

Instruction for use

Tyenne[®] 162 mg

Solution for injection
in pre-filled pen

tocilizumab

Subcutaneous use

Read these instructions carefully before using your Tyenne pre-filled pen.

Read and follow the Instructions for Use that come with your Tyenne pre-filled pen before you start using it and each time you get a refill. There may be new information. This information does not replace talking to your doctor about your medical condition or treatment.

If you have any questions about using your Tyenne pre-filled pen, please call your doctor .

Important information

- Read the patient information that comes with your pre-filled pen for important information you need to know before using it.
- Before you use the pre-filled pen for the first time, make sure your doctor shows you the right way to use it.
- **Do not** try to take apart the Tyenne pre-filled pen at any time.
- Always inject Tyenne the way your doctor taught you to.

Using the Tyenne pre-filled pen

- The pre-filled pen is for self-injection or administration with the help of a caregiver.
- The pre-filled pen is for use at home.
- **When injecting Tyenne, children may self-inject if both the doctor and caregiver find it appropriate.**
- **Do not** reuse the pre-filled pen. The pre-filled pen is for single-dose (1-time) use only.
- **Do not** share your pre-filled pen with another person. You may give another person an infection or get an infection from them.
- **Do not** remove the pre-filled pen clear cap until you are ready to inject.
- **Do not** use the pre-filled pen if it shows any signs of damage or if it has been dropped.

Storing Tyenne pre-filled pens

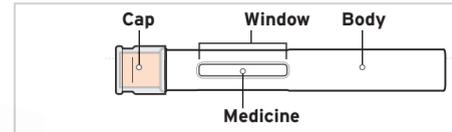
- Store Tyenne in the refrigerator between 2°C to 8°C.
- Store unused pre-filled pens in the original carton to protect from light.
- **Do not** freeze. If Tyenne freezes, throw it away in a sharp disposal container.
- Keep Tyenne out of exposure to heat or direct sunlight.
- Keep the pre-filled pen out of reach and sight of children.
- Tyenne may be stored at room temperature between 20°C to 25°C in the carton it comes in for up to 14 days.
- Throw away (dispose of) Tyenne in a sharp disposal or puncture-resistant container if it has been out of the refrigerator more than 14 days. Once stored at room temperature, do not place back in the refrigerator.

Travelling with Tyenne pre-filled pen

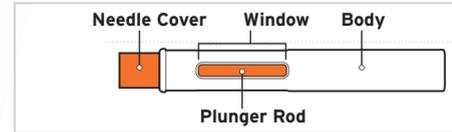
- When travelling on an airplane, always check with your airline and your doctor about bringing injectable medicine with you. Always carry Tyenne in your carry-on luggage because the aircraft luggage area can be very cold and Tyenne could freeze.

Your Tyenne pre-filled pen

Before Use

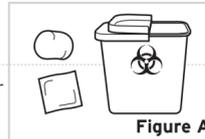


After Use

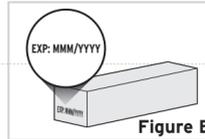


STEP 1 Prepare for your injection

- 1.1 Prepare a clean, flat surface, such as a table or counter top, in a well-lit area.
- 1.2 Gather the following supplies (not included) (see **Figure A**):
 - A sterile cotton ball or gauze
 - An alcohol swab
 - A sharps disposal container (see Step 8, "Throw away your pre-filled pen").

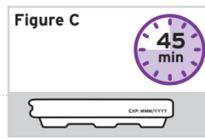


- 1.3 Remove the carton containing the pre-filled pen from the refrigerator. **Do not** keep your pre-filled pen out of the refrigerator for more than 14 days without use.
- 1.4 Check the expiration date on the carton to make sure the date has not passed (see **Figure B**). **Do not** use the pre-filled pen if the expiration date has passed.

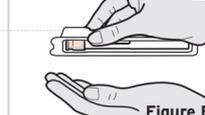
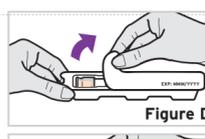


- 1.5 Remove the sealed tray from the carton. Check the sealed tray for any signs of damage, and make sure the expiration date on the tray has not passed. **Do not** use the pre-filled pen if the expiration date has passed, because it may not be safe. **Do not** use the pre-filled pen if the tray looks **damaged** or like it has been **opened**.

