

Instructions for use

Tyenne® 162 mg

Solution for injection
in pre-filled syringe
tocilizumab
Subcutaneous use



Read these instructions for Use before using your Tyenne pre-filled syringe and each time you get a prescription refill.

Storing Tyenne pre-filled syringes

- Store the pre-filled syringe in its original carton in a refrigerator between 2°C and 8°C.
 - Keep the pre-filled syringe in the original carton to protect from light.
 - Keep the pre-filled syringe out of the reach and sight of children.
- Do not** freeze Tyenne.
- Do not** use Tyenne pre-filled syringe that has been frozen or left in direct sunlight because it could lead to illness.

Using Tyenne pre-filled syringe

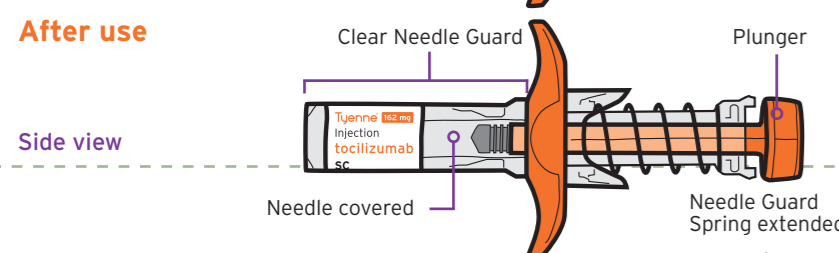
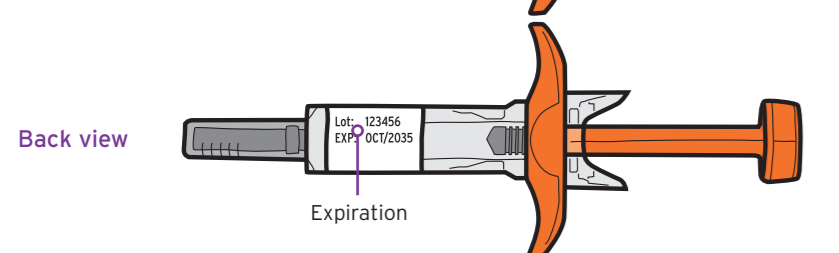
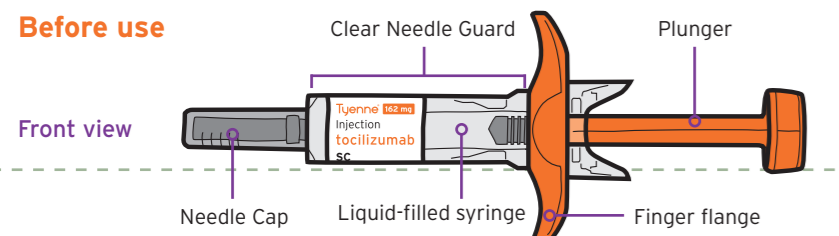
- Always inject Tyenne using the technique your doctor taught you.
 - Tyenne pre-filled syringe is for single-dose (one-time) use only.
- Do not** share your Tyenne pre-filled syringe with another person. You may give another person an infection or get an infection from them.
- Tyenne pre-filled syringe has a clear needle guard that covers the needle after the injection is complete.
- Do not** use the pre-filled syringe if the carton is open or damaged.
- Do not** use the pre-filled syringe if it has been dropped on a hard surface.
- The pre-filled syringe may be broken even if you cannot see the break.
- Do not** remove the needle cap from the pre-filled syringe until you are ready to inject.
- Do not** try to reuse the pre-filled syringe because it could lead to an infection.

Travelling with Tyenne pre-filled syringe

- If needed, for example when traveling, Tyenne pre-filled syringe can be stored at room temperature (up to 30°C) for up to 14 days.
- Throw away (dispose of) Tyenne that has been kept at room temperature (up to 30°C) and not been used within 14 days.
- When travelling on an airplane, always check with your airline and your doctor about bringing injectable medicine with you. Always carry Tyenne in your carry-on luggage because the aircraft luggage area can be very cold and Tyenne could freeze.

