PACKAGE LEAFLET

Package leaflet: Information for the user

Sperizak 25 mg powder and solvent for prolonged-release suspension for injection
Sperizak 37.5 mg powder and solvent for prolonged-release suspension for injection
Sperizak 50 mg powder and solvent for prolonged-release suspension for injection

risperidone

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sperizak is and what it is used for

Sperizak belongs to a group of medicines called 'antipsychotics'.

Sperizak is used to maintain the treatment of schizophrenia, where you may see, hear or feel things that are not there, believe things that are not true or feel unusually suspicious or confused.

Sperizak is intended for patients who are currently treated with oral (e.g. tablets, capsules) antipsychotics.

Sperizak can help alleviate the symptoms of your disease and stop your symptoms from coming back.

2. What you need to know before you use Sperizak

You should not be given Sperizak
- if you are allergic to risperidone or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
If you have never taken any form of risperidone, you should begin with oral risperidone before beginning treatment with Sperizak.

Talk to your doctor or pharmacist before you are given Sperizak if:
- you have a heart problem. Examples include an irregular heart rhythm or if you are prone to low blood pressure or if you are using medicines for your blood pressure. Sperizak may cause low blood pressure. Your dose may need to be adjusted.
- you know of any factors which would favour you having a stroke, such as high blood pressure, cardiovascular disorder or circulation disorders of the brain.
- you have ever experienced involuntary movements of the tongue, mouth and face.

- you have ever had a condition whose symptoms include high temperature, muscle stiffness, sweating or a lowered level of consciousness (also known as Neuroleptic Malignant Syndrome).
- you have Parkinson's disease or dementia.
- 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).
- you are diabetic.
- you have epilepsy.
- you are a man and have ever had a prolonged or painful erection.
- you have difficulty controlling body temperature or overheating.
- you have kidney problems.
- you have liver problems.
- you have an abnormally high level of the hormone prolactin in your blood or if you have a possible prolactin-dependent tumour.
- you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using oral risperidone or Sperizak.

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 using risperidone prolonged-release suspension, your doctor may check your white blood cell counts.

Even if you have previously tolerated oral risperidone, rarely allergic reactions occur after receiving injections of risperidone prolonged-release suspension. 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.

Sperizak may cause you to gain weight. Significant weight gain may adversely affect 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 oral risperidone, your doctor should check for signs of high blood sugar. In patients with pre-existing diabetes mellitus blood glucose should be monitored regularly.

Sperizak commonly raises levels of a hormone called "prolactin". This may cause side effects such as menstrual disorders or fertility problems in women, breast swelling in men (see section 4 "Possible side effects"). If such side effects occur, evaluation of the prolactin level in the blood is recommended.

During an operation on the eye for cloudiness of the lens (cataract), the pupil (the black circle in the middle of your eye) may not increase in size as needed. Also, the iris (the coloured part of the eye) may become floppy during surgery and that may lead to eye damage. If you are planning to have an operation on your eye, make sure you tell your eye doctor that you are using this medicine.

Elderly people with dementia
Sperizak is not for use in elderly people with dementia.

Medical treatment should be sought straight away if you or your caregiver notice a sudden change in your mental state or sudden weakness or numbness of your face, arms or legs, especially on one side, or slurred speech, even for a short period of time. These may be signs of a stroke.

People with kidney or liver problems
Although oral risperidone has been studied, risperidone prolonged-release suspension has not been studied in patients with kidney or liver problems. Sperizak should be administered with caution in this patient group.

Children and adolescents
Do not give this medicine to children and adolescents below 18 years old.

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

It is especially important to talk to your doctor or pharmacist if you are taking any of the following:
- Medicines that work on your brain to help you calm down (benzodiazepines) or some medicines for pain (opiates), medicines for allergy (some antihistamines), as risperidone may increase the sedative effect of all of these
- Medicines that may change the electrical activity of your heart, such as medicines for malaria, heart rhythm problems, allergies (antihistamines), some antidepressants or other medicines for mental problems
- Medicines that cause a slow heartbeat
- Medicines that cause low blood potassium (such as certain diuretics)
- Medicines for Parkinson's disease (such as levodopa)
- Medicines that increase the activity of the central nervous system (psychostimulants, such as methylphenidate)
- Medicines to treat raised blood pressure. Sperizak can lower blood pressure.
- Water tablets (diuretics) used for heart problems or swelling of parts of your body due to a build-up of too much fluid (such as furosemide or chlorothiazide). Sperizak taken by itself or with furosemide may have an increased risk of stroke or death in elderly people with dementia.

