

PACKAGE LEAFLET

Package leaflet: Information for the patient

Yuflyma 40 mg solution for injection in pre-filled pen adalimumab

▼ 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.
- Your doctor will also give you a **Patient Reminder Card**, which contains important safety information that you need to be aware of before you begin using Yuflyma and during treatment with Yuflyma. Keep this **Patient Reminder Card** with you during your treatment and for 4 months after your last injection of Yuflyma.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Yuflyma is and what it is used for
2. What you need to know before you use Yuflyma
3. How to use Yuflyma
4. Possible side effects
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1. What Yuflyma is and what it is used for

Yuflyma contains the active substance adalimumab, a medicine that acts on your body's immune (defence) system.

Yuflyma is intended for the treatment of the following inflammatory diseases:

- Rheumatoid arthritis
- Polyarticular juvenile idiopathic arthritis
- Enthesitis-related arthritis
- Ankylosing spondylitis
- Axial spondyloarthritis without radiographic evidence of ankylosing spondylitis
- Psoriatic arthritis
- Plaque psoriasis
- Hidradenitis suppurativa
- Crohn's disease
- Ulcerative colitis
- Non-infectious uveitis

The active ingredient in Yuflyma, adalimumab, is a human monoclonal antibody. Monoclonal antibodies are proteins that attach to a specific target in the body.

The target of adalimumab is a protein called tumour necrosis factor (TNF α), which is involved in the

immune (defence) system and is present at increased levels in the inflammatory diseases listed above. By attaching to TNF α , Yuflyma decreases the process of inflammation in these diseases.

Rheumatoid arthritis

Rheumatoid arthritis is an inflammatory disease of the joints.

Yuflyma is used to treat moderate to severe rheumatoid arthritis in adults. You may first be given other disease-modifying medicines, such as methotrexate. If you do not respond well enough to these medicines, you will be given Yuflyma.

Yuflyma can also be used to treat severe, active and progressive rheumatoid arthritis without previous methotrexate treatment.

Yuflyma can slow down the damage to the joints caused by the inflammatory disease and can help them move more freely.

Your doctor will decide if Yuflyma should be used with methotrexate or alone.

Polyarticular juvenile idiopathic arthritis

Polyarticular juvenile idiopathic arthritis is an inflammatory disease of the joints.

Yuflyma is used to treat polyarticular juvenile idiopathic arthritis in patients from 2 years of age. You may first be given other disease-modifying medicines, such as methotrexate. If you do not respond well enough to these medicines, you will be given Yuflyma.

Your doctor will decide if Yuflyma should be used with methotrexate or alone.

Enthesitis-related arthritis

Enthesitis-related arthritis is an inflammatory disease of the joints and the places where tendons join the bone.

Yuflyma is used to treat enthesitis-related arthritis in patients from 6 years of age. You may first be given other disease-modifying medicines, such as methotrexate. If you do not respond well enough to these medicines, you will be given Yuflyma.

Ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis

Ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis are inflammatory diseases of the spine.

Yuflyma is used to treat severe ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis in adults. You may first be given other medicines. If you do not respond well enough to these medicines, you will be given Yuflyma.

Psoriatic arthritis

Psoriatic arthritis is an inflammatory disease of the joints that is usually associated with psoriasis.

Yuflyma is used to treat psoriatic arthritis in adults. Yuflyma can slow down the damage to the joints caused by the disease and can help them move more freely. You may first be given other medicines. If you do not

respond well enough to these medicines, you will be given Yuflyma.

Plaque psoriasis

Plaque psoriasis is a skin condition that causes red, flaky, crusty patches of skin covered with silvery scales. Plaque psoriasis can also affect the nails, causing them to crumble, become thickened and lift away from the nail bed which can be painful.

Yuflyma is used to treat

- moderate to severe chronic plaque psoriasis in adults and
- severe chronic plaque psoriasis in children and adolescents aged 4 to 17 years for whom topical therapy and phototherapies have either not worked very well or are not suitable.

Hidradenitis suppurativa

Hidradenitis suppurativa (sometimes called acne inversa) is a chronic and often painful inflammatory skin disease. Symptoms may include tender nodules (lumps) and abscesses (boils) that may leak pus. It most commonly affects specific areas of the skin, such as under the breasts, the armpits, inner thighs, groin and buttocks. Scarring may also occur in affected areas.

Yuflyma is used to treat

- moderate to severe hidradenitis suppurativa in adults and
- moderate to severe hidradenitis suppurativa in adolescents aged 12 to 17 years.

Yuflyma can reduce the number of nodules and abscesses caused by the disease and the pain that is often associated with the disease. You may first be given other medicines. If you do not respond well enough to these medicines, you will be given Yuflyma.

Crohn's disease

Crohn's disease is an inflammatory disease of the digestive tract. Yuflyma is used to treat

- moderate to severe Crohn's disease in adults and
- moderate to severe Crohn's disease in children and adolescents aged 6 to 17 years.

You may first be given other medicines. If you do not respond well enough to these medicines, you will be given Yuflyma.

Ulcerative colitis

Ulcerative colitis is an inflammatory disease of the large intestine.

Yuflyma is used to treat

- moderate to severe ulcerative colitis in adults and
- moderate to severe ulcerative colitis in children and adolescents aged 6 to 17 years.

You may first be given other medicines. If you do not respond well enough to these medicines, you will be given Yuflyma.