Your Tyenne pre-filled syringe

Before use



Do not try to activate the clear needle guard before injecting.



STEP 1 Prepare for your injection

- 1.1 Prepare a clean, flat surface, such as a table or counter top, in a well-lit area.
- 1.2 Supplies needed (Figure B):
 - 1 alcohol swab to clean the site before injection
 - 1 sterile cotton ball or gauze to use after the injection
 - 1 sharps disposal container for safe disposal of needle cap and used syringe (see Step 7 "Throw away your syringe").

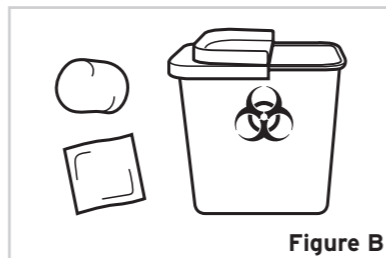


Figure B

- 1.3 Take the Tyenne carton out of the refrigerator and open it (Figure C).

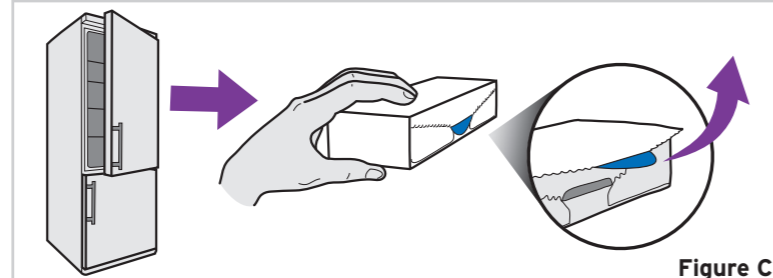


Figure C

- 1.4 Remove Tyenne plastic tray out of the carton:
 - Put the plastic tray with the pre-filled syringe on a clean flat surface.

- 1.5 Let the pre-filled syringe in its plastic tray sit at room temperature for at least 30 minutes before use to allow the medicine to reach room temperature (Figure D). Injecting cold medicine can cause your injection to feel uncomfortable and make it difficult to push the plunger in.



Figure D

Do not speed up the warming process in any way, such as in a microwave, or placing the syringe in hot water, or direct sunlight.

Do not remove the needle cap while allowing your Tyenne pre-filled syringe to reach room temperature.

- 1.6 Prepare and check your records of previous injection sites. This will help you choose the appropriate injection site for this injection (see Step 8 "Record your injection").

STEP 2 Wash your hands

- 2.1 Wash your hands well with soap and water and dry them with a clean towel (Figure E).



Figure E

STEP 3 Check the syringe

Remove Tyenne pre-filled syringe from the plastic tray

- Place two fingers on either side, in the middle of the clear needle guard.
- Pull the pre-filled syringe straight up and out of the tray (Figure F).

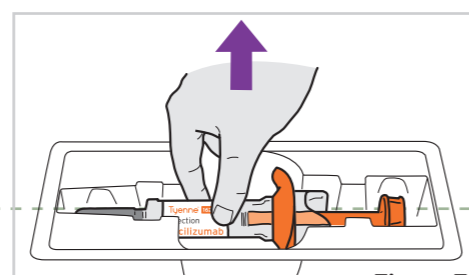


Figure F

Do not pick up the pre-filled syringe by the plunger or the needle cap. Doing so could damage the pre-filled syringe or activate the clear needle guard.

- 3.1 Check the pre-filled syringe to make sure that:
 - The pre-filled syringe, the clear needle guard, and the needle cap are not cracked or damaged (Figure G).
 - The needle cap is securely attached (Figure H).
 - The needle guard spring is not extended (Figure I).