The following medicines may reduce the effect of risperidone:
- Rifampicin (a medicine for treating some infections)
- Carbamazepine, phenytoin (medicines for epilepsy)
- Phenobarbital

If you start or stop taking such medicines, you may need a different dose of risperidone.

The following medicines may increase the effect of risperidone:
- Quinidine (used for certain types of heart disease)
- Antidepressants such as paroxetine, fluoxetines, tricyclic antidepressants
- Medicines known as beta-blockers (used to treat high blood pressure)
- Phenothiazines (such as medicines used to treat psychosis or to calm down)
- Cimetidine, ranitidine (blockers of the acidity of stomach)
- Itraconazole and ketoconazole (medicines for treating fungal infections)
- Certain medicines used in the treatment of HIV/AIDS, such as ritonavir
- Verapamil, a medicine used to treat high blood pressure and/or abnormal heart rhythm
- Sertraline and fluvoxamine, medicines used to treat depression and other psychiatric disorders

If you start or stop taking such medicines, you may need a different dose of risperidone.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before you are given Sperizak.

Sperizak with food, drink and alcohol
You should avoid drinking alcohol when using Sperizak.

Pregnancy, breast-feeding and fertility
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 using this medicine. Your doctor will decide if you can use it.

The following symptoms may occur in newborn babies of mothers that have used Sperizak in the last trimester (last three months of their pregnancy): shaking, muscle stiffness, and/or weakness,

sleepiness, agitation, breathing problems and difficulty in feeding. If your baby develops any of these symptoms, you may need to contact your doctor.

Sperizak can raise your levels of a hormone called "prolactin" that may impact fertility (see section 4 “Possible side effects”).

Driving and using machines
Dizziness, tiredness and vision problems may occur during treatment with Sperizak. Do not drive or use any tools or machines without talking to your doctor first.

Sperizak contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per mL of reconstituted suspension, that is to say essentially ‘sodium-free’.

3. How to use Sperizak

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is as follows:

Starting dose
If your daily dose of oral (e.g. tablets) risperidone was 4 mg or less for the last two weeks, your starting dose should be 25 mg Sperizak.
If your daily dose of oral (e.g. tablets) risperidone was more than 4 mg for the last two weeks, you may be given 37.5 mg Sperizak as a starting dose.

If you are currently treated with other oral antipsychotics than risperidone, your starting dose of Sperizak will depend on your current treatment. Your doctor will choose Sperizak 25 mg or 37.5 mg.

Your doctor will decide on the dose of Sperizak that is right for you.

Maintenance dose
The recommended dose is 25 mg every two weeks as an injection.
A higher dose of 37.5 or 50 mg may be necessary. Your doctor will decide on the dose of Sperizak that is right for you.
Your doctor may prescribe oral risperidone for the first three weeks following your first injection.

Sperizak is given as an intramuscular (IM) injection either in the arm or buttock every two weeks, administered by a healthcare professional. Injections should be alternated between the right and left sides and should not be given intravenously.

If you are given more Sperizak than you should
See a doctor right away.
People who have been given more risperidone prolonged-release suspension than they should have experienced the following symptoms: sleepiness, tiredness, abnormal body movements, problems with standing and walking, dizziness from low blood pressure and abnormal heartbeats. Cases of abnormal electrical conduction in the heart and convulsion have been reported.

If you stop using Sperizak
You will lose the effects of the medicine. You should not stop this medicine unless told to do so by your doctor, as your symptoms may return. Be sure not to miss your appointments when you are supposed to receive your injections every two weeks. If you cannot keep your appointment, be sure to contact your doctor right away to discuss another date when you can come in for your injection.

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.

