetic or prone to diabetes
- if you have had breast cancer or a tumour in the pituitary gland in your brain
- if you have a heart disease or heart disease treatment that makes you prone to low blood pressure
- if you have low blood pressure when you stand up or sit up suddenly
- if you have a history of seizures
- if you have kidney problems
- if you have liver problems
- if you have prolonged and/or painful erection
- if you have problems with controlling body temperature or overheating
- if you have an abnormally high level of the hormone prolactin in your blood or if you have a possible prolactin-dependent tumour
- if you or someone else in your family has a history of blood clots, as antipsychotics have been associated with formation of blood clots.

If you have any of these conditions, please talk to your doctor as he/she may want to adjust your dose or monitor you for a while.

As dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood has been seen very rarely with patients taking this medicine, your doctor may check your white blood cell counts.

Even if you have previously tolerated oral paliperidone or risperidone, rarely allergic reactions occur after receiving injections of BYANNLI. Seek medical attention right away if you experience a rash, swelling of your throat, itching, or problems breathing as these may be signs of a serious allergic reaction.

This medicine may cause you to gain or loose weight. Significant changes in weight may be bad for your health. Your doctor should regularly measure your body weight.

As diabetes mellitus or worsening of pre-existing diabetes mellitus have been seen with patients taking this medicine, your doctor should check for signs of high blood sugar. In patients with pre-existing diabetes mellitus blood glucose should be monitored regularly.

Since this medicine may reduce your urge to vomit, there is a chance that it may mask the body's normal response to ingestion of toxic substances or other medical conditions.

**Cataract operations**
If you are planning to have an operation on your eye, make sure you tell your eye doctor that you are taking this medicine. This is because during a cataract operation on the eye for cloudiness of the lens:

- the pupil (the black circle in the middle of your eye) may not increase in size as needed

- the iris (the coloured part of the eye) may become floppy during surgery and that may lead to eye damage.

**Children and adolescents**
Do not use this medicine in children and adolescents under 18 years of age. It is not known if it is safe and effective in these patients.

**Other medicines and BYANNLI**
Tell your doctor if you are taking, have recently taken or might take any other medicines.

Taking this medicine with carbamazepine (an anti-epileptic and mood stabiliser) may require a change to your dose of this medicine.

Since this medicine works primarily in the brain, using other medicines that work in the brain can cause an exaggeration of side effects such as sleepiness or other effects on the brain such as other psychiatric medicines, opioids, antihistamines and sleep medicines.

Tell your doctor if you take this medicine while you are also taking oral risperidone or paliperidone for extended periods of time. You may require a change to your dose of BYANNLI.

Since this medicine can lower blood pressure, care should be taken when this medicine is used with other medicines that lower blood pressure.

This medicine can reduce the effect of medicines against Parkinson's disease and restless legs syndrome (e.g., levodopa).

This medicine may cause an electrocardiogram (ECG) abnormality demonstrating a long time for an electrical impulse to travel through a certain part of the heart (known as "QT prolongation"). Other medicines that have this effect include some medicines used to treat the rhythm of the heart or to treat infection, and other antipsychotics.

If you have a history of seizures, this medicine may increase your risk of experiencing them. Other medicines that have this effect include some medicines used to treat depression or to treat infection, and other antipsychotics.

BYANNLI should be used with caution with medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate).

**BYANNLI with alcohol**
Alcohol should be avoided.

**Pregnancy and breast-feeding**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

*Women of childbearing potential*
A single dose of this medicine is expected to remain within the body for up to 4 years, which may be a risk for the baby. BYANNLI should, therefore, only be used in women planning to have a baby if clearly necessary.

*Pregnancy*
You should not use this medicine during pregnancy unless this has been discussed with your doctor. The following symptoms may occur in newborn babies of mothers that have used paliperidone in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. Newborns should be monitored carefully and if your baby develops any of these symptoms seek medical attention for your baby.

