



Avtozma[®] (Tocilizumab) and me

In conjunction with this patient booklet, you are also advised to read the Avtozma[®] patient brochure which is part of the risk minimisation material found on emc website.

Please click or scan the relevant QR code to access the patient brochure part of risk minimisation material for Avtozma[®]

Please refer to the Package Leaflet for further information on Avtozma[®], including a full list of side effects, warnings and precautions.



Avtozma[®]
pre-filled pen
(for subcutaneous
injection)



Avtozma[®]
pre-filled syringe
(for subcutaneous
injection)



Avtozma[®]
(for intravenous
infusion)

This booklet is for parents or caregivers of children aged 1 year and over who have been prescribed Avtozma[®] for active systemic juvenile idiopathic arthritis (sJIA), or children aged 2 years and over who have been prescribed Avtozma[®] for active polyarticular juvenile idiopathic arthritis (pJIA).

This booklet is intended as a brief overview and guide and is not a substitute for clinical advice provided by a healthcare professional, nor is it a substitute for the patient package leaflet which you are advised to read in full. If you have any additional questions, please speak to your child's healthcare professional.

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 the package 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. **Please also report side effects to Celltrion Healthcare at: ukadverseevents@celltrionhc.com or + 44(0)1753 983500.**

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See <https://yellowcard.mhra.gov.uk/> for how to report side effects.

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Note to parents and caregivers

In this booklet, we use “you” and “your” to refer to the patient, whether they are an adult or a child. For parents and caregivers of young patients, please understand that “you” and “your” will mean your child from this point forward.

Before reading this booklet, please make sure that you have read the Package Leaflet.

You should also refer to the Package Leaflet found in the carton for more information every time you have a refilled prescription as there may be new information.

Welcome to Avtozma®

You have been given this booklet as either:

- you have been prescribed Avtozma® by your doctor.
- your child has been prescribed Avtozma® by your doctor

It has been designed to help you navigate your treatment and support you in using it. Inside you will find clear information on how your treatment works, how to use it and important things to look out for.

Before we get started, here are a few important things to note:

- Before reading this booklet, please make sure that you have read the package leaflet inside your medication carton.
- 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. See section 4 of your package leaflet for a list of side effects.
- If you have any questions about your medication, please speak to your doctor or pharmacist.



About Avtozma®

Avtozma® is an immunosuppressant – a type of medicine that works by acting on part of the immune system, in order to help alleviate certain symptoms.

The active substance in Avtozma® is tocilizumab (a type of protein called a monoclonal antibody). Monoclonal antibodies recognize and bind specifically to certain proteins in the body.

What is Avtozma® used for?

Avtozma® is used to treat a number of conditions including systemic juvenile idiopathic arthritis (sJIA) and polyarticular juvenile idiopathic arthritis (pJIA). When used to treat the above conditions, it may be prescribed alongside another medicine called methotrexate.

What is

active systemic juvenile idiopathic arthritis (sJIA)?

Active systemic juvenile idiopathic arthritis is an inflammatory disease that causes pain and swelling in one or more joints as well as fever and rash.



What is

active polyarticular juvenile idiopathic arthritis (pJIA)?

Active polyarticular juvenile idiopathic arthritis is an inflammatory disease that causes pain and swelling in one or more joints.



What does Avtozma® look like?

The appearance of your Avtozma® will depend on the method of administration chosen by your doctor.

Avtozma® can be given either as a drip into a vein (intravenous) or into the fatty layer beneath the skin (subcutaneous injection) and your doctor will have chosen the most appropriate method for you and your condition.

Intravenous :

Avtozma® is presented in a glass vial containing one of the following doses:

- 80mg/ 4ml
- 200mg/ 10ml
- 400mg/ 20ml

If your doctor has selected this method of administration, your Avtozma® will be given by a doctor or nurse at your hospital or clinic

Subcutaneous (under the skin) injection:

Your doctor will have prescribed either:

- Avtozma® autoinjector pen (162mg/0.9ml)
 - Note: the auto-injector pen can only be used in adolescents aged 12 years or older
- Avtozma® pre-filled syringe (162mg/0.9ml)

This may initially be injected by your doctor or nurse. Your doctor may also decide that you can use this device for self-injection, or for a carer to administer the injection to you.



Before you use Avtozma®?

Do not use Avtozma® if:

Your child is allergic to tocilizumab or any of the other ingredients in this medicine.

Ingredients in Avtozma®

- Tocilizumab
- L-Histidine
- L-Threonine
- L-Methionine
- Polysorbate 80
- Water for injections

Avtozma® contains 0.2 mg of polysorbate 80 in each pre-filled pen and in each pre-filled syringe.

- Polysorbates may cause allergic reactions
- Tell your doctor if your child has any known allergies



Your child has an active severe infection



If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Avtozma®

Make sure you tell your doctor about any illness your child has before each treatment. Also tell your doctor if your child has recently been near anyone who might have tuberculosis (TB).

Your doctor will check your child for signs and symptoms of tuberculosis before administering Avtozma®. If your child develops possible symptoms of TB (such as persistent cough, weight loss, listlessness and mild fever) or any other infection appear during or after treatment, tell your doctor immediately.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Avtozma®. Your doctor will check that your child is well before each treatment. Make sure you tell your doctor about any illness they have before each treatment.

- If your child experiences **allergic reactions** such as chest tightness, wheezing, severe dizziness or light-headedness, swelling of the lips, tongue, face or skin itching, hives or rash during or after the injection, then **seek emergency care immediately**.
- Do not give the next dose until you have informed your doctor AND your doctor has told you to give the next dose if your child has experienced any allergic reaction symptoms after Avtozma® administration.
- If your child has any kind of infection, short- or long-term, or if your child often gets infections **tell your doctor immediately**. Also, **tell your doctor immediately** if your child is unwell. Avtozma® can reduce the body's ability to respond to infections and may make an existing infection worse or increase the chance of your child getting a new infection.

Tell your doctor if your child has any of the following:

- **Tuberculosis.** Your doctor will check for signs and symptoms of tuberculosis before starting Avtozma®. If symptoms of tuberculosis (persistent cough, weight loss, listlessness, mild fever) or any other infection appear during or after therapy **tell your doctor immediately**.
- **Intestinal ulcers or diverticulitis.** Symptoms would include abdominal pain and unexplained changes in bowel habits with a fever.
- **Liver disease.** Before giving Avtozma®, your doctor may do a blood test to measure your child's liver function.
- **A recent vaccination, or if a vaccination is planned.** Your child should be up-to-date with all their vaccinations before he or she starts treatment with Avtozma®. Certain types of vaccines should not be given while receiving Avtozma®.
- **Cancer.** Your doctor will decide if your child can still be given Avtozma®.
- **Cardiovascular risk factors** such as raised blood pressure and raised cholesterol levels. These factors need to be monitored while receiving Avtozma®.
- **Moderate to severe kidney function problems,** your doctor will monitor your child.
- **Persistent headaches.**

Your doctor will perform a blood test before your child receives Avtozma®, to determine if your child has a low white blood cell count, low platelet count or high liver enzymes.