Tell your doctor immediately if you experience any of the following uncommon side effects (may affect up to 1 in 100 people):
- Have dementia and experience a sudden change in your mental state or sudden weakness or numbness of your face, arms or legs, especially on one side, or slurred speech, even for a short period of time. These may be signs of a stroke.
- Experience tardive dyskinesia (twitching or jerking movements that you cannot control in your face, tongue or other parts of your body). Tell your doctor immediately if you experience involuntary rhythmic movements of the tongue, mouth and face. Withdrawal of Sperizak may be needed.

Tell your doctor immediately if you experience any of the following rare side effects (may affect up to 1 in 1,000 people):
- Experience blood clots in the veins, especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty breathing. If you notice any of these symptoms, seek medical advice immediately.
- Experience fever, muscle stiffness, sweating or a lowered level of consciousness (a disorder called “Neuroleptic Malignant Syndrome”). Immediate medical treatment may be needed.
- Are a man and experience prolonged or painful erection. This is called priapism. Immediate medical treatment may be needed.
- Experience severe allergic reaction characterised by fever, swollen mouth, face, lip or tongue, shortness of breath, itching, skin rash or drop in blood pressure. Even if you have previously tolerated oral risperidone, rarely allergic reactions occur after receiving injections of Sperizak.

The following other side effects may also happen:
Very common side effects (may affect more than 1 in 10 people)
- Common cold symptoms
- Difficulty falling or staying asleep
- 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.
- Headache

Common side effects (may affect up to 1 in 10 people)
- Pneumonia, infection of the chest (bronchitis), sinus infection
- Urinary tract infection, feeling like you have the flu, anaemia
- Raised levels of a hormone called "prolactin" found in a blood test (which may or may not cause symptoms). Symptoms of high prolactin occur uncommonly and may include in men breast swelling, difficulty in getting or maintaining erections, decreased sexual desire or other sexual dysfunction. In women they may include breast discomfort, leakage of milk from the breasts, missed menstrual periods or other problems with your cycle or fertility problems.
- High blood sugar, weight gain, increased appetite, weight loss, decreased appetite
- Sleep disorder, irritability, decreased sexual drive, restlessness, feeling 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)
- Blurry vision
- Rapid heart rate
- Low blood pressure, chest pain, high blood pressure
- Shortness of breath, sore throat, cough, stuffy nose
- Abdominal pain, abdominal discomfort, vomiting, nausea, stomach or intestinal infection, constipation, diarrhea, indigestion, dry mouth, toothache
- Rash
- Muscle spasms, bone or muscle ache, back pain, joint pain
- Incontinence (lack of control) of urine
- Erectile dysfunction
- Loss of menstrual periods
- Leakage of milk from the breasts
- Swelling of the body, arms or legs, fever, weakness, fatigue (tiredness)
- Pain
- A reaction at the injection site, including itching, pain or swelling
- Increased liver transaminases in your blood, increased GGT (a liver enzyme called gamma-glutamyltransferase) in your blood
- Fall

Uncommon side effects (may affect up to 1 in 100 people)
- Infection of the breathing passages, bladder infection, ear infection, eye infection, tonsillitis, fungal infection of the nails, infection of the skin, an infection confined to a single area of skin or part of the body, viral infection, skin inflammation caused by mites, abscess under the skin
- White blood cell count decreased, decrease in platelets (blood cells that help you stop bleeding), decrease in red blood cells
- Allergic reaction
- Sugar in the urine, diabetes or worsening of diabetes
- Loss of appetite resulting in malnutrition and low body weight
- High blood triglycerides (a fat), increased cholesterol in your blood
- Elated mood (mania), confusion, inability to reach orgasm, nervousness, nightmares
- Loss of consciousness, convulsion (fits), fainting
- A restless urge to move parts of your body, balance disorder, abnormal coordination, 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
- Eye infection or "pink eye", dry eye, increased tears, redness of the eyes
- Sensation of spinning (vertigo), ringing in the ears, ear pain
- Atrial fibrillation (an abnormal heart rhythm), 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, slow heart rate, abnormal electrical tracing of the heart (electrocardiogram or ECG), a fluttering or pounding feeling in your chest (palpitations)
- Low blood pressure upon standing (consequently, some people using Sperizak may feel faint, dizzy or may pass out when they stand up or sit up suddenly)
- Fast, shallow breathing, congestion of breathing passages, wheezing, nosebleeds
- Stool incontinence, difficulty swallowing, excessive passing of gas or wind
- Itching, hair loss, eczema, dry skin, skin redness, skin discolouration, acne, flaky, itchy scalp or skin
- An increase of CPK (creatine phosphokinase) in your blood, an enzyme which is sometimes released with muscle breakdown
- Joint stiffness, joint swelling, muscle weakness, neck pain
- Frequent passing of urine, inability to pass urine, pain when passing urine