- 1.6 Let the sealed tray sit on the prepared surface for 45 minutes before use to allow the medicine in the pre-filled pen to reach room temperature (see **Figure C**). **Note:** Not doing so could cause your injection to feel uncomfortable and it could take longer to inject. **Do not** warm in any other way, such as in a microwave, hot water, or direct sunlight. **Keep Tyenne out of the reach of children.**



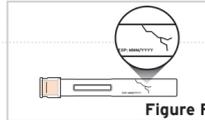
- 1.7 Peel the seal off of the tray (see **Figure D**), and invert the tray to remove the single-use pre-filled pen (see **Figure E**). **Do not** remove the clear cap of the pre-filled pen until you are ready to inject to avoid injury.



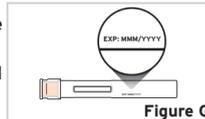
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STEP 2 Check your pre-filled pen

- 2.1 Check the pre-filled pen to make sure it is not cracked or damaged (see **Figure F**). **Do not** use if the pre-filled pen shows signs of damage or if it has been dropped.

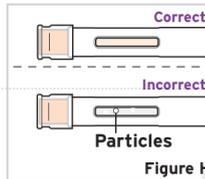


- 2.2 Check the pre-filled pen label to make sure that:
 - The name on the pre-filled pen says **Tyenne**
 - The expiration date (EXP) on the pre-filled pen has not passed (see **Figure G**).



Do not use the pre-filled pen if the name on the label is not Tyenne or the expiration date on the label has passed.

- 2.3 Look at the medicine in the viewing window. Make sure it is **clear and colorless to pale yellow** and does not contain flakes or particles (see **Figure H**). **Note:** Air bubbles in the medicine are normal. **Do not** inject if the liquid is cloudy, discolored, or has lumps or particles in it because it may not be safe to use.



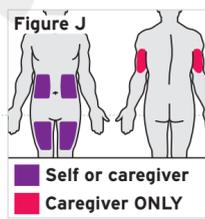
STEP 3 Wash your hands

- 3.1 Wash your hands well with soap and water, then dry them with a clean towel (see **Figure I**).



STEP 4 Choose the injection site

- 4.1 If you are giving yourself the injection, you can use:
 - The front of your upper thigh
 - The abdomen, except within 5 cm around the belly button (navel)
 - If a caregiver is giving the injection, they can use the outer area of the upper arm (see **Figure J**).



Note: Choose a different site for each injection to reduce redness, irritation or other skin problems. **Do not** inject into skin that is sore (tender), bruised, red, hard, scaly, or has lesions, moles, scars, or stretch marks or tattoos. **Do not** use the pre-filled pen through clothing.

STEP 5 Clean the injection site

- 5.1 Wipe the skin where you want to inject with an alcohol swab to clean it (see **Figure K**). Let the skin dry. **Do not** blow on or touch the site after cleaning.



Continue →

STEP 6 Give your injection

- 6.1 When you are ready to inject, hold the pre-filled pen in one hand with the clear cap on top, pointing straight up. Using your other hand, firmly pull the clear cap straight off without twisting (see **Figure L**).



Note: Use the pre-filled pen **right away** after removing the cap to avoid contamination. **Do not** try to recap the needle at any time, even at the end of the injection. **Do not** touch the needle cover (the orange part located at the tip of the pre-filled pen) because this might cause an accidental needle stick.

- 6.2 Throw away the clear cap.
- 6.3 Rotate the pre-filled pen so that the orange needle cover points downwards.
- 6.4 Position your hand on the pre-filled pen so that you can see the window.

- 6.5 Place the pre-filled pen against your skin at a 90-degree (straight) angle (see **Figure M**). **Note:** To make sure you inject under the skin (into fatty tissue), **do not** hold the pre-filled pen at an angle.



Note: You **do not** need to pinch your skin. **To make sure you inject the full dose, read all of the steps from 6.6 to 6.9 before you start:**

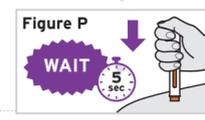
- 6.6 In a single motion, push the pre-filled pen firmly against your skin until you hear a **first click**. The orange plunger rod will move through the window during the injection (this means the injection has started) (see **Figure N**).



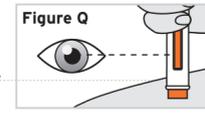
- 6.7 **WAIT** and hold the pre-filled pen in place until you hear a **second click**. This may take up to 10 seconds. Continue to **HOLD** (see **Figure O**).



- 6.8 Wait and slowly count to 5 after you hear the second click. Continue to **HOLD** the pre-filled pen in place to make sure you inject a full dose (see **Figure P**). **Do not** lift the pre-filled pen until you are sure 5 seconds has passed, and the injection is complete.



- 6.9 While holding the pre-filled pen in place, check the window to make sure the orange plunger rod has fully appeared in the viewing window, and has stopped moving (see **Figure Q**).