Avtozma® subcutaneous injection is not licensed for use in children under 1 year of age. Avtozma® pre-filled pen is not licensed for use in children under 12 years of age. Avtozma® must not be given to children with sJIA weighing less than 10 kg.

If your child has a history of **macrophage activation syndrome** (activation and uncontrolled proliferation of specific blood cells), tell your doctor. Your doctor will decide if your child can still be given Avtozma®.

Other important things to consider

Other medicines and Avtozma®

Tell your doctor if your child is taking any other medicines or has recently taken any. Avtozma® can affect the way some medicines work, and the dose of these may require adjustment. If your child is taking medicines containing any of the following active substances, **tell your doctor:**

- methylprednisolone, dexamethasone, used to reduce inflammation
- simvastatin or atorvastatin, used to reduce cholesterol levels
- calcium channel blockers (e.g. amlodipine), used to treat raised blood pressure
- theophylline, used to treat asthma
- warfarin or phenprocoumon, used as blood thinning agents
- phenytoin, used to treat convulsions
- ciclosporin, used to suppress your immune system during organ transplants
- benzodiazepines (e.g. temazepam), used to relieve anxiety

Due to lack of clinical experience, Avtozma® is not recommended for use with other biological medicines for the treatment of sJIA or pJIA.

Pregnancy, breast-feeding and fertility

- **Avtozma® is not to be used in pregnancy** unless clearly necessary. Talk to your doctor if your child is pregnant, may be pregnant, or intends to become pregnant.
- **Women of childbearing potential** must use effective contraception during and up to 3 months after treatment.
- **Stop breast-feeding if you are to be given Avtozma®.** There must be a gap of at least 3 months, after the last treatment, before you start breast-feeding. It is not known whether Avtozma® is passed into breast milk.

Driving and using machines

- Avtozma® can cause dizziness. If your child feels dizzy, he or she should not drive or use machines.

Avtozma® contains polysorbate

- Polysorbates may cause allergic reactions.

Tell your doctor if your child has any known allergies.

Please refer to the Package Leaflet inside the product carton for further information on Avtozma®, including usage instructions, a full list of side effects, warnings and precautions.

Possible serious side effects

Like all medicines, Avtozma® can cause side effects, although not everybody gets them. Side effects could occur 3 months or more after your last dose of Avtozma®.

Common (may affect up to 1 in every 10 users)

Allergic reactions during or after injection:

- difficulty with breathing, chest tightness or light-headedness
- rash, itching, hives, swelling of the lips, tongue or face

If you notice any of these, tell your doctor immediately.

Signs of serious infections:

- persistent cough
- weight loss
- throat pain or soreness
- wheezing
- mouth or skin swelling, blisters, tears or wounds
- severe weakness or tiredness
- fever and chills
- stomach ache

If you notice any of these, tell your doctor as soon as possible

Other possible serious side effects

Signs and symptoms – stomach and abdomen (diverticulitis) (may affect up to one in every 100 users)

- fever
- persistent abdominal pain with change in bowel habits
- blood in stools

Signs and symptoms of liver toxicity (may affect up to 1 in every 1,000 users)

- tiredness or confusion
- abdominal pain or swelling (especially in upper right stomach area)
- jaundice (yellow discolouration of skin or eyes)
- dark brown-coloured urine

If you notice any of these, tell your doctor as soon as possible.

Possible side effects

Very common side effects (may affect 1 in 10 patients or more)

- upper respiratory tract infections with typical symptoms such as cough, blocked nose, runny nose, sore throat and headache
- high blood fat (cholesterol) levels
- injection site reactions

Common side effects (may affect up to 1 in 10 patients)

- lung infection (pneumonia)
- shingles (herpes zoster)
- cold sores (oral herpes simplex), blisters
- skin infection (cellulitis) sometimes with fever and chills
- rash and itching, hives
- allergic (hypersensitivity) reactions
- eye infection (conjunctivitis)
- headache, dizziness, high blood pressure
- mouth ulceration, stomach pain
- fluid retention (oedema) in the lower legs, weight increase
- cough, shortness of breath
- low white blood cell counts shown by blood tests (neutropenia, leucopenia)
- abnormal liver function tests (increased transaminases)
- increased bilirubin shown by blood tests
- low fibrinogen levels in the blood (a protein involved in blood clotting)

Please refer to the Package Leaflet inside the product carton for the full list of side effects, including those which are uncommon (may affect up to 1 in 100 people), rare (may affect up to 1 in 1000 people) and very rare (may affect up to 1 in 10,000 people). In addition, this leaflet includes important further information on Avtozma® usage instructions, warnings and precautions.

Side effects in children and adolescents with sJIA or pJIA

These are generally similar to those in adults. Some side effects are seen more often in children and adolescents: inflamed nose and throat, headache, feeling sick (nausea) and lower white blood cell counts.

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 the package 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. **Please also report side effects to Celltrion Healthcare at: ukadverseevents@celltrionhc.com or + 44(0)1753 983500.**

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See <https://yellowcard.mhra.gov.uk/> for how to report side effects.



How is Avtozma[®] given?

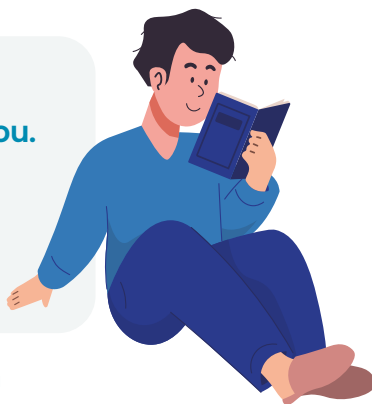
As mentioned previously, your Avtozma[™] may be given by your doctor or nurse either as intravenous therapy or by subcutaneous injection. Alternatively, subcutaneous injection may be self-administered or administered by a carer, if your doctor considers it appropriate.

If your doctor has selected subcutaneous therapy for your child, their medicine can be given using an Avtozma[®] pre-filled pen (for adolescents aged 12 years or older) or an Avtozma[®] pre-filled syringe. Your doctor will prescribe the injection device appropriate for you. If your doctor decides it is appropriate, you or your carer will be trained on how to inject using either the Avtozma[®] pre-filled pen or the Avtozma[®] pre-filled syringe. The first injection should be performed under the supervision of your doctor or nurse.