- Ejaculation disorder, a delay in menstrual periods, missed menstrual periods or other problems with your cycle (females), development of breasts in men, sexual dysfunction, breast pain, breast discomfort, vaginal discharge
- Swelling of the face, mouth, eyes or lips
- Chills, an increase in body temperature
- A change in the way you walk
- Feeling thirsty, feeling unwell, chest discomfort, feeling "out of sorts"
- Hardening of the skin
- Increased liver enzymes in your blood
- Procedural pain

Rare side effects (may affect up to 1 in 1,000 people)
- Decrease in the type of white blood cells that help to protect you against infection
- Inappropriate secretion of a hormone that controls urine volume
- Low blood sugar
- Excessive drinking of water
- Sleep walking
- Sleep-related eating disorder
- Not moving or responding while awake (catatonia)
- Lack of emotion
- Low level of consciousness
- Shaking of the head
- Problems with movement of your eyes, eye rolling, oversensitivity of the eyes to light
- Eye problems during cataract surgery. During cataract surgery, a condition called intraoperative floppy iris syndrome (IFIS) can happen if you use or have used Sperizak. If you need to have cataract surgery, be sure to tell your eye doctor if you use or have used this medicine.
- Irregular heartbeat
- Dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood, increase in eosinophils (a type of white blood cell) in your blood
- Trouble breathing during sleep (sleep apnea)
- Pneumonia caused by inhaling food, lung congestion, crackly lung sounds, voice disorder, breathing passage disorder
- Inflammation of the pancreas, a blockage in the bowels
- Very hard stool
- Rash on skin related to medicine
- Hives (or "nettle rash"), thickening of skin, dandruff, skin disorder, skin lesion
- Breakdown of muscle fibers and pain in muscles (rhabdomyolysis)
- Abnormal posture
- Breast enlargement, discharge from the breasts
- Decreased body temperature, discomfort
- Yellowing of the skin and the eyes (jaundice)
- Dangerously excessive intake of water
- Increased insulin (a hormone that controls blood sugar levels) in your blood
- Blood vessel problems in the brain
- Unresponsive to stimuli
- Coma due to uncontrolled diabetes
- Sudden loss of vision or blindness
- Glaucoma (increased pressure within the eyeball), eyelid margin crusting
- Flushing, swollen tongue
- Chapped lips
- Enlargement of the glands in your breasts
- A decrease in body temperature, coldness in arms and legs
- Symptoms of drug withdrawal

Very rare side effects (may affect up to 1 in 10,000 people)
- Life-threatening complications of uncontrolled diabetes

- Serious allergic reaction with swelling that may involve the throat and lead to difficulty breathing
- Lack of bowel muscle movement that causes blockage

Not known: frequency cannot be estimated from the available data
- 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 (Stevens-Johnson syndrome or toxic epidermal necrolysis).

The following side effect has been seen with the use of another medicine called paliperidone that is very similar to risperidone, so this can also be expected with Sperizak:
- Rapid heartbeat upon standing

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

5. How to store Sperizak

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 and the vial after "EXP". The expiry date refers to the last day of that month.

Store the entire dose pack in a refrigerator (2 °C – 8 °C).
If refrigeration is unavailable, the pack can be stored at temperatures not exceeding 25 °C for a maximum of 7 days before use.

Store in the original package in order to protect from light.