Non-infectious uveitis

Non-infectious uveitis is an inflammatory disease affecting certain parts of the eye. Yuflyma is used to treat

- adults with non-infectious uveitis with inflammation affecting the back of the eye
- children with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.

This inflammation may lead to a decrease of vision and/or the presence of floaters in the eye (black dots or wispy lines that move across the field of vision). Yuflyma works by reducing this inflammation.

You may first be given other medicines. If you do not respond well enough to these medicines, you will be given Yuflyma.

2. What you need to know before you use Yuflyma

Do not use Yuflyma:

- If you are allergic to adalimumab or any of the other ingredients of this medicine (listed in section 6).
- If you have active tuberculosis or other severe infections (see “Warnings and precautions”). It is important that you tell your doctor if you have symptoms of infections, for example, fever, wounds, feeling tired, dental problems.
- If you have moderate or severe heart failure. It is important to tell your doctor if you have had or have a serious heart condition (see “Warnings and precautions”).

Warnings and precautions

Talk to your doctor or pharmacist before using Yuflyma.

Allergic reactions

- If you get allergic reactions with symptoms such as chest tightness, wheezing, dizziness, swelling or rash do not inject more Yuflyma and contact your doctor immediately since, in rare cases, these reactions can be life threatening.

Infections

- If you have an infection, including long-term infection or an infection in one part of the body (for example, leg ulcer) consult your doctor before starting Yuflyma. If you are unsure, contact your doctor.
- You might get infections more easily while you are receiving Yuflyma treatment. This risk may increase if you have problems with your lungs. These infections may be serious and include:
 - tuberculosis
 - infections caused by viruses, fungi, parasites or bacteria
 - severe infection in the blood (sepsis)

In rare cases, these infections can be life-threatening. It is important to tell your doctor if you get symptoms such as fever, wounds, feeling tired or dental problems. Your doctor may tell you to stop using Yuflyma for some time.

- Tell your doctor if you live or travel in regions where fungal infections (for example, histoplasmosis, coccidioidomycosis or blastomycosis) are very common.
- Tell your doctor if you have had infections which keep coming back or other conditions that increase the risk of infections.

- If you are over 65 years you may be more likely to get infections while taking Yuflyma. You and your doctor should pay special attention to signs of infection while you are being treated with Yuflyma. It is important to tell your doctor if you get symptoms of infections, such as fever, wounds, feeling tired or dental problems.

Tuberculosis

It is very important that you tell your doctor if you have ever had tuberculosis, or if you have been in close contact with someone who has had tuberculosis. If you have active tuberculosis, do not use Yuflyma.

- As cases of tuberculosis have been reported in patients treated with Yuflyma, your doctor will check you for signs and symptoms of tuberculosis before starting Yuflyma. This will include a thorough medical evaluation including your medical history and appropriate screening tests (for example, chest X-ray and a tuberculin test). The conduct and results of these tests should be recorded on your **Patient Reminder Card**.
- Tuberculosis can develop during therapy even if you have received treatment for the prevention of tuberculosis.
- If symptoms of tuberculosis (for example, cough that does not go away, weight loss, lack of energy, mild fever), or any other infection appear during or after therapy tell your doctor immediately.

Hepatitis B

- Tell your doctor if you are a carrier of the hepatitis B virus (HBV), if you have active HBV or if you think you might be at risk of getting HBV.
 - Your doctor should test you for HBV. In people who carry HBV, Yuflyma can cause the virus to become active again.
 - In some rare cases, especially if you are taking other medicines that suppress the immune system, reactivation of HBV can be life-threatening.

Surgery or dental procedure

- If you are about to have surgery or dental procedures, please inform your doctor that you are taking Yuflyma. Your doctor may recommend temporary discontinuation of Yuflyma.

Demyelinating disease

- If you have or develop a demyelinating disease (a disease that affects the insulating layer around the nerves, such as multiple sclerosis), your doctor will decide if you should receive or continue to receive Yuflyma. Tell your doctor immediately if you experience symptoms like changes in your vision, weakness in your arms or legs or numbness or tingling in any part of your body.

Vaccinations

- Certain vaccines may cause infections and should not be given while receiving Yuflyma.
 - Check with your doctor before you receive any vaccines.
 - It is recommended that children, if possible, be given all the scheduled vaccinations for their age before they start treatment with Yuflyma.
 - If you received Yuflyma while you were pregnant, your baby may be at higher risk for getting such an infection for up to approximately five months after the last Yuflyma dose you received during pregnancy. It is important that you tell your baby's doctors and other health care professionals about your Yuflyma use during your pregnancy so they can decide when your baby should receive any vaccine.

Heart failure

- If you have mild heart failure and are being treated with Yuflyma, your heart failure status must be closely monitored by your doctor. It is important to tell your doctor if you have had or have a serious heart condition. If you develop new or worsening symptoms of heart failure (e.g. shortness of breath, or swelling of your feet), you must contact your doctor immediately. Your doctor will decide if you should receive Yuflyma.

Fever, bruising, bleeding or looking pale

- In some patients the body may fail to produce enough of the blood cells that fight off infections or help you to stop bleeding. Your doctor may decide to stop treatment. If you develop a fever that does not go away, develop light bruises or bleed very easily or look very pale, call your doctor right away.