Always use Avtozma[®] exactly as your doctor, pharmacist or nurse has told you.

For instructions on how to inject using Avtozma[®] pre-filled pen please read pages 14–25

For instructions on how to inject using Avtozma[®] pre-filled syringe please read pages 26–36



Avtozma[®] dose using the pre-filled pen

Child's age & condition	Child's weight	Number of pre-filled pens (162 mg)	Dosing frequency
sJIA Age 12 years & over	Less than 30 kg	1	Once every 2 weeks
	30 kg or more	1	Once every week
pJIA Age 12 years & over	Less than 30 kg	1	Once every 3 weeks
	30 kg or more	1	Once every 2 weeks

The pre-filled pen should not be used to treat children less than 12 years of age

Please refer to the Package Leaflet inside the product carton for further information on Avtozma[®], including usage instructions, a full list of side effects, warnings and precautions.

Avtozma® dose using the pre-filled syringe

Child's age & condition	Child's weight	Number of pre-filled syringes (162 mg)	Dosing frequency
sJIA Age 1 year & over	Less than 30 kg	1	Once every 2 weeks
	30 kg or more	1	Once every week
pJIA Age 2 years & over	Less than 30 kg	1	Once every 3 weeks
	30 kg or more	1	Once every 2 weeks

If a patient with sJIA misses or forgets a dose

- If you miss a weekly dose within 7 days, inject a dose on the next scheduled day.
- If you miss a once every other week dose within 7 days, inject a dose as soon as you remember and give the next dose at your regular scheduled time.
- If you miss a weekly or once every other week dose by more than 7 days, or you are not sure when to inject Avtozma®, call your doctor or pharmacist.

If a patient with pJIA misses or forgets a dose

It is very important to use Avtozma® exactly as prescribed by your doctor.

If a dose is missed within 7 days, inject a dose as soon as you remember and give the next dose at the regular scheduled time.

- If a dose is missed by more than 7 days, or you are not sure when to inject Avtozma®, call your doctor or pharmacist.

If you stop using Avtozma®

You should not stop using Avtozma® without discussing with your doctor first.

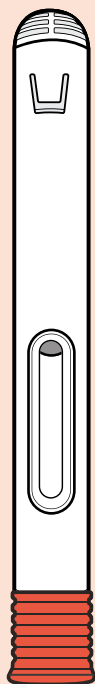
Giving the Avtozma[®] injection

The following pages offer guidance on how to use the Avtozma[®] devices to give the medicine safely.

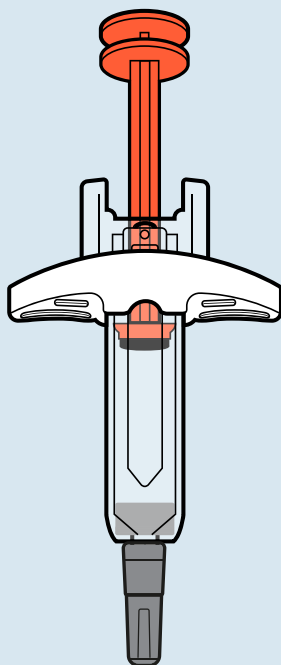
Please ensure that you are reading the section that deals with the device your doctor has prescribed for you.

Please note: the Avtozma[®] pre-filled pen is not licensed for use in children under 12 years of age

The orange pages give the instructions for using the Avtozma[®] pre-filled pen.



The blue pages give the instructions for using the Avtozma[®] pre-filled syringe.



Images not to scale: for illustration purposes only

Your Avtozma® pre-filled pen

Please note: the Avtozma® pre-filled pen is not licensed for use in children under 12 years of age

Giving Avtozma® with the Avtozma® pre-filled pen

If your doctor has decided that you may inject your child using the Avtozma® pre-filled pen there's no need to worry, you'll be fully trained by a healthcare professional so that you can give the injection confidently in the comfort of your own home.

Like many practical skills learning to use Avtozma® pre-filled pen is just a matter of training and practice. Your doctor or nurse will not expect you to give the injection until they are confident that it is appropriate for you to do so.

Preparing to use the Avtozma® pre-filled pen

Instructions on using Avtozma® pre-filled pen can be found in this booklet, starting on page 19.

You should also refer to the Package Leaflet (Instructions for the Use of Avtozma® pre-filled pen.) found in the Avtozma® package for more information.

It is important to always use Avtozma® exactly as prescribed by your healthcare professional. If you are unsure about how often you should be giving Avtozma® please check with your doctor or nurse.

If you have any outstanding questions about the Avtozma® pre-filled pen and how to use it, please contact your doctor or nurse.

Please refer to the Package Leaflet inside the product carton for further information on Avtozma®, including usage instructions, a full list of side effects, warnings and precautions.

Storing Avtozma® pre-filled pen



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 pre-filled pen label and carton (EXP). The expiry date refers to the last day of that month.

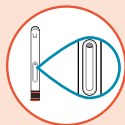


Store in a refrigerator (2°C – 8°C). **Do not freeze.**

Once removed from the refrigerator, the pre-filled pen can be stored up to 3 weeks at or below 30°C.



Keep the pre-filled pens in the outer carton to protect from light and moisture.



Do not use if the medicine is cloudy or contains particles, is any colour besides colourless to yellow, or any part of the pre-filled pen appears to be damaged.



The pen should not be shaken.

After removing the cap the injection must be started within 3 minutes to prevent the medicine from drying out and blocking the needle. If the pre-filled pen is not used within 3 minutes of cap removal, you must dispose of it in a puncture resistant container and use a new pre-filled pen.