After reconstitution: Chemical and physical in-use stability has been demonstrated for 24 hours at 25 °C.
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 6 hours at 25 °C, unless reconstitution has taken place in controlled and validated aseptic conditions.

Do not use this medicine if you notice any signs of deterioration.

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

6. Contents of the pack and other information

What Sperizak contains
- The active substance is risperidone.
  Each vial of Sperizak 25 mg powder for prolonged-release suspension for injection contains 25 mg of risperidone.
  Each vial of Sperizak 37.5 mg powder for prolonged-release suspension for injection contains 37.5 mg of risperidone.

Each vial of Sperizak 50 mg powder for prolonged-release suspension for injection contains 50 mg of risperidone.
- The other ingredients are:
  Powder: Poly(D,L-lactide-co-glycolide)
  Solvent (solution): Polysorbate 20, carmellose sodium, disodium hydrogen phosphate dihydrate, citric acid, sodium chloride, sodium hydroxide, water for injections

What Sperizak looks like and contents of the pack
Each dose pack contains the following components co-packaged in a plastic tray:
- One vial with grey chlorobutyl rubber stopper with blowback, sealed with a pink, green or blue aluminum flip-off cap for Sperizak 25 mg, 37.5 mg and 50 mg, respectively, containing white to off-white powder (within this powder is the active substance, risperidone)
- One syringe, sealed with tip cap and grey bromobutyl plunger stopper, filled with 2 mL of clear, colourless, aqueous solution, free from foreign particles to be added to the powder for prolonged–release suspension for injection
- One vial adapter for reconstitution
- Two Terumo SurGuard®3 needles for intramuscular injection: a 21G UTW 1-inch (0.8 mm x 25 mm) safety needle with needle protection device for deltoid administration and a 20G TW 2-inch (0.9 mm x 51 mm) safety needle with needle protection device for gluteal administration

Sperizak is available in cartons containing 1, 2 or 5 dose packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Accord Healthcare Ireland Ltd.
Euro House,
Euro Business Park,
Little Island,
Cork,
T45 K857,
Ireland

Manufacturer
Pharmathen International S.A
Industrial Park Sapes,
Rodopi Prefecture, Block No 5,
Rodopi 69300,
Greece

Or

Pharmathen S.A.
6, Dervenakion str.,
153 51 Pallini Attiki,
Greece

This medicinal product is authorised in the Member States of the European Economic Area under the following names:

Name of the Member State	**Name of the medicine**
Austria	Risperidone Pharmathen 25 mg, 37.5 mg & 50mg Pulver und Lösungsmittel zur Herstellung einer Depot-Injektionssuspension

Ireland	Sperizak 25 mg, 37.5 mg & 50 mg powder and solvent for prolonged-release suspension for injection

This leaflet was last revised in March 2024

The following information is intended for healthcare professionals only:

Important information
Sperizak requires close attention to these step-by-step Instructions for Use to help ensure successful administration.

Use components provided
The components in this dose pack are specifically designed for use with Sperizak. Sperizak must be reconstituted only in the solvent supplied in the dose pack.

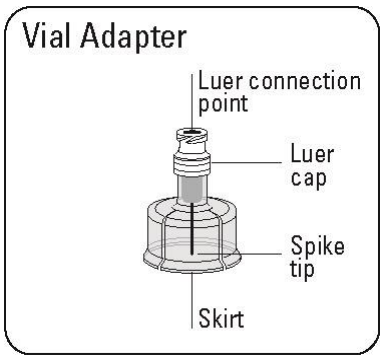
Do not substitute ANY components of the dose pack.

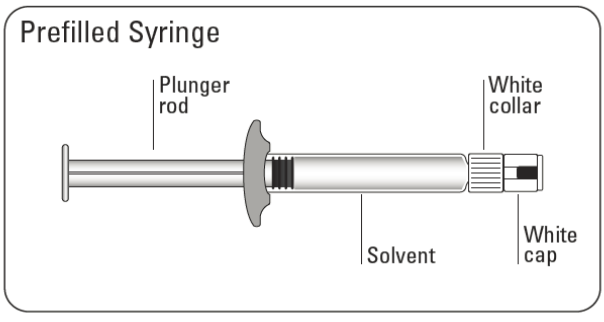
Proper dosing
The entire contents of the vial must be administered to ensure intended dose of Sperizak is delivered.

