

Package leaflet: Information for the user

OKEDI 75 mg powder and solvent for prolonged-release suspension for injection risperidone

Read all of this leaflet carefully before you start taking 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 OKEDI is and what it is used for
2. What you need to know before you use OKEDI
3. How to use OKEDI
4. Possible side effects
5. How to store OKEDI
6. Contents of the pack and other information

1. What OKEDI is and what it is used for

OKEDI contains the active substance risperidone which belongs to the group of medicines called 'antipsychotics'.

OKEDI is used in adult patients to treat 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.

OKEDI is intended for patients who show tolerability and effectiveness to oral (e.g. tablets) risperidone.

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

2. What you need to know before you use OKEDI

Do not use OKEDI:

- If you are allergic (hypersensitive) to risperidone or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking OKEDI 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. OKEDI 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 blood vessel problems in 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
- You have 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 you have ever had a prolonged or painful erection
- You have problems controlling your 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 tumour, which is possibly dependent on prolactin
- 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 are not sure if any of the above applies to you, talk to your doctor or pharmacist before using oral risperidone or OKEDI.

During treatment

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 risperidone. Your doctor may therefore check your white blood cell counts before and during treatment.

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

OKEDI may cause you to gain weight. Significant weight gain may adversely affect your health. Your doctor should regularly measure your body weight.

Diabetes mellitus or worsening of pre-existing diabetes mellitus have been seen with patients taking OKEDI. Your doctor should therefore check for signs of high blood sugar. In patients with pre-existing diabetes mellitus blood glucose should be monitored regularly.

OKEDI 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), problems may arise 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 taking this medicine.

Children and adolescents

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

Other medicines and OKEDI

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 such as to help you calm down (benzodiazepines) or some medicines for pain (opiates), medicines for allergy (some antihistamines), as OKEDI 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 to treat raised blood pressure. OKEDI can lower blood pressure
- Medicines for Parkinson's disease (such as levodopa).
- Medicines that increase the activity of the central nervous system (psychostimulants, such as methylphenidate).
- Water tablets (diuretics) used for heart problems or swelling of parts of your body due to accumulation of too much fluid (such as furosemide or chlorothiazide). OKEDI 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, fluoxetine, 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 using OKEDI.

OKEDI with food, drink and alcohol

You should avoid drinking alcohol when using OKEDI.

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 taking this medicine. Your doctor will decide if you can use it.

- The following symptoms may occur in newborn babies, of mothers that have used risperidone 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.
- OKEDI 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 OKEDI. Do not drive or use any tools or machines without talking to your doctor first.

3. How to use OKEDI

You will be given OKEDI as an intramuscular injection either in the upper arm or buttock every 28 days, by a healthcare professional. Injections should be alternated between the right and left sides.

The recommended dose is 75 mg every 28 days, but a higher dose of 100 mg every 28 days may be necessary. Your doctor will decide on the dose of OKEDI that is right for you.

If you are currently treated with other antipsychotics than risperidone, but have taken risperidone in the past, you should begin taking oral risperidone with at least 6 days before beginning treatment with OKEDI.

If you have never taken any form of risperidone, you should begin taking oral risperidone with at least 14 days before beginning treatment with OKEDI. The duration of the oral risperidone period will be determined by your physician.

If you have kidney problems

OKEDI is not recommended in patients with moderate to severe impaired kidney function.

If you are given more OKEDI than you should

- See a doctor right away.
- In case of overdose you may feel sleepy or tired, or have abnormal body movements, problems standing and walking, feel dizzy due to low blood pressure, or have abnormal heartbeats or fits.

If you stop using OKEDI

You will lose the effects of the medicine. You should not stop using this medicine unless told to do so by your doctor as your symptoms may return.

It is important not to miss your appointments when you are supposed to receive your injections of this medicine once every 28 days. If you cannot keep your appointment, make 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.

Contact a doctor or go to your nearest emergency department immediately if you experience the following uncommon side effect (may affect up to 1 in 100 people):

- Experience tardive dyskinesia (twitching or jerking movements that you cannot control in your face, tongue, or other parts of your body).