Cancer

- There have been very rare cases of certain kinds of cancer in children and adult patients taking Yuflyma or other TNF blockers.
 - People with more serious rheumatoid arthritis that have had the disease for a long time may have a higher than average risk of getting lymphoma (a cancer that affects the lymph system) and leukaemia (a cancer that affects the blood and bone marrow).
 - If you take Yuflyma the risk of getting lymphoma, leukaemia, or other cancers may increase. On rare occasions, an uncommon and severe type of lymphoma, has been seen in patients taking Yuflyma. Some of those patients were also treated with azathioprine or 6-mercaptopurine.
 - Tell your doctor if you are taking azathioprine or 6-mercaptopurine with Yuflyma.
 - Cases of non-melanoma skin cancer have been observed in patients taking Yuflyma.
 - If new skin lesions appear during or after therapy or if existing lesions change appearance, tell your doctor.
- There have been cases of cancers, other than lymphoma in patients with a specific type of lung disease called Chronic Obstructive Pulmonary Disease (COPD) treated with another TNF blocker. If you have COPD, or are a heavy smoker, you should discuss with your doctor whether treatment with a TNF blocker is appropriate for you.

Autoimmune disease

- On rare occasions, treatment with Yuflyma could result in lupus-like syndrome. Contact your doctor if symptoms such as persistent unexplained rash, fever, joint pain or tiredness occur.

Children and adolescents

- Vaccinations: if possible, children should be up to date with all vaccinations before using Yuflyma.

Other medicines and Yuflyma

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. You should not take Yuflyma with medicines containing the following active substances due to increased risk of serious infection:

- anakinra
- abatacept.

Yuflyma can be taken together with:

- methotrexate
- certain disease-modifying anti-rheumatic agents (for example, sulfasalazine, hydroxychloroquine, leflunomide and injectable gold preparations)
- steroids or pain medications including non-steroidal anti-inflammatory drugs (NSAIDs).

If you have questions, please ask your doctor.

Pregnancy and breast-feeding

- You should consider the use of adequate contraception to prevent pregnancy and continue its use for at least 5 months after the last Yuflyma treatment.
- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice about taking this medicine.
- Yuflyma should only be used during a pregnancy if needed.
- According to a pregnancy study, there was no higher risk of birth defects when the mother had received Yuflyma during pregnancy compared with mothers with the same disease who did not receive Yuflyma.
- Yuflyma can be used during breast-feeding.
- If you receive Yuflyma during your pregnancy, your baby may have a higher risk for getting an infection.
- It is important that you tell your baby's doctors and other health care professionals about your Yuflyma use during your pregnancy before the baby receives any vaccine. For more information on vaccines see the "Warnings and precautions" section.

Driving and using machines

Yuflyma may have a small effect on your ability to drive, cycle or use machines. Room spinning sensation and vision disturbances may occur after taking Yuflyma.

YUFLYMA contains sodium

This medicine contains less than 1 mmol of sodium (23 mg) per 0.4 mL dose, i.e. essentially 'sodium free'.

3. How to use Yuflyma

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

Yuflyma is injected under the skin (subcutaneous use). It is available as 40 mg presentations and 80 mg presentations in pre-filled pen. Thus, it is not possible to use Yuflyma for children who require less than a full 40 mg dose. If such a dose is required, other adalimumab medicines should be used.

Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis or axial spondyloarthritis without radiographic evidence of ankylosing spondylitis		
Age or body weight	How much and how often to take?	Notes
Adults	40 mg every other week	In rheumatoid arthritis, methotrexate is continued while using Yuflyma. If your doctor decides that methotrexate is inappropriate, Yuflyma can be given alone. If you have rheumatoid arthritis and you do not receive methotrexate with your Yuflyma therapy, your doctor may decide to give Yuflyma 40 mg every week or 80 mg every other week.

Polyarticular juvenile idiopathic arthritis		
Age or body weight	How much and how often to take?	Notes
Children, adolescents and adults from 2 years of age weighing 30 kg or more	40 mg every other week	Not applicable

Enthesitis-related arthritis		
Age or body weight	How much and how often to take?	Notes
Children, adolescents and adults from 6 years of age weighing 30 kg or more	40 mg every other week	Not applicable

Plaque psoriasis		
Age or body weight	How much and how often to take?	Notes
Adults	First dose of 80 mg (two 40 mg injections in one day), followed by 40 mg every other week starting one week after the first dose.	If you have an inadequate response, your doctor may increase the dosage to 40 mg every week or 80 mg every other week.
Children and adolescents from 4 to 17 years of age weighing 30 kg or more	First dose of 40 mg, followed by 40 mg one week later. Thereafter, the usual dose is 40 mg every other week.	Not applicable

Hidradenitis suppurativa		
Age or body weight	How much and how often to take?	Notes

Adults	First dose of 160 mg (four 40 mg injections in one day or two 40 mg injections per day for two consecutive days), followed by an 80 mg dose (two 40 mg injections in one day) two weeks later. After two further weeks, continue with a dose of 40 mg every week or 80 mg every other week, as prescribed by your doctor.	It is recommended that you use an antiseptic wash daily on the affected areas.
Adolescents from 12 to 17 years of age weighing 30 kg or more	First dose of 80 mg (two 40 mg injections in one day), followed by 40 mg every other week starting one week later.	If you have an inadequate response to Yuflyma 40 mg every other week, your doctor may increase the dosage to 40 mg every week or 80 mg every other week. It is recommended that you use an antiseptic wash daily on the affected areas.