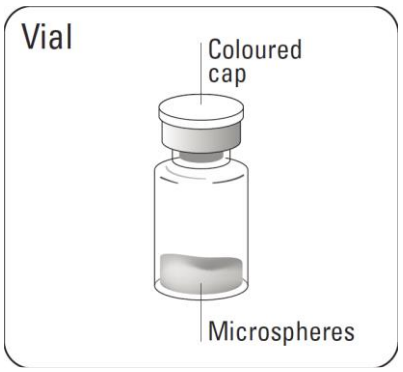
SINGLE-USE DEVICE

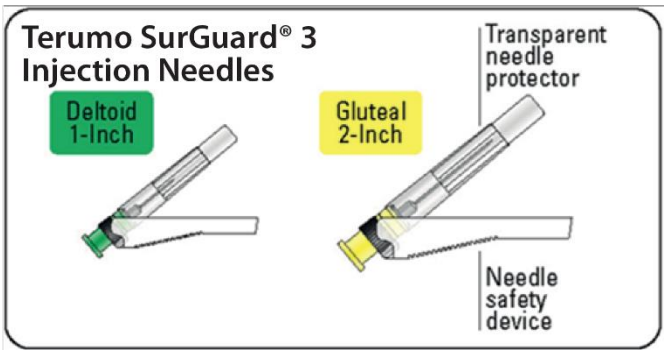
Do not reuse
Medical devices require specific material characteristics to perform as intended. These characteristics have been verified for single use only. Any attempt to re-process the device for subsequent re-use may adversely affect the integrity of the device or lead to deterioration in performance.

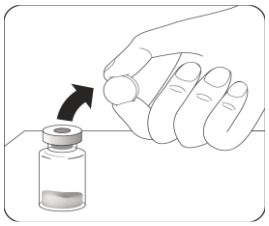
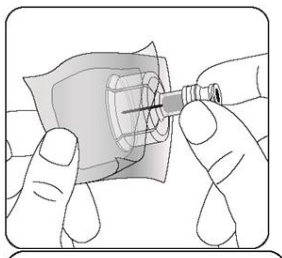
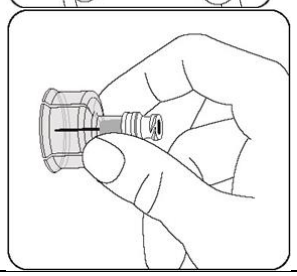
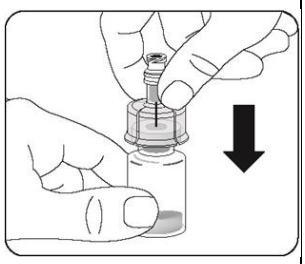
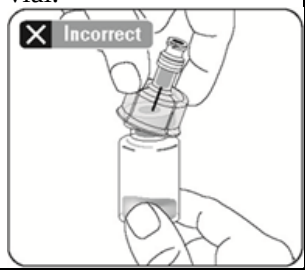
Dose pack contents






Vial
Coloured cap
Microspheres


Terumo SurGuard® 3 Injection Needles
Deltoid 1-Inch
Gluteal 2-Inch
Transparent needle protector
Needle safety device

Step 1	**Assemble components**		
Take out the dose pack	**Connect vial adapter to vial**		
		 	
Wait 30 minutes Remove 1 dose pack from the refrigerator and allow to sit at room temperature for at least **30 minutes** before reconstituting. **Do not** warm any other way.	**Remove cap from vial** Flip off coloured cap from vial. Wipe top of the grey stopper with an alcohol swab. Allow to air dry. **Do not** remove grey rubber stopper.	**Prepare vial adapter** Peel back the blister pouch and remove the vial adapter by holding between the white luer cap and the skirt. **Do not** touch spike tip or luer connection point at any time. This will result in contamination.	**Connect vial adapter to vial** Place vial on a hard surface and hold by the base. Center vial adapter over the grey rubber stopper. Push vial adapter straight down onto vial top until it snaps securely into place, confirmed by an audible “click”. **Do not** place vial adapter on at an angle or solvent may leak upon transfer to the vial. 