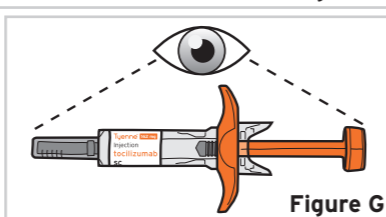


Figure G

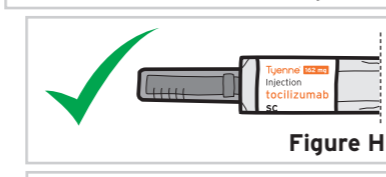


Figure H

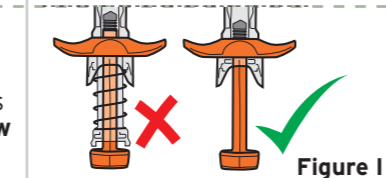


Figure I

Do not use the syringe if it shows any sign of damage. If damaged, call your doctor or pharmacist right away and throw away the syringe in your sharps disposal container (see Step 7 "Throw away your syringe").

- 3.2 Check the liquid through the clear window of the syringe to make sure that:
 - The liquid is clear and colorless to pale yellow, and free of particles and flakes (Figure J).

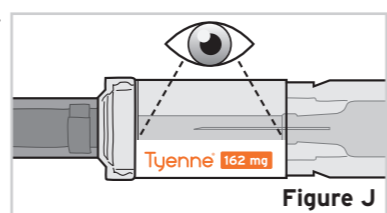


Figure J

Do not use the pre-filled syringe if the liquid is cloudy, discolored, contains particles or flakes, or shows any sign of damage. If the liquid is cloudy, discolored, contains particles or flakes, call your doctor or pharmacist right away and throw away the syringe in your sharps disposal container (see Step 7 "Throw away your syringe").

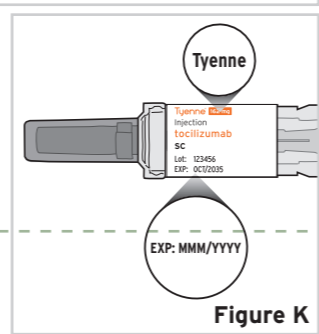


Figure K

- 3.3 Check the label on the pre-filled syringe to make sure that:
 - The name on the pre-filled syringe says Tyenne (Figure K).
 - The expiration date (EXP:) on the pre-filled syringe has not passed (Figure K).

Do not use the pre-filled syringe if:

- The name on the pre-filled syringe is not Tyenne.
- The expiration date on the pre-filled syringe has passed.

If the label does not have Tyenne on it or the expiration date has passed contact your doctor or pharmacist right away and throw away the pre-filled syringe in your sharps disposal container (see Step 7 "Throw away your syringe").

STEP 4 Choose the injection site

- 4.1 Choose an injection site (Figure L):
 - The front of the thighs, or
 - Stomach area (lower abdomen), except for 5 cm around the navel (belly button).
 - If you are injecting someone else, you may use the back of the arm (Figure M).

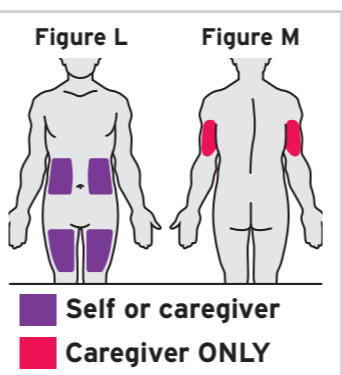


Figure L

Figure M

Do not attempt to use the upper arm area by yourself. Only inject into the sites shown.

- 4.2 Choose a different injection site (at least 3 cm from the last area you injected) for each new injection to reduce redness, irritation or other skin problems.

Do not inject into an area that is sore (tender), bruised, red, hard, scarred or where you have stretch marks, moles or tattoos.

If you have psoriasis, **do not** inject into any lesions or red, thick, raised or scaly patches.

STEP 5 Clean the injection site

- 5.1 Wipe the skin of your injection site with an alcohol swab in a circular motion to clean it (Figure N). Let the skin dry before injecting.
- Do not** blow or touch the injection site after cleaning.



Figure N

STEP 6 Give your injection

- 6.1 Remove the needle cap
 - Hold the pre-filled syringe by the clear needle guard in one hand (Figure O).
 - Use your other hand to remove the needle cap by pulling the cap straight off (Figure O).