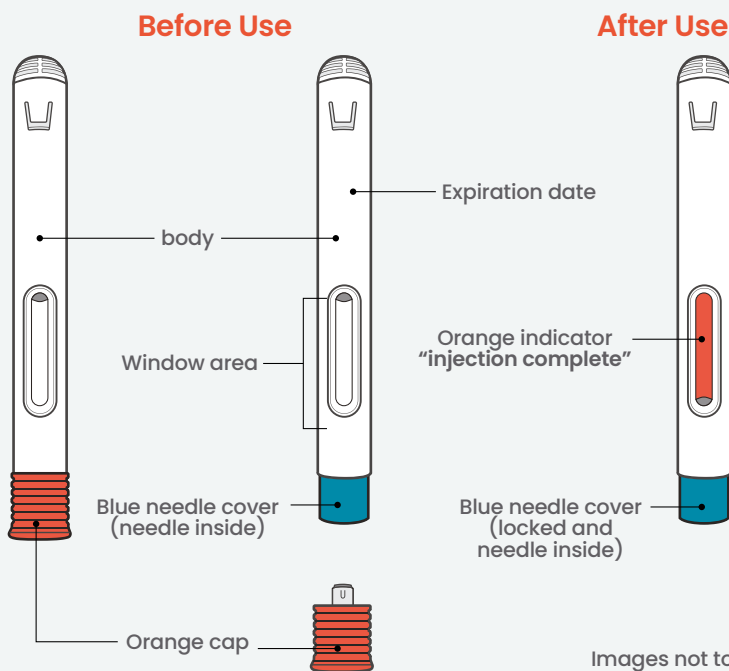
If following pressing the needle cover the orange indicator does not move, you must dispose of the pre-filled pen in a puncture resistant container. Do not try to re-use the pre-filled pen. The pre-filled pen is locked, and the needle is covered inside the needle cover when trying to re-use. Do not repeat the injection with another pre-filled pen. Call your doctor or nurse for help.

Get to know your Avtozma[®] pre-filled pen

Each Avtozma[®] pre-filled pen contains the active ingredient tocilizumab (162 mg in 0.9 mL).

Avtozma[®] is a solution for injection. The solution is colourless to yellow.

Parts of your Avtozma[®] pre-filled pen



Images not to scale: For illustration purposes only.



Click or scan the QR code to view 'How to inject using the Avtozma[®] pre-filled pen' video and see the instructions on the following pages.

Dos & don'ts before the injection



- ✓ Keep the pre-filled pens in the outer carton to protect from light and moisture until ready for use
- ✓ Keep the cap on the pre-filled pen until just before you give the injection
- ✓ After removing the cap start the injection within 3 minutes to prevent the medicine from drying out
- ✓ Read and follow the 'Instructions for Use' that come with the Avtozma® pre-filled pen before you start using it and each time you get a prescription refill, as there may be new information



- ✗ Do not try to take apart the pre-filled pen at any time
- ✗ Do not reuse the same pre-filled pen
- ✗ Do not shake the pre-filled pen
- ✗ Do not use the pre-filled pen if it has been dropped or damaged
- ✗ Do not remove the pre-filled pen cap until you are ready to inject Avtozma®



Important advice regarding hypersensitivity reactions (or anaphylaxis):

If your child develops symptoms such as, but not limited to, skin rash, itching, chills, swelling of face, lips, tongue or throat, chest pain, wheezing, difficulty breathing or swallowing or feeling dizzy or faint during or following an injection **seek emergency care immediately.**

Read and follow the 'Instructions for Use' that come with your Avtozma® pre-filled pen before you start using it and each time you get a refill. There may be new information. Before you use Avtozma® pre-filled pen, make sure your healthcare provider shows you the right way to use it.

Please refer to the Package Leaflet inside the product carton for further information on Avtozma®, including usage instructions, a full list of side effects, warnings and precautions.

How to inject using the Avtozma® pre-filled pen

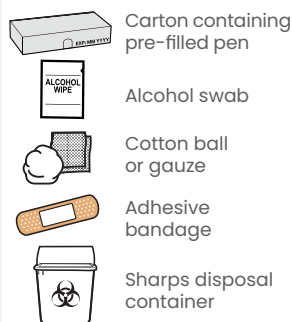
The following steps provide a guide to the administration procedure of Avtozma® pre-filled pen for parents and carers of children 12 years or older prescribed Avtozma®.

This information does not take the place of talking to your healthcare professional about your child's medical condition or treatment.

Preparing for the injection

STEP 1

Gather the supplies for the injection



- Prepare a clean, flat surface, such as a table or countertop, in a well-lit area.
- Take the carton containing the pre-filled pen out of the refrigerator.
- Make sure you have the following supplies.

Not included in the carton:

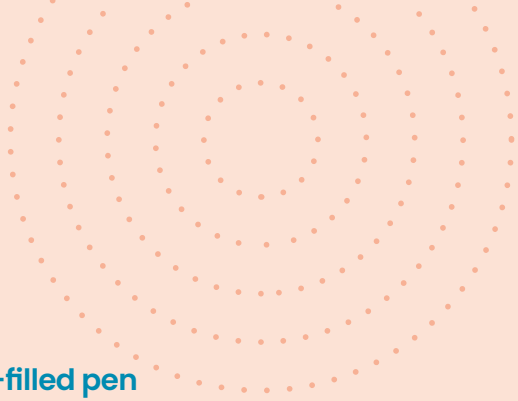
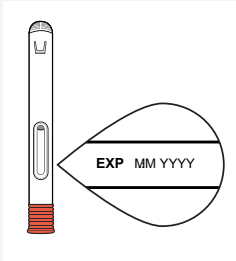
- Cotton ball or gauze.
- Adhesive bandage.
- Sharps disposal container.
- Alcohol swab.

STEP 2

Inspect the carton

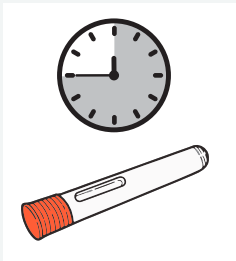


- Look at the carton and make sure you have the correct medicine and dose strength. (Avtozma®)
- Check the expiration date on the carton to make sure the date has not passed.
 - **Do not** use the pre-filled pen if the expiration date has passed.
 - If you are opening the carton for the first time check to make sure that it is properly sealed.
 - **Do not** use the pre-filled pen if the carton looks like it has been opened or damaged.

**STEP 3****Inspect the pre-filled pen**

- a. Open the carton and remove one single-dose pre-filled pen from the carton. Return any remaining Avtozma® pre-filled pens in the box to the refrigerator.
- b. Check the expiration date on the Avtozma® pre-filled pen.
 - **Do not** use the pre-filled pen if the expiration date has passed. If the expiration date has passed, safely dispose of the pre-filled pen in your sharps disposal container and get a new one.
- c. Check the pre-filled pen to make sure it is not damaged, and shows no sign of leakage.
 - **Do not** use the pre-filled pen if it has been dropped, damaged, or has leaked.

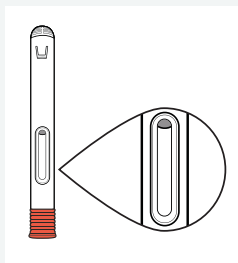
Note: A small gap between the orange cap and injector body is normal.

STEP 4**Wait 45 minutes**

- a. Leave the pre-filled pen outside of the carton at room temperature 20°C to 25°C for 45 minutes to allow it to warm up.
 - **Do not** warm the pre-filled pen using heat sources such as hot water or a microwave.
 - **Do not** leave the pre-filled pen in the direct sunlight.
 - **Do not** remove the cap while allowing your pre-filled pen to reach room temperature.
 - If the pre-filled pen does not reach room temperature, this could cause discomfort.