Connect pre-filled syringe to vial adapter

Swab connection point

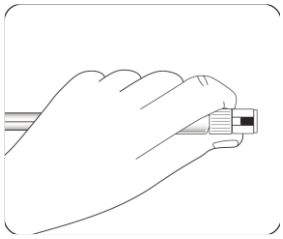
Keep vial vertical to prevent leakage.

Hold base of vial and swab the luer connection point (blue circle) of the vial adapter with an alcohol wipe and allow to dry prior to attaching the syringe.

Do not shake.

Do not touch luer connection point on vial adapter.

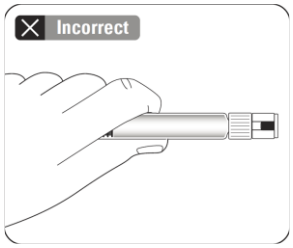
This will result in contamination.

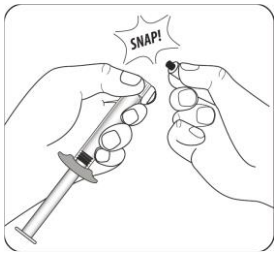


Use proper grip

Hold by white collar at the tip of the syringe.

Do not hold syringe by the glass barrel during assembly.



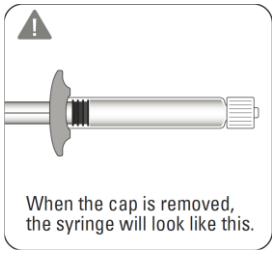


Remove cap

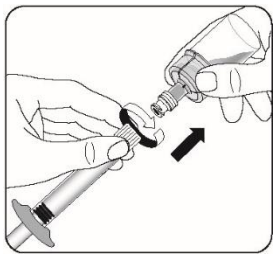
Holding the white collar, snap off the white cap.

Do not twist or cut off the white cap.

Do not touch syringe tip. This will result in contamination.



The broken-off cap can be discarded.



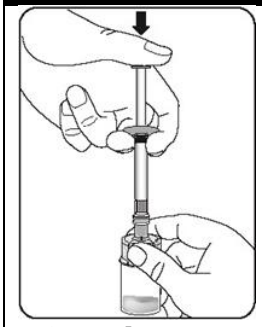
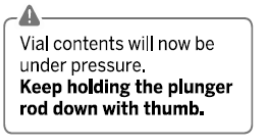
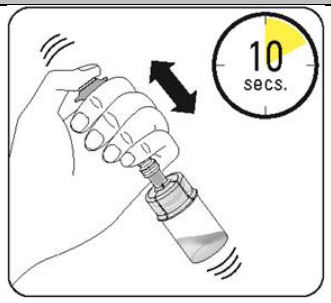
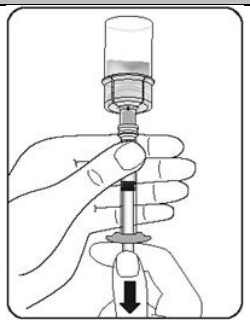
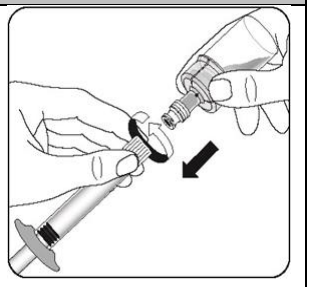
Connect syringe to vial adapter