Contact a doctor or go to your nearest emergency department 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.
- Experience fever, muscle stiffness, sweating or a lowered level of consciousness (a disorder called “Neuroleptic Malignant Syndrome”).
- Are a man and experience prolonged or painful erection. This is called priapism.
- Experience severe allergic reaction characterised by fever, swollen mouth, face, lip or tongue, shortness of breath, itching, skin rash or drop in blood pressure (anaphylactic reaction or angioedema). Even if you have previously tolerated oral risperidone, rarely allergic reactions occur after receiving injections of OKEDI.
- Have a dark red or brown urine or notable decreased urination along with muscle weakness or trouble moving arms and legs. These may be signs of rhabdomyolysis (a rapid damage of your muscles).
- Have weakness or lightheadedness, fever, chills or sores in the mouth. These may be signs of very low number of granulocytes (a type of white blood cell to help you against infection).

The following other side effects may also happen:

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

- Difficulty falling or staying asleep
- Parkinsonism: movement disorders that may include slow or impaired movements, sensation of stiffness or tightness of the muscles, and sometimes even a sensation of movement "freezing up" and then restarting. Other signs include a slow shuffling walk, 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 (lung infection), bronchitis (infection of the main airways of the lungs), sinus infection, urinary tract infection, ear infection, flu, flu-like symptoms, sore throat, cough, stuffy nose, fever, eye infection or “pink eye”
- Raised levels of a hormone called "prolactin" found in a blood test. Symptoms of high prolactin occur uncommonly and may include in men breast swelling, difficulty in getting or maintaining erections, decreased sexual desire. In women they may include leakage of milk from the breasts, menstrual disorders, missed menstrual periods, lack of ovulation, fertility problems
- Weight gain, increased or decreased appetite
- Sleep disorder, irritability, depression, anxiety, feeling sleepy, or less alert
- Dystonia (involuntary contraction of muscles that cause slow repetitive movements or abnormal postures), dyskinesia (another condition which affects involuntary

muscle movements including repetitive, spastic or writhing movements, or twitching)

- Tremor (shaking), muscle spasms, bone or muscle pain, back pain, joint pain, fall
- Blurry vision
- Urinary incontinence (involuntary leakage of urine)
- Rapid heart rate, high blood pressure, shortness of breath
- Abdominal pain, abdominal discomfort, vomiting, nausea, dizziness, constipation, diarrhoea, indigestion, dry mouth, toothache
- Rash, skin redness, reaction at the injection site (including discomfort, pain, redness or swelling), swelling of the body, arms or legs, chest pain, lack of energy and strength, fatigue, pain.

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

- Bladder infection, tonsillitis, fungal infection of nails, infection of the deeper layers of the skin, viral infection, inflammation of the skin caused by mites
- Decrease or increase in white blood cells in your blood, decrease in platelets (blood cells that help you stop bleeding), anemia or haematocrit decreased (decrease in red blood cells), blood creatine phosphokinase enzyme increased, increased liver enzymes in your blood
- Low blood pressure, drop in blood pressure after standing, flushing, brain ischemia (insufficient blood flow to the brain)
- Diabetes, high blood sugar, excessive drinking of water, increased cholesterol in your blood, weight loss, anorexia, high blood triglycerides (a fat)
- Mania (elated mood), confusion, decreased sexual drive, nervousness, nightmares
- Fainting, convulsion (fits), sensation of spinning (vertigo), tinnitus, ear pain
- A restless urge to move parts of your body, balance disorder, abnormal coordination, poor 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 on the skin
- Irregular and often rapid heart rate, slow heart rate, abnormal electrocardiogram (test that measures the electrical activity of the heartbeat), palpitations (a fluttering or pounding feeling in your chest), an interruption in conduction between the upper and lower parts of the heart
- Congestion of breathing passages, wheezing (coarse/whistling sound during breathing), nose bleeds
- Abnormal posture, joint stiffness, joint swelling, muscle weakness, neck pain, walking abnormality, thirst, feeling unwell, chest discomfort or general discomfort, feeling “out of sorts”
- Stomach or intestinal infection or irritation, fecal incontinence, difficulty swallowing, excessive passing of gas or wind, frequent passing of urine, inability to pass urine, pain when passing urine
- Loss of menstrual periods or other problems with your cycle, leakage of milk from the breasts, sexual dysfunction, breast pain or discomfort, vaginal discharge, erectile dysfunction, ejaculation disorder, development of breast in men
- Hives, thickening of skin, skin disorder, intense itching of the skin, hair loss, eczema (patches of skin become inflamed, itchy, cracked, and rough), dry skin, skin discoloration, acne, seborrheic dermatitis (red, scaly, greasy, itchy, and inflamed skin), skin lesion
- Oversensitivity of the eyes to light, dry eye, increased tears
- Allergic reaction, chills.