*Breast-feeding*
This medicine can pass from mother to baby through breast milk. It may harm the baby, even a long time after the latest dose. Therefore, you should not breast-feed if you are using, or have used, this medicine in the past 4 years.

**Driving and using machines**
Dizziness, extreme tiredness and vision problems may occur during treatment with this medicine (see section 4). This should be considered in cases where full alertness is required, e.g., when driving a car or handling machines.

**BYANNLI 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 BYANNLI

This medicine is administered by your doctor or other healthcare professional. Your doctor will tell you when you need your next injection. It is important not to miss your scheduled dose. If you cannot keep your appointment, make sure you call right away so another appointment can be made as soon as possible.

You will receive an injection of BYANNLI in the buttocks once every 6 months.

Depending on your symptoms, your doctor may increase or decrease the amount of medicine you receive at the time of your next scheduled injection.

Patients with kidney problems
If you have mild kidney problems your doctor will determine if BYANNLI is appropriate based on the dose of 1-monthly or 3-monthly paliperidone palmitate injectable that you have been receiving. The 1000 mg dose of BYANNLI is not recommended.
If you have moderate or severe kidney problems this medicine should not be used.

Elderly
Your doctor may adjust your dose of this medicine if your kidney function is reduced.

**If you are given more BYANNLI than needed**
This medicine will be given to you under medical supervision; it is, therefore, unlikely that you will be given too much.

Patients who have been given too much paliperidone may experience the following symptoms: drowsiness or sedation, fast heart rate, low blood pressure, an abnormal electrocardiogram (electrical tracing of the heart), or slow or abnormal movements of the face, body, arms or legs.

**If you stop using BYANNLI**
If you stop receiving your injections, your symptoms of schizophrenia may get worse. You should not stop using this medicine unless told to do so by your doctor.

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

## 4. Possible side effects

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

**Serious side effects**
If you get any of the following serious side effects, you may need immediate medical treatment. Tell your doctor or go to the nearest hospital straight away:

- Blood clots in the veins, especially in the legs. This is rare (may affect up to 1 in 1000 people). Symptoms include:
    - swelling, pain, and redness in the leg – "deep vein thrombosis"
    - chest pain and difficulty breathing caused by blood clots that travelled through blood vessels to the lungs – "pulmonary embolism".
- Signs of a stroke, the frequency is not known (cannot be estimated from the available data). Symptoms include:
    - sudden change in your mental state
    - sudden weakness or numbness of your face, arms or legs, especially on one side, or slurred speech, even for a short period of time.
- Neuroleptic malignant syndrome. This is rare (may affect up to 1 in 1000 people). Symptoms include:
    - Fever, muscle stiffness, sweating or a lowered level of consciousness.
- Prolonged erection, which may be painful (priapism). This is rare (may affect up to 1 in 1000 people).
- Twitching or jerking rhythmic movements that you cannot control in your tongue, mouth and face or other parts of your body (Tardive Dyskinesia). This is uncommon (may affect up to 1 in 100 people).
- Severe allergic reaction (anaphylactic reaction), the frequency is not known (cannot be estimated from the available data). Symptoms include:
    - fever,
    - swollen mouth, face, lip or tongue,
    - shortness of breath,
    - itching, skin rash and sometimes drop in blood pressure.

Even if you have previously tolerated oral risperidone or oral paliperidone, rarely allergic reactions occur after receiving injections of paliperidone.

- Floppy iris syndrome, when the iris (the coloured part of the eye) become floppy during eye cataract surgery. This may lead to eye damage (see also '*Cataract operations*' in section 2). The frequency is not known (cannot be estimated from the available data).
- Stevens-Johnson syndrome or toxic epidermal necrolysis. Severe or life-threatening rash with blisters and peeling skin that may start in and around the mouth, nose, eyes and genitals and spread to other areas of the body. The frequencies are not known (cannot be estimated from the available data).

