

**PACKAGE LEAFLET**

## Package leaflet: Information for the patient

### Yuflyma 20 mg solution for injection in pre-filled syringe

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 your child starts using this medicine because it contains important information.**

- 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 your child begins using Yuflyma and during treatment with Yuflyma. Keep this **Patient Reminder Card** with you or your child.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child.
- If your child 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 your child uses Yuflyma
3. How to use Yuflyma
4. Possible side effects
5. How to store Yuflyma
6. Contents of the pack and other information
7. Instructions for use

#### 1. What Yuflyma is and what it is used for

Yuflyma contains the active substance adalimumab.

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

- Polyarticular juvenile idiopathic arthritis
- Enthesitis-related arthritis
- Paediatric plaque psoriasis
- Paediatric Crohn's disease
- Paediatric 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 $\alpha$ ), which is involved in the immune (defence) system and is present at increased levels in the inflammatory diseases listed above. By attaching to TNF $\alpha$ , Yuflyma decreases the process of inflammation in these diseases.

#### Polyarticular juvenile idiopathic arthritis

Polyarticular juvenile idiopathic arthritis is an inflammatory disease of the joints that usually first appears in childhood.

Yuflyma is used to treat polyarticular juvenile idiopathic arthritis in patients from 2 years of age. Your child may first be given other disease-modifying medicines, such as methotrexate. If these medicines do not work well enough, your child will be given Yuflyma to treat his/her polyarticular juvenile idiopathic arthritis.

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. Your child may first be given other disease-modifying medicines, such as methotrexate. If these medicines do not work well enough, your child will be given Yuflyma to treat his/her enthesitis-related arthritis.

### **Paediatric 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. Psoriasis is believed to be caused by a problem with the body's immune system that leads to an increased production of skin cells.

Yuflyma is used to treat 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.

### **Paediatric 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 children and adolescents aged 6 to 17 years.

Your child may first be given other medicines. If these medicines do not work well enough, your child will be given Yuflyma to reduce the signs and symptoms of his/her disease

### **Paediatric uveitis**

Non-infectious uveitis is an inflammatory disease affecting certain parts of the eye.

Yuflyma is used to treat 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.

Your child may first be given other medicines. If these medicines do not work well enough, your child will be given Yuflyma to reduce the signs and symptoms of his/her disease.

## **2. What you need to know before your child use Yuflyma**

### **Do not use Yuflyma:**

- If your child is allergic to adalimumab or any of the other ingredients of this medicine (listed in section 6).

- If your child has active tuberculosis or other severe infections (see “Warnings and precautions”). It is important that you tell your doctor if your child has symptoms of infections, for example, fever, wounds, feeling tired, dental problems.
- If your child has moderate or severe heart failure. It is important to tell your doctor if your child has had or has a serious heart condition (see “Warnings and precautions”).

## **Warnings and precautions**

Talk to your doctor or pharmacist before using Yuflyma.

### Allergic reactions

- If your child gets 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 your child has 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.
- Your child might get infections more easily while he/she is receiving Yuflyma treatment. This risk may increase if your child has problems with his/her 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 your child gets 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 your child lives or travels in regions where fungal infections (for example, histoplasmosis, coccidioidomycosis or blastomycosis) are very common.
- Tell your doctor if your child has infections which keep coming back or other conditions that increase the risk of infections.
- Your child and his/her doctor should pay special attention to signs of infection while your child being treated with Yuflyma. It is important to tell your doctor if your child gets symptoms of infections, such as fever, wounds, feeling tired or dental problems.

### Tuberculosis

- As cases of tuberculosis have been reported in patients treated with Yuflyma, your doctor will check your child for signs and symptoms of tuberculosis before starting Yuflyma. This will include a thorough medical evaluation including your child’s 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 child’s **Patient Reminder Card**.
  - It is very important that you tell your doctor if your child has ever had tuberculosis, or if your

child has been in close contact with someone who has had tuberculosis. If your child has active tuberculosis, do not use Yuflyma.

- Tuberculosis can develop during therapy even if your child has 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 your child is 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 your child is taking other medicines that suppress the immune system, reactivation of HBV can be life-threatening.

### Surgery or dental procedure

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

### Demyelinating disease

- If your child has or develops a demyelinating disease (a disease that affects the insulating layer around the nerves, such as multiple sclerosis), your doctor will decide if he/she 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 your child receives 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 your child received Yuflyma while she was pregnant, her baby may be at higher risk for getting such an infection for up to approximately five months after the last Yuflyma dose she received during pregnancy. It is important that you tell her baby's doctors and other health care professionals about your child's Yuflyma use during her pregnancy so they can decide when her baby should receive any vaccine.

### Heart failure

- If your child has mild heart failure and is being treated with Yuflyma, his/her heart failure status must be closely monitored by your doctor. It is important to tell your doctor if your child has had or has a serious heart condition. If he/she develops 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 your child to stop bleeding. Your doctor may decide to stop treatment. If your child develops a fever that does not go away, develops 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 your child takes 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 your child is 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 your child has COPD, or is a heavy smoker, you should discuss with your doctor whether treatment with a TNF blocker is appropriate for your child.

### 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.

### **Other medicines and Yuflyma**

Tell your doctor or pharmacist if your child is taking, have recently taken or might take any other medicines.