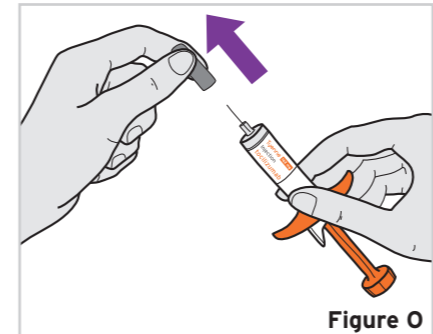


Figure O

Do not hold the plunger while you remove the needle cap.

If you cannot remove the needle cap, you should ask a caregiver for help or contact your doctor.

- Throw away the needle cap in your sharps container.

You may see drops of liquid at the needle tip. This is normal and will not affect your dose.

Do not touch the needle or let it touch any surface after removing the needle cap, because this might cause an accidental needle stick.

- 6.2 Pinch the skin
 - With your free hand, gently pinch around the area where you plan to inject (without squeezing or touching the cleaned area) and hold it firmly to avoid injecting into muscle (Figure P). Injection into muscle could cause the injection to feel uncomfortable.

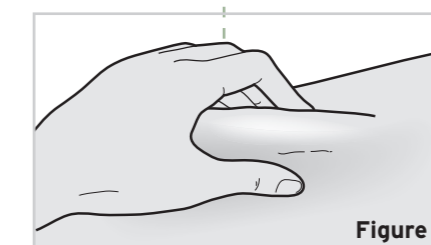


Figure P

- 6.3 Insert the needle
 - Hold the pre-filled syringe like a pencil.
 - With a quick, short motion, insert the needle all the way into the pinched skin at an angle between 45° to 90° (Figure Q). Give the injection at the angle your doctor instructed you to use.

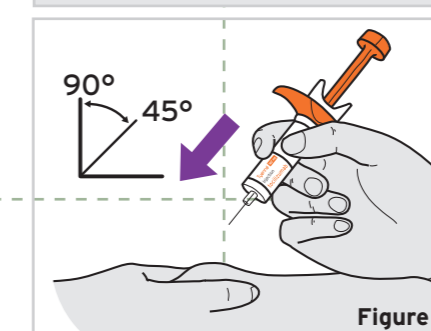


Figure Q

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.

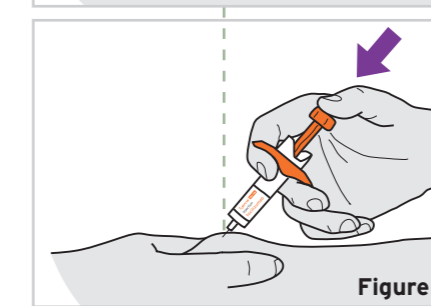


Figure R

- 6.4 Inject
 - Use your thumb to gently push the plunger all the way down (Figure R).
 - Keep pressing down on the plunger to deliver the full dose until you cannot press any more (Figure S).
- Do not** pull the needle out of the skin when the plunger is pushed all the way

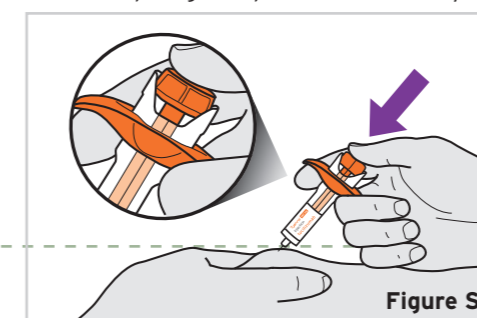


Figure S

down.