Tell your doctor straight away or go to the nearest hospital immediately if you notice any of the serious side effects above.

- Agranulocytosis, dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood. The frequency of this is not known (cannot be estimated from the available data).

**Other side effects**

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

- difficulty falling or staying asleep.

**Common side effects: may affect up to 1 in 10 people**

- common cold symptoms, urinary tract infection, feeling like you have the flu.
- BYANNLI can raise your levels of a hormone called "prolactin" found on a blood test (which may or may not cause symptoms). When symptoms of high prolactin occur, they may include: (in men) breast swelling, difficulty in getting or maintaining erections, or other sexual dysfunction; (in women) breast discomfort, missed menstrual periods, or other problems with your cycle.

- high blood sugar, weight gain, weight loss, decreased appetite.
- irritability, depression, anxiety.
- parkinsonism: This condition may include slow or impaired movement, sensation of stiffness or tightness of the muscles (making your movements jerky), and sometimes even a sensation of movement "freezing up" and then restarting. Other signs of parkinsonism include a slow shuffling walk, a tremor while at rest, increased saliva and/or drooling, and a loss of expression on the face.
- feeling restless, sleepy, or less alert.
- dystonia: This is a condition involving slow or sustained involuntary contraction of muscles. While it can involve any part of the body (and may result in abnormal posture), dystonia often involves muscles of the face, including abnormal movements of the eyes, mouth, tongue or jaw.
- dizziness.
- dyskinesia: This is a condition involving involuntary muscle movements, and can include repetitive, spastic or writhing movements, or twitching.
- tremor (shaking).
- headache.
- rapid heart rate.
- high blood pressure.
- cough, stuffy nose.
- abdominal pain, vomiting, nausea, constipation, diarrhoea, indigestion, toothache.
- increased liver transaminases in your blood.
- bone or muscle ache, back pain, joint pain.
- loss of menstrual periods.
- fever, weakness, fatigue (tiredness).
- a reaction at the injection site, including itching, pain or swelling.

**Uncommon side effects: may affect up to 1 in 100 people**
- pneumonia, infection of the chest (bronchitis), infection of the breathing passages, sinus infection, bladder infection, ear infection, tonsillitis, fungal infection of the nails, infection of the skin.
- white blood cell count decreased.
- anaemia.
- allergic reaction.
- diabetes or worsening of diabetes, increased insulin (a hormone that controls blood sugar levels) in your blood.
- increased appetite.
- loss of appetite resulting in malnutrition and low body weight.
- high blood triglycerides (a fat), increased cholesterol in your blood.
- sleep disorder, elated mood (mania), decreased sexual drive, nervousness, nightmares.
- fainting, a restless urge to move parts of your body, dizziness upon standing, disturbance in attention, problems with speech, loss or abnormal sense of taste, reduced sensation of skin to pain and touch, a sensation of tingling, pricking, or numbness of skin.
- blurry vision, eye infection or "pink eye", dry eye.
- sensation of spinning (vertigo), ringing in the ears, ear pain.
- an interruption in conduction between the upper and lower parts of the heart, abnormal electrical conduction of the heart, prolongation of the QT interval from your heart, rapid heartbeat upon standing, slow heart rate, abnormal electrical tracing of the heart (electrocardiogram or ECG), a fluttering or pounding feeling in your chest (palpitations).
- low blood pressure, low blood pressure upon standing (consequently, some people taking this medicine may feel faint, dizzy, or may pass out when they stand up or sit up suddenly).
- shortness of breath, sore throat, nosebleeds.
- abdominal discomfort, stomach or intestinal infection, difficulty swallowing, dry mouth, excessive passing of gas or wind.
- increased GGT (a liver enzyme called gamma-glutamyltransferase) in your blood, increased liver enzymes in your blood.