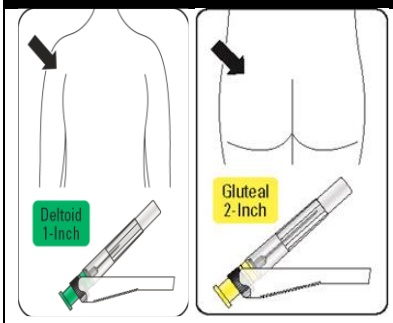
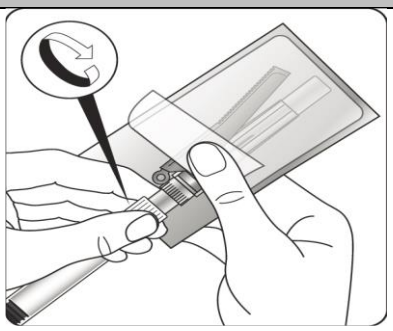
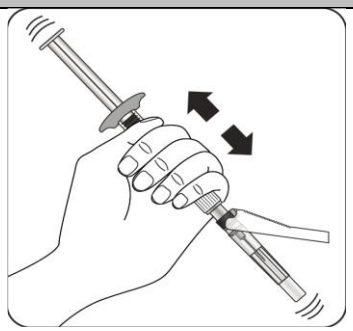
Hold vial adapter by skirt to keep stationary.

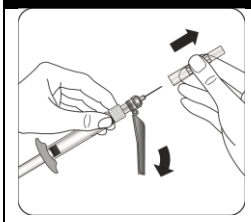
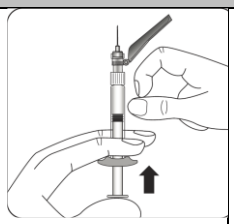
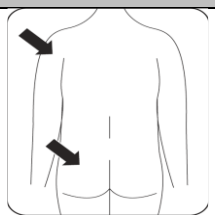
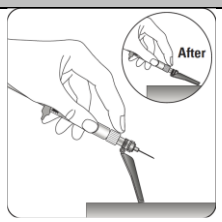
While holding the white collar of the syringe, insert and press the syringe tip into the blue circle of the vial adapter and twist in a clockwise motion to secure the connection of the syringe to the vial adapter (avoid over tightening).

Do not hold the glass syringe barrel.

This may cause the white collar to loosen or detach.

Step 2	Reconstitute microspheres		
 **Inject solvent** Inject entire amount of solvent from syringe into the vial.  	 **Suspend microspheres in solvent** Continuing to hold down the plunger rod, **shake <u>vigorously</u> for at least 10 seconds**, as shown. <u>Check the suspension.</u> When properly mixed, the suspension appears uniform, thick and milky in colour. Microspheres will be visible in the liquid. Immediately proceed to the next step so suspension does not settle.	 **Transfer suspension to syringe** Invert vial completely. Slowly pull plunger rod down to withdraw entire content from the vial into the syringe.	 **Remove vial adapter** Hold white collar on the syringe and unscrew from vial adapter. Discard both vial and vial adapter appropriately.

Step 3	Attach needle	
		
Select appropriate needle Choose needle based on injection location (gluteal or deltoid).	**Attach needle** Peel blister pouch open part way and use to grasp the base of the needle, as shown. **Holding the white collar on the syringe**, attach syringe to needle luer connection with a firm **clockwise twisting motion** until snug. **Do not** touch needle luer opening. This will result in contamination.	**Resuspend microspheres** Fully remove the blister pouch. Just before injection, shake syringe vigorously again, as some settling will have occurred.

Step 4	Inject dose			
				
Remove transparent needle protector Move the needle safety device back towards the syringe, as shown. Then, hold white collar on syringe and carefully pull the transparent needle protector straight off. **Do not** twist transparent needle protector, as the luer connection may loosen.	**Remove air bubbles** Hold syringe upright and tap gently to make any air bubbles rise to the top. Slowly and carefully press plunger rod upward to remove air.	**Inject** Immediately inject entire contents of syringe intramuscularly into the gluteal or deltoid muscle of the patient. Gluteal injection should be made into the upper-outer quadrant of the gluteal area. **Do not administer intravenously.**	**Secure needle in safety device** Using <u>one hand</u>, place needle safety device at a 45 degree angle on a hard, flat surface. Press down with a firm, quick motion until needle is fully engaged in safety device. **Avoid needle stick injury:** **Do not** use two hands. **Do not** intentionally disengage or mishandle the needle safety device. **Do not** attempt to straighten the needle or engage the safety device if the needle is bent or damaged.	**Properly dispose of needles** Check to confirm needle safety device is fully engaged. Discard in an approved sharps container. Also discard the unused needle provided in the dose pack.