Crohn's disease		
Age or body weight	How much and how often to take?	Notes
Children, adolescents and adults from 6 years of age weighing 40 kg or more	<p>First dose of 80 mg (two 40 mg injections in one day), followed by 40 mg two weeks later.</p> <p>If a faster response is required, the doctor may prescribe a first dose of 160 mg (four 40 mg injections in one day or two 40 mg injections per day for two consecutive days), followed by 80 mg (two 40 mg injections in one day) two weeks later.</p> <p>Thereafter, the usual dose is 40 mg every other week.</p>	Your doctor may increase the dosage to 40 mg every week or 80 mg every other week.

Ulcerative colitis		
Age or body weight	How much and how often to take?	Notes
Adults	<p>First dose of 160 mg (four 40 mg injections in one day or two 40 mg injections per day for two consecutive days), followed by 80 mg (two 40 mg injections in one day) two weeks later.</p> <p>Thereafter, the usual dose is 40 mg every other week.</p>	Your doctor may increase the dosage to 40 mg every week or 80 mg every other week.

Children and adolescents from 6 years of age weighing less than 40 kg	First dose of 80 mg (two 40 mg injections in one day), followed by 40 mg (one 40 mg injection) two weeks later. Thereafter, the usual dose is 40 mg every other week	You should continue taking Yuflyma at your usual dose, even after turning 18 years of age.
Children and adolescents from 6 years of age weighing 40 kg or more	First dose of 160 mg (four 40 mg injections in one day or two 40 mg injections per day for two consecutive days), followed by 80 mg (two 40 mg injections in one day) two weeks later. Thereafter, the usual dose is 80 mg every other week.	You should continue taking Yuflyma at your usual dose, even after turning 18 years of age.

Non-infectious uveitis		
Age or body weight	How much and how often to take?	Notes
Adults	First dose of 80 mg (two 40 mg injections in one day), followed by 40 mg every other week starting one week after the first dose.	Corticosteroids or other medicines that influence the immune system may be continued while using Yuflyma. Yuflyma can also be given alone.
Children and adolescents from 2 years of age weighing at least 30 kg	40 mg every other week	Your doctor may prescribe an initial dose of 80 mg to be administered one week prior to the start of the usual dose of 40 mg every other week. Yuflyma is recommended for use in combination with methotrexate.

Method and route of administration

Yuflyma is administered by injection under the skin (by subcutaneous injection).

Detailed instructions on how to inject Yuflyma are provided in section 7 'Instructions for use'.

If you use more Yuflyma than you should

If you accidentally inject Yuflyma more frequently than told to by your doctor or pharmacist, call your doctor or pharmacist and tell them that you have taken more. Always take the outer carton of the medicine with you, even if it is empty.

If you forget to use Yuflyma

If you forget to give yourself an injection, you should inject the next dose of Yuflyma as soon as you remember. Then take your next dose as you would have on your originally scheduled day, had you not forgotten a dose.

If you stop using Yuflyma

The decision to stop using Yuflyma should be discussed with your doctor. Your symptoms may return if you stop using Yuflyma.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects are mild to moderate. However, some may be serious and require treatment. Side effects may occur at least up to 4 months after the last Yuflyma injection.

Tell your doctor immediately if you notice any of the following

- severe rash, hives or other signs of allergic reaction
- swollen face, hands, feet
- trouble breathing, swallowing
- shortness of breath with physical activity or upon lying down or swelling of the feet

Tell your doctor as soon as possible if you notice any of the following

- signs of infection such as fever, feeling sick, wounds, dental problems, burning on urination
- feeling weak or tired
- coughing
- tingling
- numbness
- double vision
- arm or leg weakness
- a bump or open sore that doesn't heal
- signs and symptoms suggestive of blood disorders such as persistent fever, bruising, bleeding, paleness

The symptoms described above can be signs of the below listed side effects, which have been observed with Yuflyma.

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

- injection site reactions (including pain, swelling, redness or itching)
- respiratory tract infections (including cold, runny nose, sinus infection, pneumonia)
- headache
- abdominal pain
- nausea and vomiting
- rash
- musculoskeletal pain

Common (may affect up to 1 in 10 people)

- serious infections (including blood poisoning and influenza)
- intestinal infections (including gastroenteritis)
- skin infections (including cellulitis and shingles)

- ear infections
- oral infections (including tooth infections and cold sores)
- reproductive tract infections
- urinary tract infection
- fungal infections
- joint infections
- benign tumours
- skin cancer
- allergic reactions (including seasonal allergy)
- dehydration
- mood swings (including depression)
- anxiety
- difficulty sleeping
- sensation disorders such as tingling, prickling or numbness
- migraine
- nerve root compression (including low back pain and leg pain)
- vision disturbances
- eye inflammation
- inflammation of the eye lid and eye swelling
- vertigo (feeling of dizziness or spinning)
- sensation of heart beating rapidly
- high blood pressure
- flushing
- haematoma (collection of blood outside of blood vessels)
- cough
- asthma
- shortness of breath
- gastrointestinal bleeding
- dyspepsia (indigestion, bloating, heart burn)
- acid reflux disease
- sicca syndrome (including dry eyes and dry mouth)
- itching
- itchy rash
- bruising
- inflammation of the skin (such as eczema)
- breaking of finger nails and toe nails
- increased sweating
- hair loss
- new onset or worsening of psoriasis
- muscle spasms
- blood in urine
- kidney problems
- chest pain
- oedema (swelling)
- fever
- reduction in blood platelets which increases risk of bleeding or bruising
- impaired healing