- hives (or “nettle rash”), itching, rash, hair loss, eczema, dry skin, skin redness, acne, abscess under the skin, flaky, itchy scalp or skin.
- an increase of CPK (creatine phosphokinase), an enzyme in your blood.
- muscle spasms, joint stiffness, muscle weakness.
- incontinence (lack of control) of urine, frequent passing of urine, pain when passing urine.
- erectile dysfunction, ejaculation disorder, missed menstrual periods or other problems with your cycle (females), development of breasts in men, sexual dysfunction, breast pain, leakage of milk from the breasts.
- swelling of the face, mouth, eyes, or lips, swelling of the body, arms, or legs.
- an increase in body temperature.
- a change in the way you walk.
- chest pain, chest discomfort, feeling unwell.
- hardening of the skin.
- fall.

**Rare side effects: may affect up to 1 in 1000 people**

- eye infection.
- skin inflammation caused by mites.
- increase in eosinophils (a type of white blood cell) in your blood.
- decrease in platelets (blood cells that help you stop bleeding).
- inappropriate secretion of a hormone that controls urine volume.
- sugar in the urine.
- life-threatening complications of uncontrolled diabetes.
- low blood sugar.
- excessive drinking of water.
- confusion.
- not moving or responding while awake (catatonia).
- sleep walking.
- lack of emotion.
- inability to reach orgasm.
- unresponsive to stimuli, loss of consciousness, low level of consciousness, convulsion (fits), balance disorder.
- abnormal coordination.
- glaucoma (increased pressure within the eyeball).
- problems with movement of your eyes, eye rolling, oversensitivity of the eyes to light, increased tears, redness of the eyes.
- head shaking that you cannot control.
- atrial fibrillation (an abnormal heart rhythm), irregular heartbeat.
- flushing.
- trouble breathing during sleep (sleep apnoea).
- lung congestion, congestion of breathing passages.
- crackly lung sounds.
- wheezing.
- inflammation of the pancreas,
- swollen tongue,
- stool incontinence, very hard stool, a blockage in the bowels.
- chapped lips.
- rash on skin related to drug, thickening of skin, dandruff.
- joint swelling.
- breakdown of muscle tissue (“rhabdomyolysis”).
- inability to pass urine.
- breast discomfort, enlargement of the glands in your breasts, breast enlargement.
- vaginal discharge.
- very low body temperature, chills, feeling thirsty.

- symptoms of drug withdrawal.
- accumulation of pus caused by infection at injection site, deep skin infection, a cyst at the injection site, bruising at injection site.

**Not known: frequency cannot be estimated from the available data**
- dangerously excessive intake of water.
- sleep-related eating disorder.
- coma due to uncontrolled diabetes.
- fast, shallow breathing, pneumonia caused by inhaling food, voice disorder.
- decreased oxygen in parts of your body (because of decreased blood flow).
- lack of bowel movement that causes blockage.
- yellowing of the skin and the eyes (jaundice).
- skin discolouration.
- abnormal posture.
- newborn babies born to mothers who have taken BYANNLI during pregnancy may experience side effects of the medicine and/or withdrawal symptoms, such as irritability, slow, or sustained muscle contractions, shaking, sleepiness, breathing, or feeding problems.
- a decrease in body temperature.
- dead skin cells at injection site, an ulcer at injection site.

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store BYANNLI

Keep this medicine out of the sight and reach of children.

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

This medicine does not require any special temperature storage conditions.

Ship and store in a horizontal position. See arrows on product carton for proper orientation.

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 to protect the environment.

## 6. Contents of the pack and other information

**What BYANNLI contains**
The active substance is paliperidone.
Each BYANNLI 700 mg pre-filled syringe contains 1 092 mg paliperidone palmitate equivalent to 700 mg paliperidone in 3.5 mL.
Each BYANNLI 1000 mg pre-filled syringe contains 1 560 mg paliperidone palmitate equivalent to 1000 mg paliperidone in 5 mL.