- 6.5 Finish injection
 - Hold the syringe firmly without moving it, at the same angle as inserted.
 - Slowly release your thumb off the plunger. The plunger will move up. The safety system will remove the needle from the skin and cover the needle (Figure T).
 - Release the pinched skin

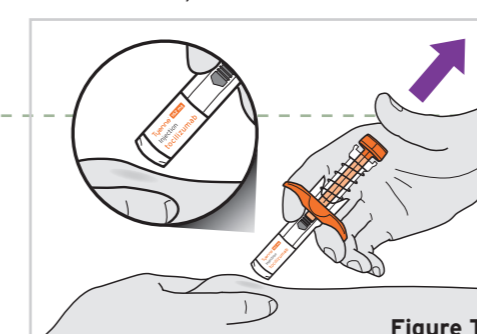


Figure T

Important: Call your doctor right away if:

- The clear needle guard does not cover the needle after injecting.

Injecting an incorrect amount of medicine could affect your treatment.

Do not reuse a syringe even if all of the medicine was not injected.

Do not try to recap the needle as it could lead to needle stick injury.

- 6.6 After injection

If there is blood or liquid on the injection site, gently press a cotton ball or gauze on the skin (Figure U). You may use an adhesive bandage if needed.

Do not rub the injection site.

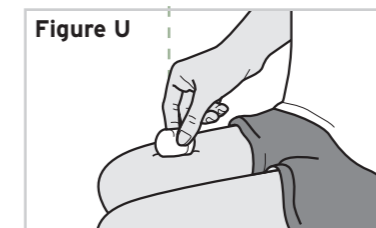


Figure U

STEP 7 Throw away used pre-filled syringe

- 7.1 Put your used syringe in a sharps disposal container right away after use (Figure V).

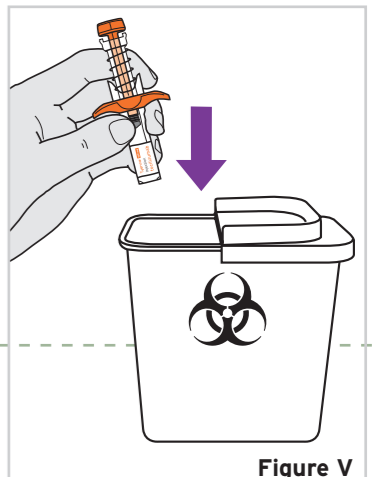


Figure V

If you do not have a sharps disposal container, you may use a household container that is:

- Made of a heavy-duty plastic;
- Can be closed with a tight-fitting, puncture-resistant lid; that will keep sharps from coming out,
- Upright and stable during use,
- Leak-resistant and
- Properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your local guidelines to dispose of your sharps disposal container. **Do not** throw away (dispose of) used syringes in your household trash.

Do not dispose of your used sharps disposal container in your household trash unless your local guidelines permit this.

Do not recycle your used sharps disposal container.

Keep Tyenne pre-filled syringes and disposal container out of the reach and sight of children.



- Read the Patient Information that comes with your Tyenne pre-filled syringe for important information you need to know before using it.
- Before you use Tyenne pre-filled syringe for the first time, make sure your doctor shows you or your caregiver the right way to use it. Note that the syringe comes in an opened plastic tray.
- People who are blind or have vision problems should not use the Tyenne pre-filled syringe without help from a person trained to use the Tyenne pre-filled syringe.
- Talk to your doctor if you have any questions or concerns.

Important information

Tyenne® 162 mg

Solution for injection in pre-filled syringe

tocilizumab

Subcutaneous use



STEP 8 Record your injection

- 8.1 To help you remember when and where to give your next injection, write the date, time, and specific part of your body where you injected yourself (Figure W).

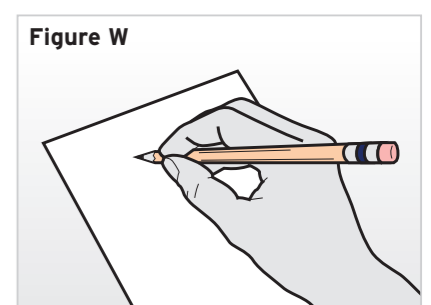


Figure W

It may also be helpful to write any questions or concerns about the injection, so you can ask your doctor.

If you have questions or concerns about your Tyenne pre-filled syringe, please contact your doctor familiar with Tyenne.