STEP 5

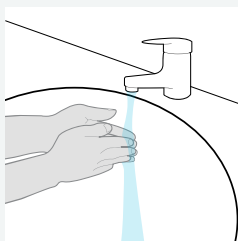
Inspect the medication



- a. Hold your Avtozma® with the cap pointing down.
 - b. Look at the medicine and confirm that the liquid is clear to slightly opalescent and colourless to yellow and does not contain any particles or flakes.
- **Do not** use the pre-filled pen if the liquid is discoloured, cloudy, or has particles or flakes in it. Safely dispose of the pre-filled pen in a sharps disposal container and use a new one.
 - Air bubbles are normal.

STEP 6

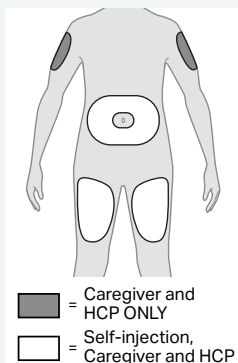
Wash your hands



- a. Wash your hands with soap and water and dry them thoroughly.

STEP 7

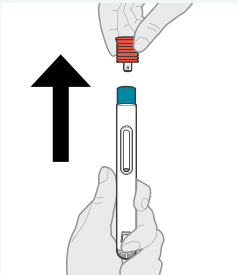
Choose an appropriate injection site



- a. You may inject into
 - The front of the thighs.
 - The abdomen, except for the 5 cm around the belly button.
 - The outer area of the upper arm (only if you are a caregiver or healthcare professional (HCP)).
- **Do not** inject into the upper arm by yourself.
- Choose a different injection site for each new injection at least 2.5 cm from the last area you injected.
- **Do not** inject into moles, scars, bruises, or areas where the skin is tender, red, hard or not intact.

STEP 8**Clean the injection site**

- a. Wipe the injection site with an alcohol swab and let it air dry. This will reduce the chance of getting an infection.
- **Do not** touch the injection site again before giving the injection.
- **Do not** fan or blow on the clean area.

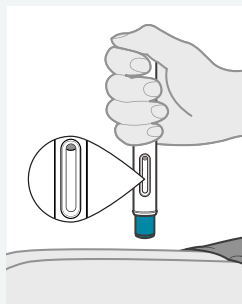
STEP 9**Remove the cap**

- a. Hold the pre-filled pen by the injector body with the cap on top using one hand. Gently pull the cap straight off with the other hand.

Note: If you cannot remove the cap, you should ask a caregiver for help or contact your healthcare provider.

- b. Dispose of the cap right away in your sharps disposal container (see step 14)
- **Do not** re-cap the pre-filled pen.
- **Do not** touch the needle shield at the tip of the pre-filled pen to avoid accidental needle stick injury.
- After you remove the cap, the pre-filled pen is ready for use. If the pre-filled pen is not used within 3 minutes of cap removal, throw away the pre-filled pen in a sharps disposal container and use a new pre-filled pen.

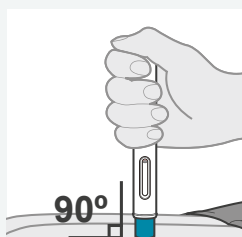
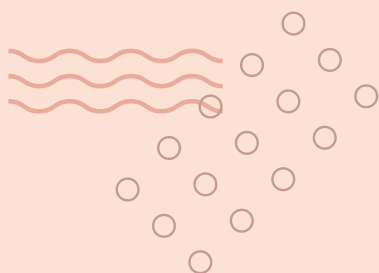
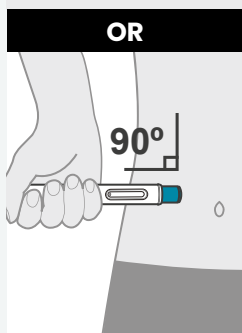


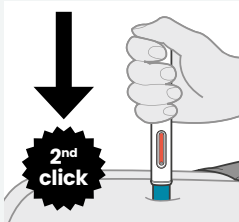
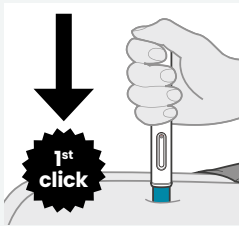
STEP 10**Place the pre-filled pen on the injection site**

- a. Hold the pre-filled pen comfortably in one hand so that you can see the window.
- b. Without pinching or stretching the skin, place the pre-filled pen against the skin at a 90-degree angle.

Note: It is important to use the correct angle to make sure the medicine is delivered under the skin (into fatty tissue), or the injection could be painful, and the medicine may not work.

- **Do not** administer into muscle or a blood vessel.

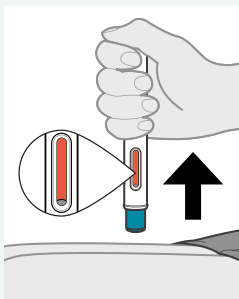
**OR**

STEP 11**Give the injection**

Then, count slowly to 5

- a. Firmly press the pre-filled pen into the skin to begin the injection.
- b. When the injection starts you will hear the 1st “click” and the orange indicator will begin to fill the window.
- c. Keep holding the pre-filled pen firmly against the skin and listen for the 2nd “click”.
- d. After you hear the 2nd “click”, continue to hold the pre-filled pen firmly against the skin and count slowly to 5 to make sure you inject the full dose.
- e. Watch the orange indicator until it stops moving and has reached the end of the window to be sure the full dose of medicine is injected.

Note: If the orange indicator does not move, discard the pre-filled pen and use a new one

STEP 12**Remove the pre-filled pen from the injection site**

- a. When the orange indicator has stopped moving, lift the pre-filled pen straight off of the injection site at a 90-degree angle to remove the needle from the skin.
- The needle cover will automatically move out and lock into place covering the needle.

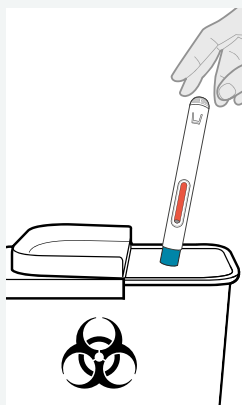
Note: If the window has not turned completely orange or if the medicine is still injecting, this means you have not received a full dose. Carefully place the pre-filled pen into the sharps disposal container and call your healthcare provider immediately.

- **Do not** touch the needle cover of the pre-filled pen.
- **Do not** try to re-use the pre-filled pen.
- **Do not** repeat the injection with another pre-filled pen.