The other ingredients are:
Polysorbate 20
Polyethylene glycol 4000
Citric acid monohydrate

Sodium dihydrogen phosphate monohydrate
Sodium hydroxide (for pH adjustment)
Water for injections

**What BYANNLI looks like and contents of the pack**
BYANNLI is a white to off-white prolonged-release suspension for injection in a pre-filled syringe. pH is approximately 7.0. The doctor or nurse will shake the syringe very fast to resuspend the suspension before it is given as an injection.

Each pack contains 1 pre-filled syringe and 1 needle.

**Marketing Authorisation Holder**
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HP12 4EG
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**Manufacturer**
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**For information in large print, tape, CD or Braille, telephone 0800 7318450.**

**This leaflet was last revised in April 2026.**

***Information intended for healthcare professionals***

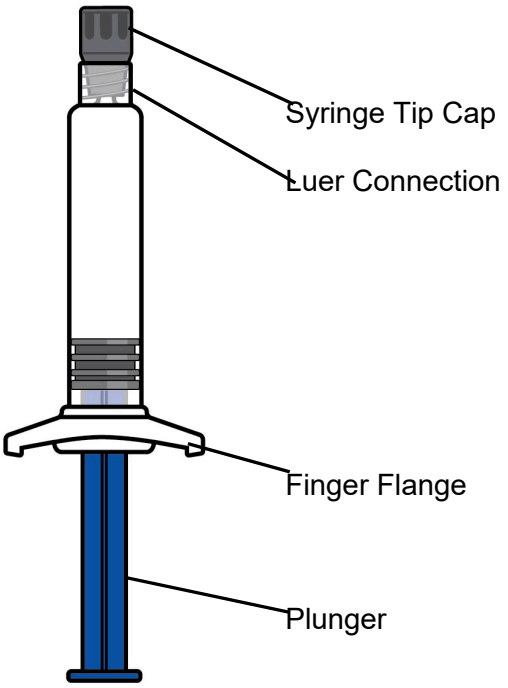
The following information is intended for healthcare professionals only and should be read by the healthcare professional in conjunction with the full prescribing information (Summary of Product Characteristics).

**Important safety summary**

| | |
|---|---|
| | Shake syringe with the syringe tip cap pointing up VERY FAST for at least 15 seconds, rest briefly, then shake again for 15 seconds. |
| **Shipping and storing**<br> | Shipping and storing the carton in a horizontal orientation improves the resuspendability of this highly concentrated product. |
| **Preparation** | BYANNLI (6-month paliperidone palmitate extended-release injectable suspension) requires longer and faster shaking than 1 month paliperidone palmitate extended-release injectable suspension.<br><br>BYANNLI should be administered by a healthcare professional as a single injection.<br><br>- Do not divide dose into multiple injections.<br>BYANNLI is intended for gluteal intramuscular use only.<br><br>- Inject slowly, deep into the muscle taking care to avoid injection into a blood vessel. |
| **Dosing** | Administer BYANNLI once every 6 months. |
| **Thin wall safety needle** | It is important to only use the thin wall safety needle (1½ inch, 20 gauge 0.9 mm × 38 mm) provided in the kit. It is designed to be used only with BYANNLI. |

**Dose pack contents**

**Prefilled Syringe**




**Thin wall safety needle**

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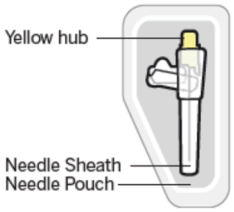
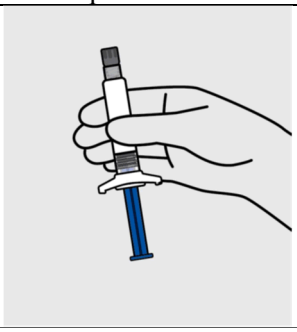
**20G × 1½"**
**Only use the needle included in this kit**




**Thin Wall Safety Needle**

**1. Prepare for the injection.**
This highly concentrated product requires specific steps to resuspend.

Always hold the syringe with the tip cap pointing up.