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

- Infection
- Inappropriate secretion of a hormone that controls urine volume, dangerously excessive intake of water, excess of sugar in the urine, low blood sugar, increased insulin (a hormone that controls blood sugar levels) in your blood
- Not responsive to stimulation, catatonia (not moving or responding while awake), low level of consciousness, sleep walking, sleep-related eating disorder, trouble breathing during sleep (sleep apnea), fast shallow breathing, lung infection caused by inhaling food into the breathing passages, lung congestion, breathing passage disorder, voice disorder, crackly lung sounds, lack of emotion, inability to reach orgasm
- Blood vessel problems in the brain, coma due to uncontrolled diabetes, involuntary shaking of the head
- Glaucoma (increased pressure within the eye), problems with movement of your eyes, eye rolling, eyelid margin crusting/inflammation, eye problems during cataract surgery
- Inflammation of the pancreas, blockage in the bowels
- Swollen tongue, chapped lips, dandruff, jaundice (yellowing of the skin and the eyes), hardening of the skin
- Breast enlargement, breast engorgement (hard, swollen, painful breasts from too much breast milk production)
- Decreased body temperature, coldness in arms and legs
- Symptoms of drug withdrawal (also in newborns)

Very rare side effects (may affect up to 1 in 10,000 people):

- Life threatening complications of uncontrolled diabetes
- 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).

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 Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard 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 OKEDI

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, aluminium pouches or syringe labels after (EXP). The expiry date refers to the last day of that month.

Store below 30°C. Store in the original package in order to protect from moisture.

Use OKEDI immediately after reconstitution.

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 OKEDI contains

The active substance is risperidone.

Only the powder syringe contains the active substance. Once reconstituted the amount of risperidone delivered is 75 mg.

The other ingredients are:

Pre-filled syringe of powder: poly-(D, L-lactide-co-glycolide).

Pre-filled syringe of solvent: dimethyl sulfoxide.

What OKEDI looks like and contents of the pack

Each kit box of OKEDI powder and solvent for prolonged-release suspension for injection contains:

- An aluminium pouch with one pre-filled syringe containing powder (within this powder is the active substance, risperidone) and a silica gel desiccant sachet. The powder is white to white-yellowish, non-aggregated.
- An aluminium pouch with one pre-filled syringe containing the solvent and a silica gel desiccant sachet. The pre-filled syringe of the solvent contains a clear solution and has a RED finger flange.
- One sterile needle for IM injection 2 inch (0.90 x 51mm [20G]) with safety shield used for gluteus administration.
- One sterile needle for IM injection 1 inch (0.80 x 25mm [21G]) with safety shield used for deltoid administration.

Marketing Authorisation Holder and Manufacturer

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The following information is intended for healthcare professionals only

INSTRUCTIONS FOR HEALTHCARE PROFESSIONALS

OKEDI 75 mg powder and solvent for prolonged-release suspension for injection

Important information

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

Use components provided

The components in the kit box are specifically designed for use with OKEDI. OKEDI must be reconstituted only with the solvent supplied in the kit box.

Do not substitute ANY components of the kit box.

Administer dose immediately after reconstitution. For intramuscular use only after reconstitution.

Proper dosing



The entire content of the reconstituted syringe must be administered to ensure intended dose of OKEDI is delivered.

Single use device

1. CHECK CONTENTS

Working on a clean surface, open the sachets and discard the desiccant pack.