Uncommon (may affect up to 1 in 100 people)

- opportunistic infections (which include tuberculosis and other infections that occur when resistance

to disease is lowered)

- neurological infections (including viral meningitis)
- eye infections
- bacterial infections
- diverticulitis (inflammation and infection of the large intestine)
- cancer
- cancer that affects the lymph system
- melanoma
- immune disorders that could affect the lungs, skin and lymph nodes (most commonly presenting as sarcoidosis)
- vasculitis (inflammation of blood vessels)
- tremor (shaking)
- neuropathy (disorder of the nerves)
- stroke
- hearing loss, buzzing
- sensation of heart beating irregularly such as skipped beats
- heart problems that can cause shortness of breath or ankle swelling
- heart attack
- a sac in the wall of a major artery, inflammation and clot of a vein, blockage of a blood vessel
- lung diseases causing shortness of breath (including inflammation)
- pulmonary embolism (blockage in an artery of the lung)
- pleural effusion (abnormal collection of fluid in the pleural space)
- inflammation of the pancreas which causes severe pain in the abdomen and back
- difficulty in swallowing
- facial oedema (swelling of the face)
- gallbladder inflammation, gallbladder stones
- fatty liver
- night sweats
- scar
- abnormal muscle breakdown
- systemic lupus erythematosus (including inflammation of skin, heart, lung, joints and other organ systems)
- sleep interruptions
- impotence
- inflammations

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

- leukaemia (cancer affecting the blood and bone marrow)
- severe allergic reaction with shock
- multiple sclerosis
- nerve disorders (such as eye nerve inflammation and Guillain-Barré syndrome that may cause muscle weakness, abnormal sensations, tingling in the arms and upper body)
- heart stops pumping
- pulmonary fibrosis (scarring of the lung)
- intestinal perforation (hole in the intestine)
- hepatitis
- reactivation of hepatitis B
- autoimmune hepatitis (inflammation of the liver caused by the body's own immune system)
- cutaneous vasculitis (inflammation of blood vessels in the skin)
- Stevens-Johnson syndrome (early symptoms include malaise, fever, headache and rash)

- facial oedema (swelling of the face) associated with allergic reactions
- erythema multiforme (inflammatory skin rash)
- lupus-like syndrome
- angioedema (localised swelling of the skin)
- lichenoid skin reaction (itchy reddish-purple skin rash)

Not known (frequency cannot be estimated from the available data)

- hepatosplenic T-cell lymphoma (a rare blood cancer that is often fatal)
- Merkel cell carcinoma (a type of skin cancer)
- Kaposi's sarcoma, a rare cancer related to infection with human herpes virus 8. Kaposi's sarcoma most commonly appears as purple lesions on the skin.
- liver failure
- worsening of a condition called dermatomyositis (seen as a skin rash accompanying muscle weakness)
- weight gain (for most patients, the weight gain was small)

Some side effects observed with Yuflyma may not have symptoms and may only be discovered through blood tests. These include:

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

- low blood measurements for white blood cells
- low blood measurements for red blood cells
- increased lipids in the blood
- elevated liver enzymes

Common (may affect up to 1 in 10 people)

- high blood measurements for white blood cells
- low blood measurements for platelets
- increased uric acid in the blood
- abnormal blood measurements for sodium
- low blood measurements for calcium
- low blood measurements for phosphate
- high blood sugar
- high blood measurements for lactate dehydrogenase
- autoantibodies present in the blood
- low blood potassium

Uncommon (may affect up to 1 in 100 people)

- elevated bilirubin measurement (liver blood test)

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

- low blood measurements for white blood cells, red blood cells and platelet count

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at:

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 Yuflyma

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the label/carton after EXP.

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

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

Alternative Storage:

When needed (for example when you are travelling), a single Yuflyma pre-filled pen may be stored at room temperature (up to 25°C) for a maximum period of 31 days – be sure to protect it from light. Once removed from the refrigerator for room temperature storage, the pen **must be used within 31 days or discarded**, even if it is returned to the refrigerator.

You should record the date when the pen is first removed from refrigerator and the date after which it should be discarded.

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

6. Contents of the pack and other information

What Yuflyma contains

The active substance is adalimumab.

The other ingredients are acetic acid, sodium acetate trihydrate, glycine, polysorbate 80, and water for injections.

What the Yuflyma pre-filled pen looks like and contents of the pack

Yuflyma 40 mg solution for injection in pre-filled pen is supplied as a sterile solution of 40 mg adalimumab dissolved in 0.4 ml solution.

The Yuflyma pre-filled pen is a single-use disposable needle-based injection system with automated functions. There is a window on each side of the pen through which you can see the Yuflyma solution inside the pen.

The Yuflyma pre-filled pen is available in packs containing 1, 2, 4 and 6 pre-filled pens. The 1 pre-filled pen pack comes with 2 alcohol pads (1 spare). For the 2, 4 and 6 pre-filled pen packs, each pre-filled pen comes with 1 alcohol pad.

Not all pack sizes may be marketed.

Yuflyma may be available as a pre-filled syringe and/or a pre-filled pen.