STEP 13 Care for the injection site

- a. If a little bleeding occurs, treat the injection site by gently pressing, not rubbing, a cotton ball or gauze to the site and apply an adhesive bandage if needed.
- **Do not** rub the injection site.

STEP 14 Dispose of Avtozma®



- a. Put the used pre-filled pen in your sharps disposal container right away after use.

Note: If your injection is given by another person, this person must also be careful when removing the pre-filled pen and disposing of it to prevent accidental needle stick injury and passing infection.

- **Do not** re-use the pre-filled pen.
- **Do not** put the cap back onto the pre-filled pen.
- **Do not** dispose of your used sharps disposal container in your household trash.
- **Do not** recycle your used sharps disposal container.
- Keep the Avtozma® pre-filled pen and disposal container out of the reach of children.
- Dispose of the full container as instructed by your healthcare provider or pharmacist. If you do not have a sharps disposal container, you may use a household container that is closable and puncture resistant. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

STEP 15 Record your injection

- a. Write the date, time, and specific part of your body where you injected yourself.

Your Avtozma® pre-filled syringe

Giving Avtozma® with the Avtozma® pre-filled syringe

If your doctor has decided that you may inject your child using the Avtozma® pre-filled syringe there's no need to worry, you'll be fully trained by a healthcare professional so that you can give the injection confidently in the comfort of your own home.

Like many practical skills learning to use Avtozma® pre-filled syringe is just a matter of training and practice. Your doctor or nurse will not expect you to give the injection until they are confident that it is appropriate for you to do so.

Preparing to use the Avtozma® pre-filled syringe

Instructions on using Avtozma® pre-filled syringe can be found in this booklet, starting on page 31.

You should also refer to the Package Leaflet (Instructions for the Use of Avtozma® pre-filled syringe.) found in your Avtozma® package for more information.

It is important to always use Avtozma® exactly as prescribed by your healthcare professional. If you are unsure about how often you should be giving Avtozma® please check with your healthcare professional.

If you have any outstanding questions about Avtozma® pre-filled syringe and how to use it, please contact your doctor or nurse.



Please refer to the Package Leaflet inside the product carton for further information on Avtozma®, including usage instructions, a full list of side effects, warnings and precautions.

Storing Avtozma® pre-filled syringe



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 pre-filled syringe label and carton (EXP). The expiry date refers to the last day of that month.

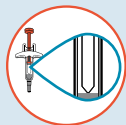


Store in a refrigerator (2°C – 8°C). **Do not freeze.**

Once removed from the refrigerator, the pre-filled syringe can be stored up to 3 weeks at or below 30°C.



Keep the pre-filled syringes in the outer carton in order to protect from light and moisture.



Do not use if the medicine is cloudy or contains particles, is any colour besides colourless to yellow, or any part of the pre-filled syringe appears to be damaged.



The syringe should not be shaken.

After removing the cap the **injection must be started within 5 minutes** to prevent the medicine from drying out and blocking the needle. If the pre-filled syringe is not used within 5 minutes of cap removal, you must dispose of it in a puncture resistant container and use a new pre-filled syringe.



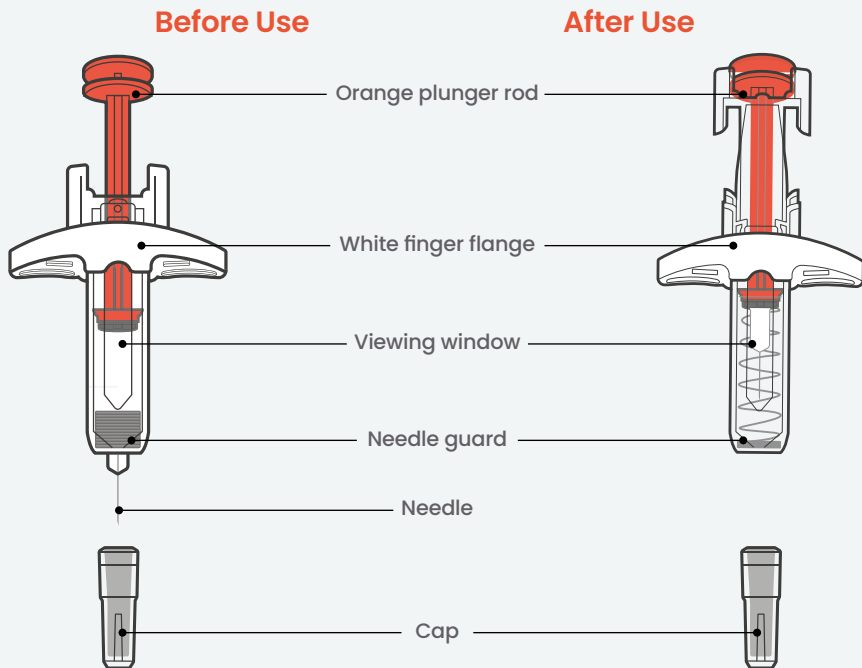
If following insertion of the needle, you cannot depress the plunger, you must dispose of the pre-filled syringe in a puncture resistant container and use a new pre-filled syringe.

The Avtozma[®] pre-filled syringe

Each Avtozma[®] pre-filled syringe contains the active ingredient tocilizumab (162 mg in 0.9 mL).

Avtozma[®] is a solution for injection. The solution is colourless to yellow.

Parts of your pre-filled syringe



Images not to scale: For illustration purposes only.



Click or scan the QR code to view 'How to inject using the Avtozma[®] pre-filled syringe' video and see the instructions on the following pages.

Dos & don'ts before the injection

DO



- ✓ Keep the pre-filled syringes in the outer carton to protect from light and moisture until ready for use
- ✓ Keep the cap on the pre-filled syringe until just before you give the injection
- ✓ After removing the cap start the injection within 5 minutes to prevent the medicine from drying out
- ✓ Read and follow the 'Instructions for Use' that come with the Avtozma® pre-filled syringe before you start using it and each time you get a prescription refill, as there may be new information

DON'T



- ✗ Do not try to take apart the pre-filled syringe at any time
- ✗ Do not reuse the same pre-filled syringe
- ✗ Do not shake the pre-filled syringe
- ✗ Do not use the pre-filled syringe if it has been dropped or damaged
- ✗ Do not remove the syringe cap until you are ready to inject Avtozma®



Important advice regarding hypersensitivity reactions (or anaphylaxis):

If your child develops symptoms such as, but not limited to, skin rash, itching, chills, swelling of face, lips, tongue or throat, chest pain, wheezing, difficulty breathing or swallowing or feeling dizzy or faint during or following an injection **seek emergency care immediately.**

Read and follow the 'Instructions for Use' that come with your Avtozma® pre-filled syringe before you start using it and each time you get a refill. There may be new information. Before you use Avtozma® pre-filled syringe, make sure your healthcare provider shows you the right way to use it.