The kit box of OKEDI contains:

- One aluminium foil pouch with a OKEDI pre-filled syringe with a WHITE plunger rod and WHITE finger flange. The syringe is marked with .
- One aluminium foil pouch with SOLVENT for OKEDI pre-filled syringe with a TRANSPARENT plunger rod and a RED finger flange. The syringe is marked with .
- Two administration needles (21G, 1 inch for deltoid [green cap] and a 20G, 2 inch for gluteus [yellow cap]).

Discard the kit if any component is damaged.

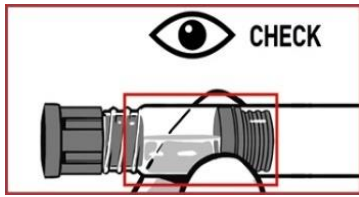
In the event of any foreign particulate matter and/or variation of physical aspect is observed, do not administer OKEDI.

1.1 Inspect solvent syringe

ENSURE that SOLVENT syringe content flows normally as a liquid.

The solvent freezes below 19°C.

If it is frozen or partially frozen, allow to thaw using hands contact or leaving it at room temperature until liquid flow recovered before continuing.



1.2 Dislodge powder syringe

TAP the OKEDI syringe to dislodge potential packed powder near the cap.



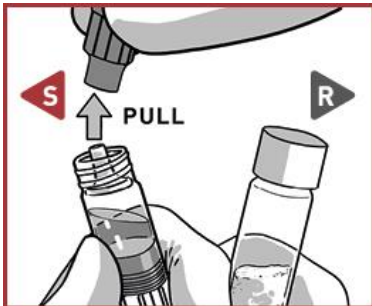
2. CONNECT THE SYRINGES

2.1 Uncap syringes in upright position

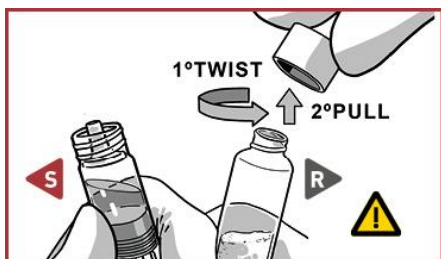
Hold both syringes in **upright position** to prevent loss of product.



PULL the cap off the Solvent syringe.



TWIST and PULL the Powder syringe cap off.

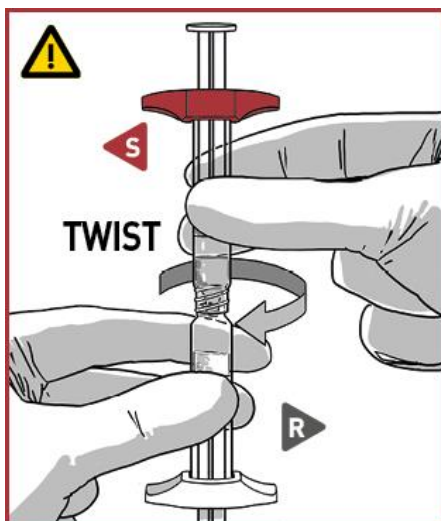


2.2 Connect the syringes

Pick the solvent syringe S that has the coloured finger flange and place it on TOP of the powder syringe R, or slightly lean it when connecting.

TWIST the syringes together until you feel a slight resistance.

Make sure that Powder syringe R is in the upright position to prevent loss of product.