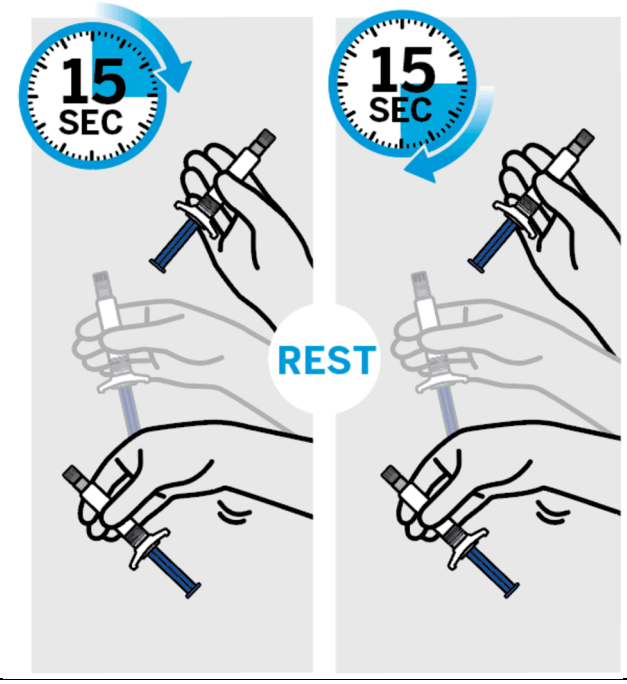


To ensure complete resuspension shake syringe with:

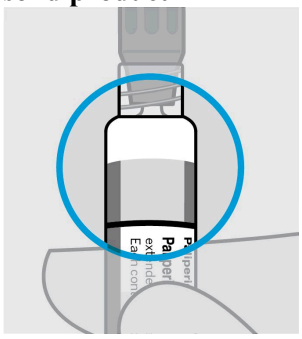
- Short VERY FAST up and down motion
- Loose wrist

Shake syringe VERY FAST for at least 15 seconds, rest briefly, then shake again for 15 seconds.

**If more than <u>5 minutes</u> pass before injection, shake the syringe VERY FAST with the tip cap pointing up** again for at least 30 seconds to resuspend the medication.




**Check suspension for solid product**



**Mixed well**

- Uniform, thick and milky white
- It is normal to see air bubbles

**Not mixed well**

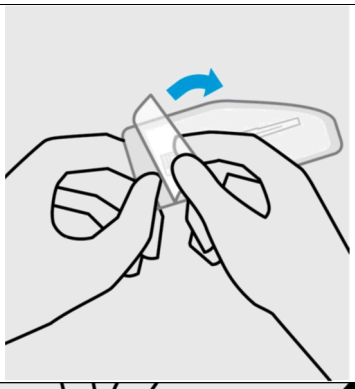
**STOP**

- Solid product on the sides and top of syringe
- Uneven mix
- Thin liquid

**The product may clog.** If this happens, shake the syringe with the syringe tip cap pointing up VERY FAST for at least 15 seconds, rest, then shake again for 15 seconds.

**Open needle pouch**

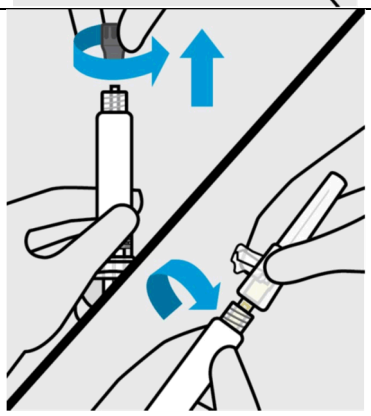
Peel off the pouch cover.
Place pouch with the needle inside on a clean surface.