Please refer to the Package Leaflet inside the product carton for further information on Avtozma®, including usage instructions, a full list of side effects, warnings and precautions.

How to inject using the Avtozma® pre-filled syringe

The following steps provide a guide to the administration procedure of Avtozma® pre-filled syringe for parents and carers of young patients prescribed Avtozma®.

This information does not take the place of talking to your healthcare professional about your child's medical condition or treatment.

Preparing for the injection

STEP 1

Gather the supplies for the injection



Carton containing pre-filled pen



Alcohol swab



Cotton ball or gauze



Adhesive bandage



Sharps disposal container

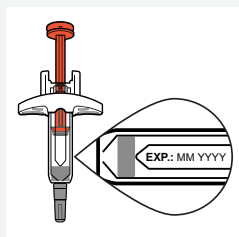
- a. Prepare a clean, flat surface, such as a table or countertop, in a well-lit area.
- b. Take the carton containing the pre-filled syringe out of the refrigerator.
- c. Make sure you have the following supplies.
 - Carton containing Avtozma® pre-filled syringe

Not included in the carton:

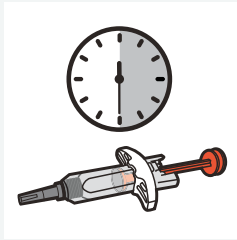
- Cotton ball or gauze.
- Adhesive bandage.
- Sharps disposal container.
- Alcohol swab.

STEP 2**Inspect the carton**

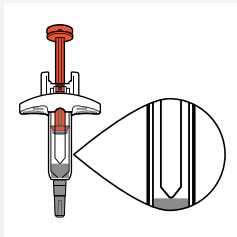
- a. Look at the carton and make sure you have the correct medicine and dose strength. (Avtozma®).
- b. Check the expiration date on the carton to make sure the date has not passed.
 - **Do not** use the pre-filled syringe if the expiration date has passed.
 - **Do not** use the pre-filled syringe if the carton looks like it has been opened or damaged if you are opening the carton for the first time and check to make sure that it is properly sealed.

STEP 3**Inspect the Pre-filled Syringe**

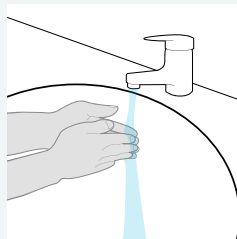
- a. Open the carton and remove 1 single-dose pre-filled syringe from the carton. Return any remaining Avtozma® pre-filled syringes in the carton to the refrigerator.
- b. Check the expiration date on the Avtozma® pre-filled syringe.
 - **Do not** use the pre-filled syringe if the expiration date has passed. If the expiration date has passed, safely dispose of the pre-filled syringe in your sharps disposal container and get a new one.
- c. Check the pre-filled syringe to make sure it is not damaged, and shows no sign of leakage.
 - **Do not** use the pre-filled syringe if it has been dropped, damaged, or has leaked.

STEP 4**Wait 30 minutes**

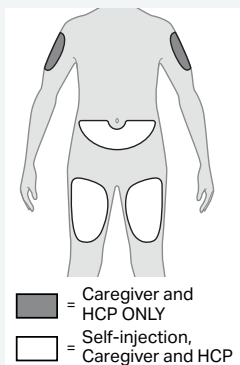
- a. Leave the pre-filled syringe outside of the carton at room temperature 20°C to 25°C for 30 minutes to allow it to warm up.
- **Do not** warm the pre-filled syringe using heat sources such as hot water or a microwave.
- **Do not** leave the pre-filled syringe in the direct sunlight.
- **Do not** remove the cap while allowing your pre-filled syringe to reach room temperature.
- If the pre-filled syringe does not reach room temperature, this could cause discomfort and make it hard to push the plunger.

STEP 5**Inspect the medication**

- a. Hold your Avtozma® with the cap pointing down.
- b. Look at the medicine and confirm that the liquid is clear to slightly opalescent and colourless to yellow and does not contain any particles or flakes.
- **Do not** use the pre-filled syringe if the liquid is discoloured, cloudy, or has particles or flakes in it. Safely dispose of the pre-filled syringe in a sharps disposal container and use a new one.
- Air bubbles are normal.

STEP 6**Wash your hands**

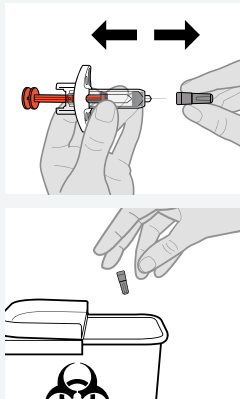
- a. Wash your hands with soap and water and dry them thoroughly.

STEP 7**Choose an appropriate injection site**

- a. You may inject into
- The front of the thighs.
 - The abdomen, except for the 5 cm around the belly button.
 - The outer area of the upper arm (only if you are a caregiver or healthcare professional (HCP)).
- **Do not** inject into the upper arm by yourself.
 - Choose a different injection site for each new injection at least 2.5 cm from the last area you injected.
 - **Do not** inject into moles, scars, bruises, or areas where the skin is tender, red, hard or not intact.

STEP 8**Clean the injection site**

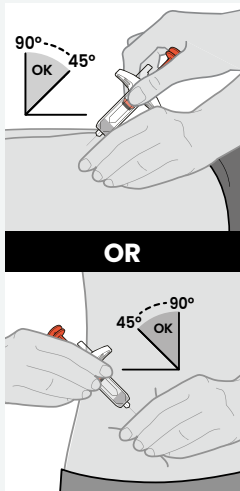
- a. Wipe the injection site with an alcohol swab and let it air dry. This will reduce the chance of getting an infection.
- **Do not** touch the injection site again before giving the injection.
 - **Do not** fan or blow on the clean area.

STEP 9**Remove the cap**

- a. Hold the pre-filled syringe by the syringe body using one hand. Gently pull the cap straight off with the other hand.

Note: If you cannot remove the cap, you should ask a caregiver for help or contact your healthcare provider

- **Do not** hold the plunger while removing the cap.
 - You may see a drop of liquid at the tip of the needle. This is normal.
 - If the pre-filled syringe is not used within 5 minutes of needle cap removal, the prefilled syringe should be disposed of in the puncture resistant container or sharps container and a new prefilled syringe should be used.
- b. Dispose of the cap right away in your sharps disposal container (see step 14 and Dispose of pre-filled syringe).
- **Do not** re-cap the pre-filled syringe.
 - **Do not** touch the needle shield at the tip of the pre-filled syringe to avoid accidental needle stick injury.