Marketing Authorisation Holder

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7. Instructions for use

- The following instructions explain how to give yourself a subcutaneous injection of Yuflyma using the pre-filled pen. First read all the instructions carefully and then follow them step by step.
- You will be instructed by your doctor, nurse or pharmacist on the technique of self-injection.
- **Do not** attempt to self-inject until you are sure that you understand how to prepare and give the injection.
- After proper training, the injection can be given by yourself or given by another person, for example, a family member or friend.
- Only use each pre-filled pen for one injection.

Yuflyma Pre-filled Pen

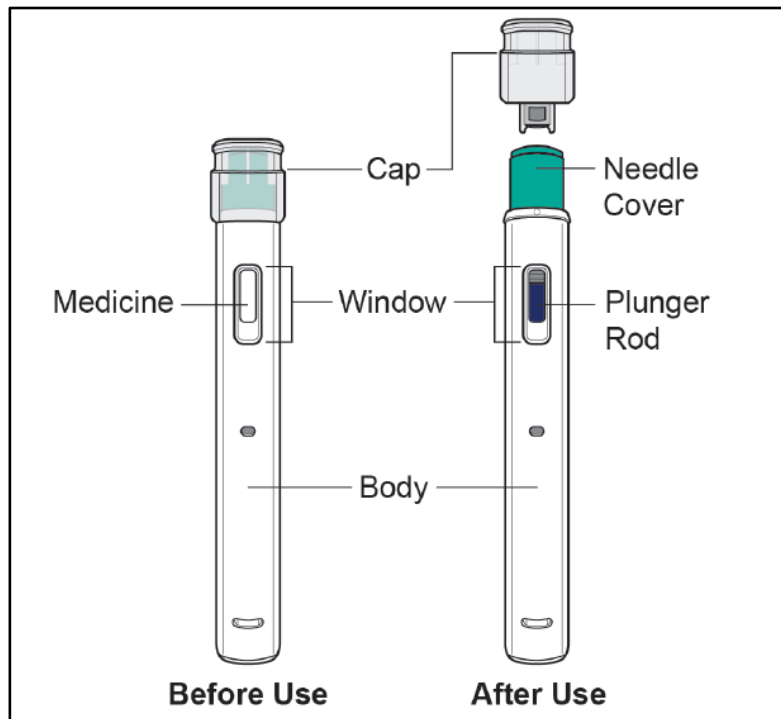


Figure A

Do not use the pre-filled pen if:

- it is cracked or damaged
- the expiration date has passed.
- It has been dropped onto a hard surface.

Do not remove the cap until you are ready to inject. Keep the Yuflyma out of the reach of children.

1. Gather the supplies for the injection

- a. Prepare a clean, flat surface, such as a table or countertop, in a well-lit area.
- b. Remove 1 pre-filled pen from the carton stored in your refrigerator.
- c. Make sure you have the following supplies:
 - Pre-filled Pen
 - 1 Alcohol swab

Not included in the carton:

- Cotton ball or gauze
- Adhesive bandage
- Sharps disposal container

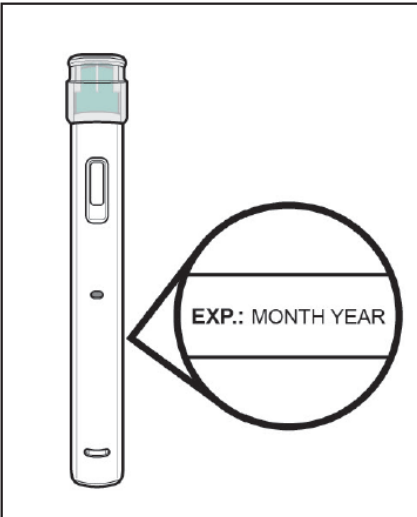


Figure B

2. Inspect the Pre-filled Pen

- a. Ensure you have the correct medicine (Yuflyma) and dosage.
- b. Look at the pre-filled pen and make sure it is not cracked or damaged.
- c. Check the expiration date on the label of the pre-filled pen.

Do not use the pre-filled pen if:

- it is cracked or damaged.
- the expiration date has passed.
- It has been dropped onto a hard surface.

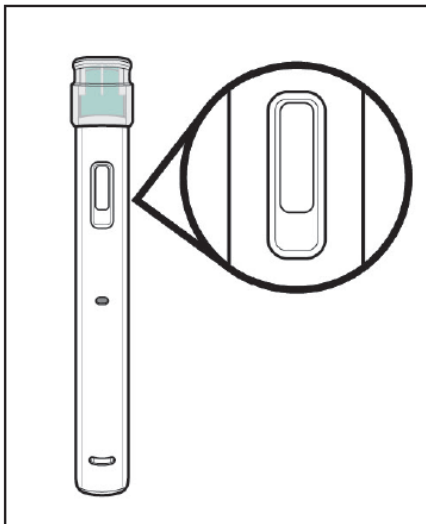


Figure C

3. Inspect the Medicine.

- a. Look through the window and make sure that the liquid is clear, colourless to pale brown, and free of particles.
- **Do not** use the pre-filled syringe if the liquid is discoloured (yellow or dark brown), cloudy or contains particles in it.
 - You may see air bubbles in the liquid. This is normal.