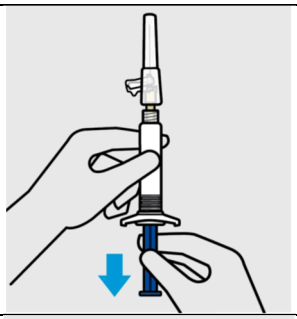
**Remove syringe tip cap and attach needle**

1. Hold the syringe with the tip cap pointing up.
2. Twist and pull the cap off.
3. Attach the safety needle to the syringe using a gentle twisting motion to avoid needle hub cracks or damage. Always check for signs of damage or leakage prior to administration.

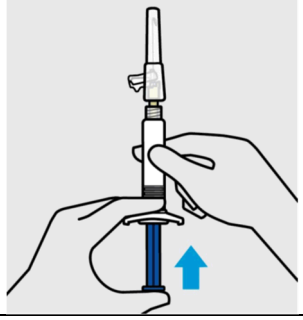
**Only use the needle included in this kit.**



1. Pull back plunger
2. Hold the syringe upright.
3. Gently pull back the plunger to clear the syringe tip of any solid product. This will make pressing the plunger easier during the injection.

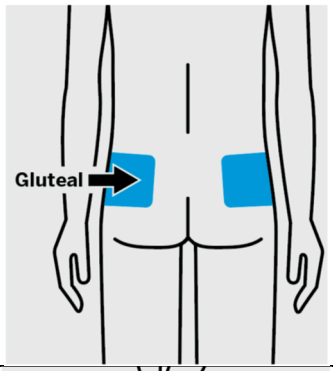


**Remove air bubbles**
Press the plunger carefully until a drop of liquid comes out of the needle tip.



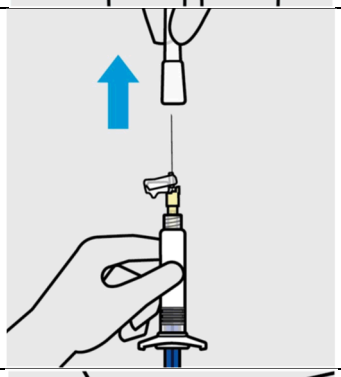
**2. Slowly inject entire content and confirm**

Select and clean an upper-outer quadrant gluteal injection site
**Do not** administer by any other route.
Wipe the injection site with an alcohol swab and allow it to dry.
**Do not touch**, fan or blow the injection site after you have cleaned it.




**Remove needle sheath**

Pull the needle sheath away from the needle in a straight motion.
**Do not** twist the sheath, as this may loosen the needle from the syringe.



**Slowly inject and confirm**

Use slow, firm consistent pressure to press the plunger **completely**. This should take approximately 30-60 seconds.
**Continue to press the plunger if you feel resistance. This is normal.**

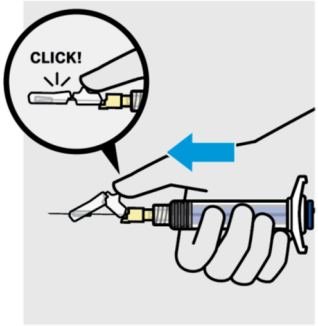
**While the needle is in the muscle, confirm that the entire content of the syringe has been injected.**

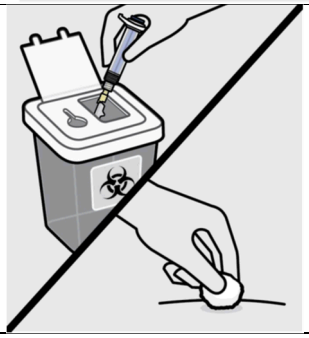
Remove needle from the muscle.

**3. After the injection**

**Secure needle**

After the injection is compete, use your thumb or a flat surface to secure the needle in the safety device.
The needle is secure when you hear a “click” sound.




**Dispose of properly and check injection site**

Dispose of the syringe in an approved sharps container.
There may be a small amount of blood or liquid at the injection site. Hold pressure over the skin with a cotton ball or gauze pad until any bleeding stops.
Do not rub the injection site.
If needed, cover injection site with a bandage.