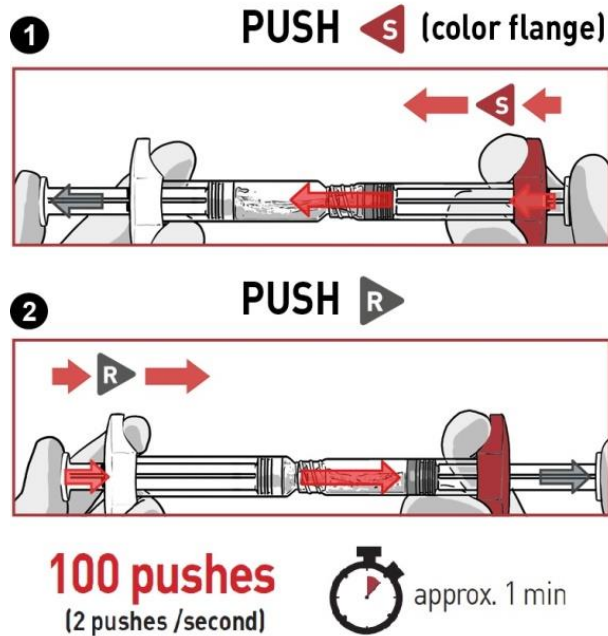
3. MIX THE CONTENTS

STOP AND READ THIS SECTION BEFORE STARTING OR THE MEDICINE MAY NOT CORRECTLY RECONSTITUTE.

- **PUSH VIGOROUSLY** the Solvent content towards the Powder syringe.
- **DO NOT WAIT** for powder wetting and **QUICKLY** start mixing contents by **pushing the plungers FAST** and alternately for 100 pushes (2 pushes within 1 second, approximately 1 minute).
- **ENSURE** medicine is passing between both syringes for a properly mixing: **medicine is viscous** and you will need to apply force when pressing on the plunger rods.

Mix for at least **100 pushes** by doing alternately

① followed by ②



Make sure medicine is passing between both syringes

When medicine is correctly mixed, the appearance will be a uniform suspension off white to yellowish colour and thick consistency.



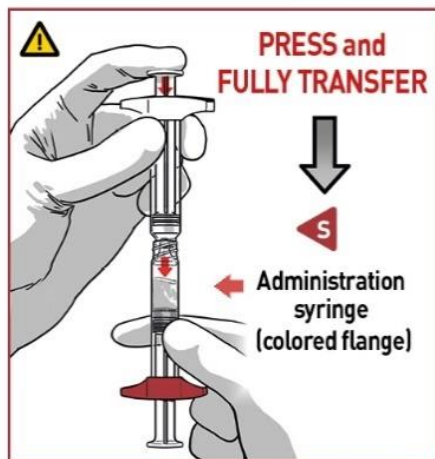
Once reconstituted, proceed immediately to prepare the injection syringe for administration to avoid loss of homogeneity.

4. PREPARE INJECTION SYRINGE

4.1 Transfer medicine

Place downward pressure on the **R** plunger rod and transfer all the content into the **S** syringe that has attached the **coloured finger flange**.

Make sure all the content is transferred.



4.2 Detach syringes

Once the medicine is fully transferred, separate the two syringes by untwisting.

OKEDI should be **administered immediately to avoid loss of homogeneity.**



4.3 Attach the sterile needle with safety shield

Choose the proper needle:

- Deltoid: 21G, 1 inch for deltoid (green cap).
- Gluteus: 20G, 2 inch for gluteus (yellow cap).

Attach it using a clockwise twisting motion. **Do not over-tighten.**

4.4 Remove exceeding air

Remove needle cover and push out the excess of air (only big bubbles) from the syringe barrel.

DO NOT expel any drops of medicine

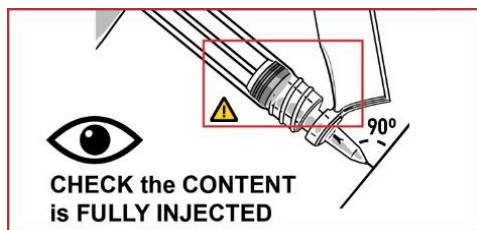
If medicine is seen at the needle tip, pull back slightly on the plunger to prevent medicine spillage.



5. ADMINISTER AND DISPOSE

5.1 Inject medicine

Insert the needle fully into the muscle. **DO NOT INJECT BY ANY OTHER ROUTE.**



THICK MEDICINE. INJECT IT SLOWLY AND STEADILY. MAKE SURE TO FULLY INJECT IT.

- The injection time is longer than usual due to the viscosity of the medicine.
- Wait a few seconds before removing the needle.
- Avoid inadvertent injection into a blood vessel.

5.2 Dispose medicine

Cover the needle pressing on the needle guard using a finger or a flat surface and dispose immediately in a secure sharps disposal container.