STEP 10**Insert the pre-filled syringe into the injection site**

- a. Gently pinch a fold of skin at the injection site with one hand.

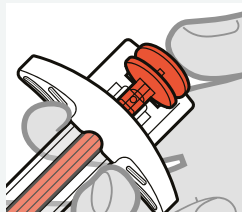
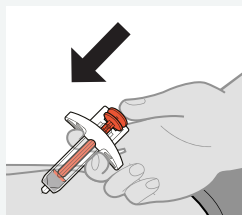
Note: Pinching the skin is important to make sure that you inject under the skin (into fatty tissue) but not any deeper (into muscle).

- **Do not** pull back on the plunger rod at any time.
- b. With a quick and “dart-like” motion, insert the Needle completely into the fold of skin at a 45 to 90-degree angle.

Note: It is important to use the correct angle to make sure the medicine is delivered under the skin (into fatty tissue), or the injection could be painful, and the medicine may not work.

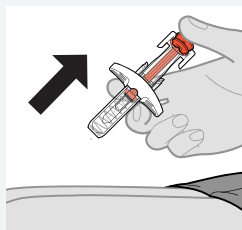
- **Do not** touch the plunger while inserting the needle into the skin.

STEP 11 Give the injection



- a. After the needle is inserted, release the pinch.
- b. Slowly push the plunger **all the way down** until the full dose of medicine gets injected, and the syringe is empty.
 - If the plunger cannot be depressed, discard the pre-filled syringe and use a new pre-filled syringe.
 - **Do not** change the position of the pre-filled syringe after the injection has started.
 - If the plunger is not fully pressed, the needle guard will not extend to cover the needle when it is removed.
 - If the needle is not covered, proceed carefully to dispose of the syringe (**see step 14. Dispose of pre-filled syringe**).

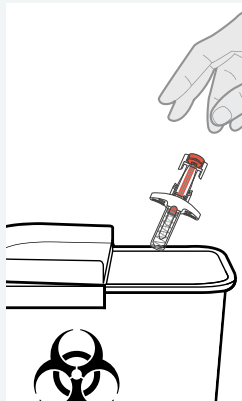
STEP 12 Remove the pre-filled syringe from the injection site



- a. After the pre-filled syringe is empty, remove the needle from the injection site and release the plunger until the entire needle is covered by the guard.
 - Some bleeding may occur (**see step 13. Care for the injection site**).
 - In case of skin contact with medicine, wash the area that touched the medicine with water.
 - Do not reuse the pre-filled syringe.

STEP 13 Care for the injection site

- a. If a little bleeding occurs, treat the injection site by gently pressing, not rubbing, a cotton ball or gauze to the site and apply an adhesive bandage if needed.
 - **Do not** rub the injection site.

STEP 14**Dispose of the pre-filled syringe.**

- a. Put the used pre-filled syringe in your sharps disposal container right away after use.

Note: If your injection is given by another person, this person must also be careful when removing the pre-filled syringe and disposing of it to prevent accidental needle stick injury and passing infection.

- **Do not** re-use the pre-filled syringe.
- **Do not** put the cap back onto the pre-filled syringe.
- **Do not** throw away (dispose of) your used sharps disposal container in your household trash.
- **Do not** recycle your used sharps disposal container.
- Keep the Avtozma® pre-filled syringe and disposal container out of the reach of children.
- Dispose of the full container as instructed by your healthcare provider or pharmacist. If you do not have a sharps disposal container, you may use a household container that is closable and puncture resistant. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

STEP 15**Record your injection**

- a. Write the date, time, and specific part of your body where you injected yourself.



Travelling with Avtozma®

Checklist before you travel

- ☐ If travelling by plane, check with the airline to see if there are any specific rules for travelling with medication to your destination
- ☐ Make sure you ask your healthcare provider in good time to prescribe enough Avtozma® to cover your child for the whole of your trip.
- ☐ Make sure you take enough medication with you for your whole trip plus extra in case of delays.
- ☐ Make sure you take your medication in its original packaging, in case you need to show it at customs
- ☐ If you are travelling abroad, remember to obtain a letter from your doctor explaining that you need to keep your medication with you in your hand luggage
- ☐ Because your medicine is sensitive to light and temperature, be sure to carry your medication with you in your hand luggage

Storing your Avtozma®

- Once removed from the refrigerator, Avtozma® must not be exposed to temperatures above 30 °C. Avtozma® must be stored in its original carton and used within 3 weeks. If not used within the 3 week period, Avtozma® should be discarded. For trips longer than 30 days, or if the destination you are going to may reach temperatures above 25°C, please speak to your healthcare professional.



FAQs

What should I do if I need to travel with Avtozma®?

If you plan to travel when your child's dose is due, speak to your doctor or nurse for guidance. If you are travelling abroad, they may give you a letter permitting you to travel with your child's medication, and this should be shown to security. If you are travelling and will complete your return journey in between your doses you do not need to take Avtozma® with you.

What will happen if I stop using Avtozma®?

You should not stop giving Avtozma® without discussing with your doctor first. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

Why have I been given the Avtozma® patient alert card?

Your doctor may give you a patient alert card which contains important safety information that you need to be aware of before giving Avtozma®. The patient alert card will be given to you by your doctor separately and is not part of this booklet.



Your Homecare service provider

- If your doctor decides that you may inject Avtozma® yourself, you might be assigned a homecare service.
- Record your homecare provider details here, if applicable:

Provider name:

Contact person:

Phone number:

Email address:

Service Hours:

Emergency Contact Number:

- It is important to remember the homecare service is for the supply of your medicine only. You should still attend all clinic appointments.

Keeping track of your Avtozma[®] injections

You can record your child's injections using the Avtozma[®] pre-filled pen or the Avtozma[®] pre-filled syringe on the following pages.

Avtozma[®] treatment starting date:

Doctor's contact details:

1

Injection site:

Injection date:

Note:

2

Injection site:

Injection date:

Note:

3

Injection site:

Injection date:

Note:

4

Injection site:

Injection date:

Note:

5

Injection site:

Injection date:

Note:

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Injection site:

Injection date:

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Injection site:

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Injection site:

Injection date:

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Injection site:

Injection date:

Note:

22

Injection site:

Injection date:

Note:



Please refer to the Package Leaflet inside the product carton for further information on Avtozma® including usage instructions, a full list of side effects, warnings and precautions. This booklet is not intended as a substitute for clinical advice provided by your healthcare professional. For any questions regarding your child's treatment, or for clinical advice, please contact your healthcare professional.