Package leaflet: Information for the user

 **Tyenne** 162 mg

Solution for injection in pre-filled syringe

tocilizumab

Subcutaneous use

▼ 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 the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it onto 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In addition to this leaflet, you will be given a **Patient Alert Card**, which contains important safety information that you need to be aware of before and during treatment with Tyenne.

What is in this leaflet

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

1. What Tyenne is and what it is used for

Tyenne contains the active substance tocilizumab, which is a protein made from specific immune cells (monoclonal antibody), that blocks the action of a specific protein (cytokine) called interleukin-6. This protein is involved in inflammatory processes of the body, and blocking it can reduce the inflammation in your body. Tyenne is used to treat:

- **adults with moderate to severe active rheumatoid arthritis (RA)**, an autoimmune disease, if previous therapies did not work well enough.
- **adults with severe, active and progressive rheumatoid arthritis (RA)**, who have not had previous treatment with methotrexate.
- Tyenne helps to reduce RA symptoms such as pain and swelling in your joints, and can also improve your performance of daily tasks. Tyenne has been shown to slow the damage to the cartilage and bone of the joints caused by the disease and to improve your ability to do normal daily activities.
- Tyenne is usually given in combination with another medicine for RA called methotrexate. However, Tyenne can be given alone if your doctor determines that methotrexate is inappropriate.
- **adults with a disease of the arteries called giant cell arteritis (GCA)**, caused by inflammation of the body's largest arteries, especially those that supply blood to the head and neck. Symptoms include headache, fatigue (tiredness) and jaw pain. Effects can include strokes and blindness.

Tyenne can reduce pain and swelling in the arteries and veins in your head, neck and arms.

GCA is often treated with medicines called steroids. They are usually effective, but can have side effects if used at high doses for a long time. Reducing the steroid dose can also lead to a flare-up of the GCA. Adding Tyenne to the treatment means that steroids can be used for a shorter time, while still controlling the disease.

- **children and adolescents, aged 1 year and over**, with active **systemic juvenile idiopathic arthritis (sJIA)**, an inflammatory disease that causes pain and swelling in one or more joints as well as fever and rash.

Tyenne is used to improve the symptoms of sJIA. It can be given in combination with methotrexate or alone.

- **children and adolescents, aged 2 years and over**, with active **polyarticular juvenile idiopathic arthritis (pJIA)**. This is an inflammatory disease that causes pain and swelling in one or more joints.

Tyenne is used to improve the symptoms of pJIA. It can be given in combination with methotrexate or alone.

2. What you need to know before you use Tyenne

Do not use Tyenne

- if you or a child patient you look after are allergic to tocilizumab or any of the other ingredients of this medicine (listed in section 6).
- if you or a child patient you look after have an active, severe infection. If either of these applies to you, tell a doctor. Do not use Tyenne.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Tyenne.

- If you experience **allergic reactions** such as chest tightness, wheezing, severe dizziness or lightheadedness, swelling of the lips, tongue, face or skin itching, hives or rash during or after the injection, then **tell your doctor immediately**.

Do not take the next dose until you have informed your doctor AND your doctor has told you to take the next dose if you have experienced any allergic reaction symptoms after Tyenne administration.

If you have any kind of **infection**, short- or long-term, or if you often get infections. **Tell your doctor immediately** if you feel unwell. Tyenne can reduce your body's ability to respond to infections and may make an existing infection worse or increase the chance of getting a new infection.

If you have had **tuberculosis**, tell your doctor. Your doctor will check for signs and symptoms of tuberculosis before starting Tyenne. If symptoms of tuberculosis (persistent cough, weight loss, listlessness, mild fever) or any other infection appear during or after therapy tell your doctor immediately.

If you have **had intestinal ulcers or diverticulitis**, tell your doctor. Symptoms would include abdominal pain and unexplained changes in bowel habits with a fever.

If you have **liver disease**, tell your doctor. Before you use Tyenne, your doctor may do a blood test to measure your liver function.