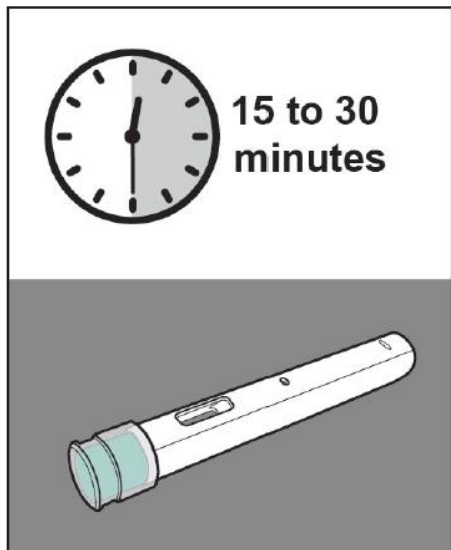


Figure D

4. Wait 15 to 30 minutes

a. Leave the pre-filled pen at room temperature for 15 to 30 minutes to allow it to warm up.

- **Do not** warm the pre-filled pen using heat sources such as hot water or a microwave.

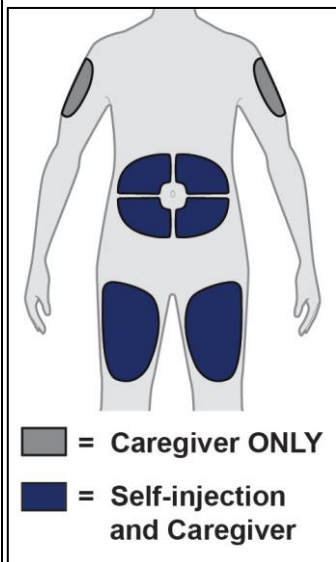


Figure E

5. Choose an appropriate injection site

a. You may inject into:

- the front of your thighs.
- your abdomen except for the 5 cm (2 in) around the belly button (navel).
- the outer area of the upper arm (ONLY if you are a caregiver).

- **Do not** inject into skin that is within 5 cm (2 in) of your belly button (navel), or is red, hard, tender, damaged, bruised, or scarred.
- If you have psoriasis, do not inject directly into any raised, thick, red or scaly skin patches or lesions on your skin.
- **Do not** inject through your clothes.

b. Rotate the injection site each time you give an injection. Each new injection site should be at least 3 cm (1.2 in) away from the injection site you used before.



Figure F

6. Wash your hands

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

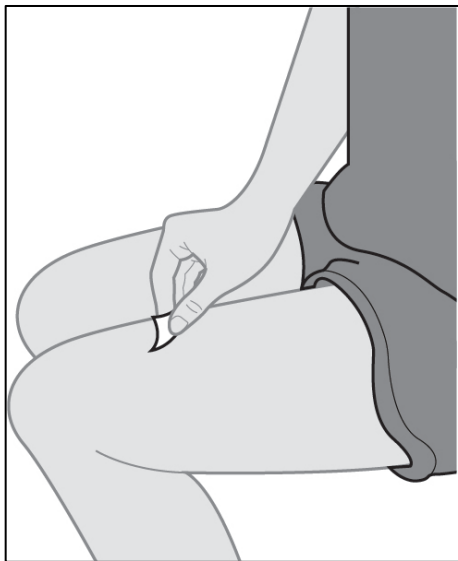


Figure G

7. Clean the injection site

- a.** Clean the injection site with an alcohol swab using a circular motion
 - b.** Let the skin dry before injecting.
-
- **Do not** blow on or touch the injection site again before giving the injection.

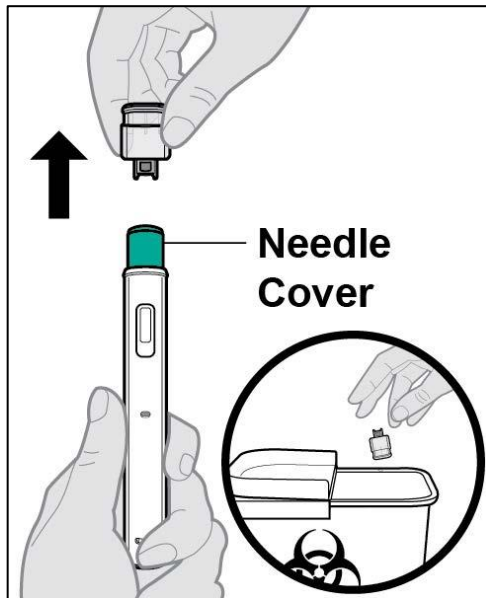


Figure H

8. 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.

- **Do not** remove the cap until you are ready to inject.
- **Do not** touch the needle or needle cover. Doing so may result in a needle stick injury.
- **Do not** recap the pre-filled pen. Dispose the cap immediately into the sharps disposal container.

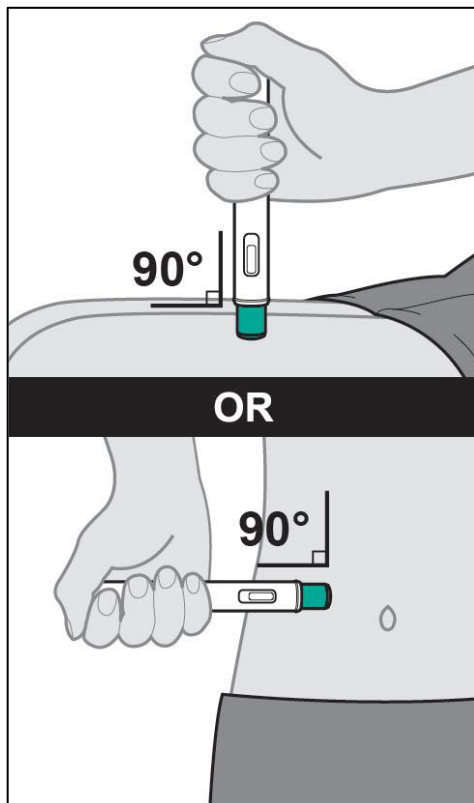


Figure I

9. Place the pre-filled pen on the injection site.

- Hold the pre-filled pen so that you can see the window.
- Without pinching or stretching the skin, place the pre-filled pen over the injection site at a 90-degree angle.