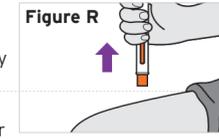


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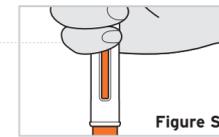
Note: If the orange plunger rod did not come all the way down or you believe you did not get a full injection, call your doctor. **Do not** try to repeat the injection with a new pre-filled pen.

STEP 7 Remove and check the pre-filled pen

- 7.1 When the injection is complete, lift the pre-filled pen straight away from your skin (see **Figure R**). **Note:** The needle cover will slide down and cover the needle. **Do not** recap the pre-filled pen.



- 7.2 Check the window to make sure the orange plunger rod came all the way down (see **Figure S**). **Note:** If the orange plunger rod did not come all the way down or you believe you did not get a full injection, call your doctor. **Do not** try to repeat the injection with a new pre-filled pen.



- 7.3 If you see blood on the injection site, press gauze or a cotton ball against the skin until the bleeding stops (see **Figure T**). **Do not** rub the injection site.



STEP 8 Throw away your pre-filled pen

- 8.1 Put your used pre-filled pen in a sharps disposal container right away after use (see **Figure U**). **Do not** put the clear cap back on the pre-filled pen. **Do not** throw away (dispose of) your pre-filled pen in your household trash. **Do not** reuse the pre-filled pen. If you **do not** have a sharps disposal container, you can use a household container that is:



- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come 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 for the right way to dispose of your sharps disposal container.

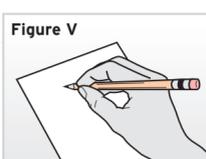
Do not throw away (dispose of) your used sharps disposal container in your household trash unless your local guidelines permit this. **Do not** recycle your used sharps disposal container.

Always keep the sharps disposal container out of reach of children.

STEP 9 Record your injection

- 9.1 Record your injection date and site (see **Figure V**).

Note: This is to help you remember when and where to do your next injection.



Subcutaneous use
tocilizumab
Injection
Tyenne[®] 162 mg

Tyenne[®] 162 mg

Injection
tocilizumab
Subcutaneous use

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Injection tocilizumab SC

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 12 years 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 12 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 pen is not recommended for use in children under 12 years 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

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) or GCA (giant cell arteritis) for adults is 162 mg (the content of 1 pre-filled pen) given once a week.

Adolescents with sJIA (aged 12 years 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 pen) once every 2 weeks
- If the patient weighs **30 kg or more**: the dose is 162 mg (the content of 1 pre-filled pen) once every week

Adolescents with pJIA (aged 12 years 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 pen), once every 3 weeks
- If the patient weighs **30 kg or more**: the dose is 162 mg (the content of 1 pre-filled pen), 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.

Talk to your doctor if you have any questions about giving yourself or an adolescent 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 pen, 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 an 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 other week 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 weekly or once every other week dose by more than 7 days, or you are not sure when to inject Tyenne, call your doctor or pharmacist.

If an 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 1000 people

- tiredness,
- abdominal pain,
- jaundice (yellow discoloration 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 1000 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 10000 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRa Pharmacovigilance

Website: www.hpra.ie

UK

Yellow Card Scheme Website: www.mhra.gov.uk/ yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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 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.

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

A single or pre-filled pen may be stored at temperatures up to a maximum of 25°C for a single period of up to 14 days. The pre-filled pen must be protected from light, and discarded if not used within the 14 day period.

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 pen appears to be damaged.

The pen 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 pen is not used right away after cap removal, you must dispose of it in a puncture resistant container and use a new pre-filled pen.

If following pressing the activation button the orange plunger rod 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. Do not repeat the injection with another pre-filled pen. Call your healthcare provider for help.

6. Contents of the pack and other information

What Tyenne contains

- The active substance is tocilizumab. Each pre-filled pen contains 162 mg tocilizumab in 0.9 mL.
- The other ingredients are L-arginine, L-histidine, L-lactic acid, sodium chloride, polysorbate 80, hydrochloric acid (E507) and/or sodium hydroxide (E524), water for injections.

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 pen containing 162 mg tocilizumab solution for injection.

Each pack contains 1 or 4 pre-filled pens with multipacks containing 12 (3 packs of 4) pre-filled pens. **Not all pack sizes may be marketed.**

Marketing Authorisation Holder

For EU:
Fresenius Kabi Deutschland GmbH
Else-Kroener-Strasse 1
61352 Bad Homburg v.d.Hoehe
Germany

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

Manufacturer

Fresenius Kabi Austria GmbH
Hafnerstrasse 36 8055 Graz Austria

This leaflet was last revised in July 2023.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency website:

<http://www.ema.europa.eu/>.