If any patient has recently been vaccinated, or is planning a vaccination, tell your doctor. All patients should be up-to-date with all their vaccinations before they start treatment with Tyenne. Certain types of vaccines should not be given while receiving Tyenne.

If you have **cancer**, tell your doctor. Your doctor will have to decide if you can still be given Tyenne.

If you have **risk factors for heart disease** such as raised blood pressure and raised cholesterol levels, tell your doctor. These factors need to be monitored while receiving Tyenne.

If you have moderate to severe **kidney function problems**, your doctor will monitor you.

If you have **persistent headaches**.

Your doctor will perform a blood test before you receive Tyenne, to determine if you have a low white blood cell count, low platelet count or high liver enzymes.

Children and adolescents

Tyenne pre-filled syringe is not recommended for use in children under 1 year of age.

Tyenne must not be given to children with sJIA (systemic juvenile idiopathic arthritis) weighing less than 10 kg.

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

Other medicines and Tyenne

Tell your doctor if you are taking any other medicines, or have recently taken any. Tyenne can affect the way some medicines work, and the dose of these may require adjustment. If you are using 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 (such as amlodipine), used to treat high blood pressure
 - theophylline, used to treat asthma
 - warfarin or phenprocoumon, used as a blood thinning agents
 - phenytoin, used to treat convulsions
 - ciclosporin, used to suppress your immune system during organ transplants
 - benzodiazepines (such as temazepam), used to relieve anxiety
- Regarding vaccinations, please see the section on warnings above. Due to lack of clinical experience, Tyenne is not recommended for use with other biological medicines for the treatment of RA, sJIA, pJIA or GCA.

Pregnancy and breast-feeding

Tyenne is not to be used in pregnancy unless clearly necessary. Talk to your doctor if you are pregnant, may be pregnant, or intend 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 Tyenne, and talk to your doctor. Leave a gap of at least 3 months after your last treatment before you start breast-feeding. It is not known whether Tyenne passes into breast milk.

Driving and using machines

This medicine can cause dizziness. If you feel dizzy, do not drive or use machines.

Tyenne contains sodium

This medicinal product contains less than 1 mmol of sodium (23 mg) per 0.9 mL dose, that is to say essentially 'sodium-free'.

Tyenne contains polysorbate 80

This medicinal product contains 0.18 mg of polysorbate 80 in each 162 mg/0.9 mL syringe, which is equivalent to 0.2 mg/mL. Polysorbates may cause allergic reactions. Tell your doctor if you have or your child has any known allergies.

3. How to use Tyenne

Always use this medicine exactly as your doctor, pharmacist or nurse has told you. You should check with your doctor, pharmacist or nurse if you are not sure.

The treatment will be prescribed and started by healthcare professionals experienced in the diagnosis and treatment of RA, sJIA, pJIA or GCA.

Adults with RA or GCA

The recommended dose for RA (rheumatoid arthritis) and GCA (giant cell arteritis) for adults is 162 mg (the content of 1 pre-filled syringe) given once a week.

Children and adolescents with sJIA (aged 1 year and over)

The usual dose of Tyenne depends on the patient's weight.

- If the patient weighs **less than 30 kg**: the dose is 162 mg (the content of 1 pre-filled syringe) once every 2 weeks
- If the patient weighs **30 kg or more**: the dose is 162 mg (the content of 1 pre-filled syringe) once every week

Children and adolescents with pJIA (aged 2 and over)

The usual dose of Tyenne depends on the patient's weight.

- If the patient weighs **less than 30 kg**: the dose is 162 mg (the content of 1 pre-filled syringe), once every 3 weeks
- If the patient weighs **30 kg or more**: the dose is 162 mg (the content of 1 pre-filled syringe), once every 2 weeks.

Tyenne is given by injection under the skin (subcutaneously). At the start, your doctor or nurse may inject Tyenne. However, your doctor may decide that you may inject Tyenne yourself. In this case you will get training on how to inject Tyenne yourself. Parents and carers will get training on how to inject Tyenne for patients who cannot inject themselves, such as children.