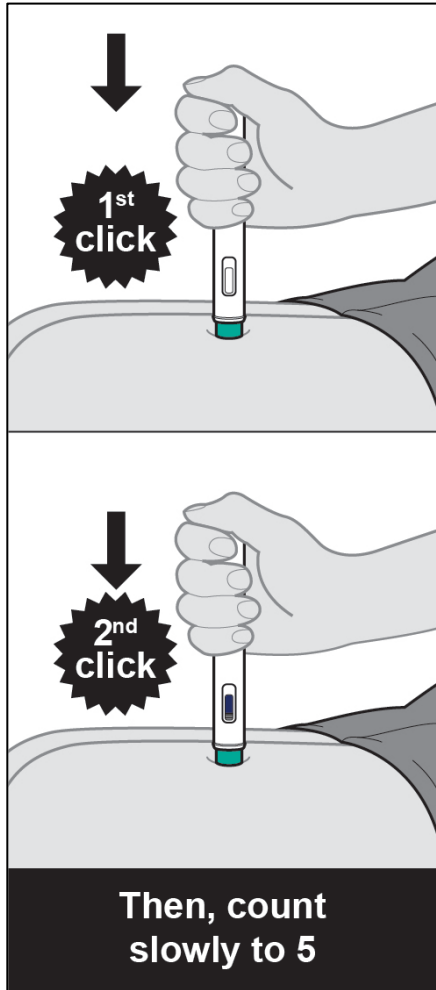


Figure J

10. Give the injection

- a. Press the pre-filled pen **firmly** against the skin. When the injection starts you will hear the 1st loud “click” and the blue plunger rod will begin to fill the window.
 - b. Keep holding the pre-filled pen firmly against the skin and listen for the 2nd loud “click.”
 - c. After you hear the 2nd loud “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.
- **Do not** change the position of the pre-filled pen after the injection has started.

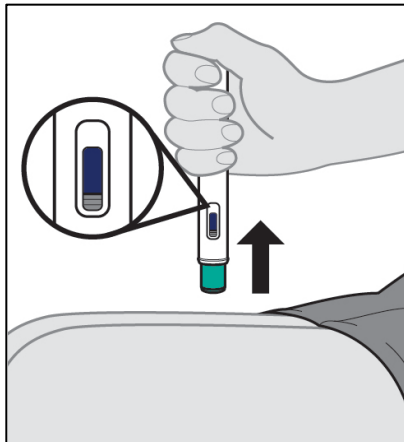


Figure K

11. Remove the Pre-filled Pen from the injection site and care for the injection site

- a. Look at the pre-filled pen and make sure that the blue plunger rod with the grey top is filling the window completely.
- b. Remove the pre-filled pen from your skin.

- After you remove the pre-filled pen from the injection site, the needle will be automatically covered. **Do not** recap the pen.

- If the window has not turned completely blue or if the medicine is still injecting, this means you have not received a full dose. Call your healthcare provider immediately.

- c. Treat the injection site by gently pressing, not rubbing, a cotton ball or gauze to the site and apply an adhesive bandage, if necessary. Some bleeding may occur.

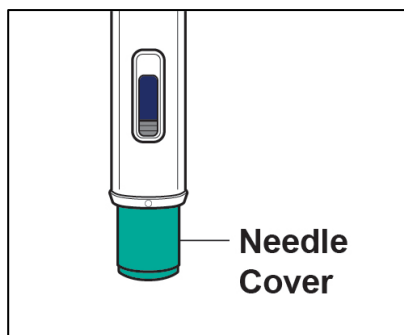


Figure L

- **Do not** reuse the pre-filled pen.
- **Do not** rub the injection site.

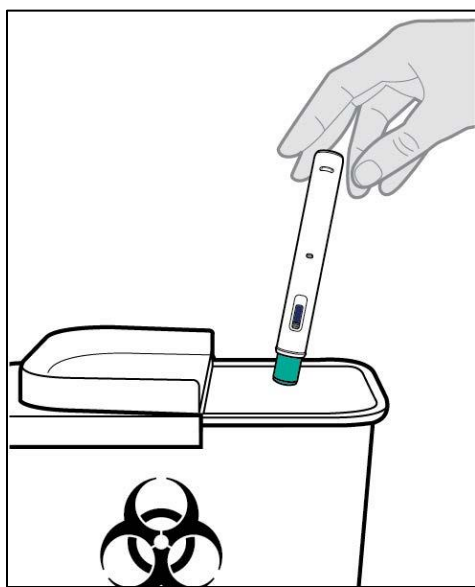


Figure M

12. Dispose of the Pre-filled Pen

- a. Throw away the used pre-filled pen in a special sharps disposal container as instructed by your doctor, nurse or pharmacist.
- b. The alcohol pad and packaging may be put in your household waste.

- Always keep the pre-filled pen and the special sharps disposal container out of the sight and reach of children.