Talk to your doctor if you have any questions about giving yourself or a child patient you look after an injection. You will find detailed "Instructions for administration" at the end of this leaflet.

If you use more Tyenne than you should

Because Tyenne is given in one pre-filled syringe, it is unlikely that you will receive too much. However, if you are worried, talk to your doctor, pharmacist or nurse.

If an adult with RA or GCA or a child or adolescent with sJIA misses or forgets a dose, it is very important to use Tyenne exactly as prescribed by your doctor. Keep track of your next dose.

- If you miss your weekly dose within 7 days, take your dose on the next scheduled day.
- If you miss your once every 2 weeks dose within 7 days, inject a dose as soon as you remember and take your next dose at your regular scheduled time.
- If you miss your dose by more than 7 days, or you are not sure when to inject Tyenne, call your doctor or pharmacist.

If a child or adolescent with pJIA misses or forgets a dose

It is very important to use Tyenne exactly as prescribed by the doctor. Keep track of the next dose.

- 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 Tyenne, call the doctor or pharmacist.

If you stop using Tyenne

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

4. Possible side effects

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

Possible serious side effects: tell a doctor straight away.

These are common: they may affect up to 1 in 10 people

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:

- fever and chills
- mouth or skin blisters
- stomach ache

Signs and symptoms of liver toxicity

These may affect up to 1 in 1 000 people

- tiredness,
- abdominal pain,
- jaundice (yellow discolouration of skin or eyes)

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

Very common side effects:

These may affect 1 in 10 people 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:

These may affect up to 1 in 10 people

- 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).

Uncommon side effects:

These may affect up to 1 in 100 people

- diverticulitis (fever, nausea, diarrhoea, constipation, stomach pain)
- red swollen areas in the mouth
- high blood fat (triglycerides)
- stomach ulcer
- kidney stones
- underactive thyroid.

Rare side effects:

These may affect up to 1 in 1 000 people

- Stevens-Johnson syndrome (skin rash, which may lead to severe blistering and peeling of the skin)
- fatal allergic reactions (anaphylaxis [fatal])
- inflammation of the liver (hepatitis), jaundice

Very rare side effects:

These may affect up to 1 in 10 000 people

- low counts for white blood cells, red blood cells and platelets in blood tests.

- liver failure

Additional side effects in children and adolescents with sJIA or pJIA

Side effects in children and adolescents with sJIA or pJIA 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 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 Tyenne

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.

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

Pre-filled syringes may be stored at room temperature (up to 30°C) for a single period of up to 14 days. The pre-filled syringes must be protected from light, and discarded if not used within the 14 day period at room temperature (up to 30°C) or by the original expiry date, whichever is earlier.

Do not use if the medicine is cloudy or contains particles, is any colour besides colourless to pale 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 right away to prevent the medicine from drying out and blocking the needle. If the pre-filled syringe is not used right away after 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.

6. Contents of the pack and other information

What Tyenne contains

The active substance is tocilizumab

- Each pre-filled syringe contains 162 mg tocilizumab in 0.9 mL.

The other ingredients are L-arginine, L-histidine, L-lactic acid, sodium chloride, polysorbate 80 (E 433), hydrochloric acid (E 507) and/or sodium hydroxide (E 524), water for injections. Regarding sodium and polysorbate 80, please see section 2 "Tyenne contains sodium" and "Tyenne contains polysorbate 80" above.

What Tyenne looks like and contents of the pack

Tyenne is a solution for injection. The solution is clear and colourless to pale yellow.

Tyenne is supplied as a 0.9 mL pre-filled syringe containing 162 mg tocilizumab solution for injection.

Each pack contains 1, 4 or 12 pre-filled syringes. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Fresenius Kabi Limited
Cestrian Court
Eastgate Way, Manor Park
Runcorn, Cheshire, WA7 1NT
United Kingdom

Manufacturer

Fresenius Kabi Austria GmbH
Hafnerstrasse 36 B055 Graz Austria

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