Your child 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 child 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 your child is pregnant, think she may be pregnant or is planning to have a baby, ask her 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 your child receives Yuflyma during your pregnancy, her baby may have a higher risk for getting an infection.
- It is important that you tell her baby’s doctors and other health care professionals about her Yuflyma use during her 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 0.2 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.

The recommended doses for Yuflyma in each of the approved uses are shown in the following table. Your doctor may prescribe another strength of Yuflyma if your child needs a different dose.

<b>Polyarticular juvenile idiopathic arthritis</b>		
<b>Age or body weight</b>	<b>How much and how often to take?</b>	<b>Notes</b>
Children, adolescents and adults from 2 years of age weighing 30 kg or more	40 mg every other week	Not applicable
Children and adolescents from 2 years of age weighing 10 kg to less than 30 kg	20 mg every other week	Not applicable

<b>Enthesitis-related arthritis</b>		
<b>Age or body weight</b>	<b>How much and how often to take?</b>	<b>Notes</b>
Children, adolescents and adults from 6 years of age weighing 30 kg or more	40 mg every other week	Not applicable
Children and adolescents from 6 years of age weighing 15 kg to less than 30 kg	20 mg every other week	Not applicable

<b>Paediatric plaque psoriasis</b>
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<b>Age or body weight</b>	<b>How much and how often to take?</b>	<b>Notes</b>
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
Children and adolescents from 4 to 17 years of age weighing 15 kg to less than 30 kg	First dose of 20 mg, followed by 20 mg one week later.  Thereafter, the usual dose is 20 mg every other week.	Not applicable

#### **Paediatric Crohn's disease**

<b>Age or body weight</b>	<b>How much and how often to take?</b>	<b>Notes</b>
Children and adolescents from 6 to 17 years of age weighing 40 kg or more	First dose of 80 mg followed by 40 mg two weeks later.  If a faster response is required, your child's doctor may prescribe a first dose of 160 mg followed by 80 mg two weeks later.  Thereafter, the usual dose is 40 mg every other week.	Your child's doctor may increase the dosage to 40 mg every week or 80 mg every other week.
Children and adolescents from 6 to 17 years of age weighing less than 40 kg	First dose of 40 mg, followed by 20 mg two weeks later.  If a faster response is required, the doctor may prescribe a first dose of 80 mg, followed by 40 mg two weeks later.  Thereafter, the usual dose is 20 mg every other week.	Your child's doctor may increase the dosage to 20 mg every week.

#### **Paediatric uveitis**

<b>Age or body weight</b>	<b>How much and how often to take?</b>	<b>Notes</b>
Children and adolescents from 2 years of age weighing less than 30 kg	20 mg every other week	Your doctor may prescribe an initial dose of 40 mg to be administered one week prior to the start of the usual dose of 20 mg every other week. Yuflyma is recommended for use in combination with methotrexate.



Children and adolescents from 2 years of age weighing 30 kg or more	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.
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### **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 your child has 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 your child an injection, you should inject the next dose of Yuflyma as soon as you remember. Then give your child's 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 child's 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 your child gets 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](http://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 syringe 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 syringe 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 syringe **must be used within 31 days or discarded**, even if it is returned to the refrigerator.

You should record the date when the syringe 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 syringe looks like and contents of the pack**

Yuflyma 20 mg solution for injection in pre-filled syringe is supplied as a sterile solution of 20 mg adalimumab dissolved in 0.2 ml solution.

The Yuflyma pre-filled syringe is a glass syringe containing a solution of adalimumab.

The 2 pre-filled syringes pack comes with 2 alcohol pads.

### **Marketing Authorisation Holder**

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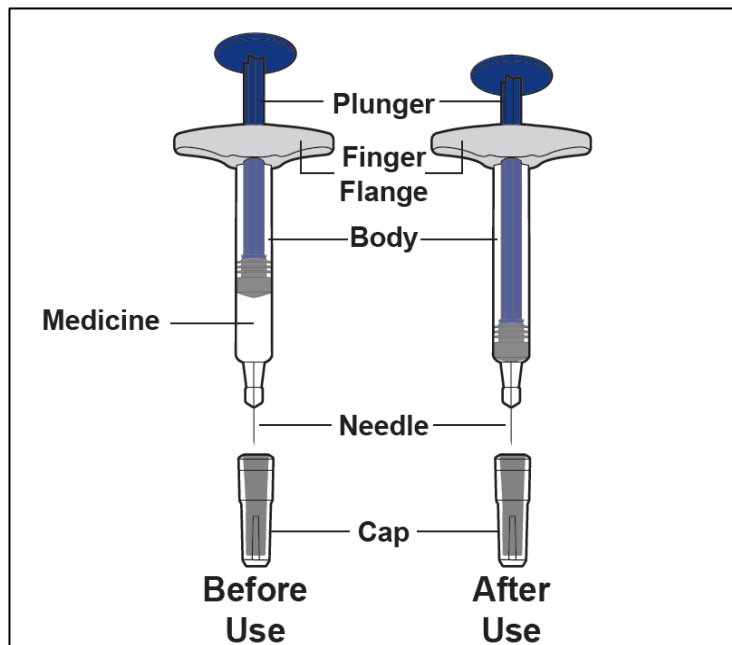
Tel: +44 (0)1753 983500

This leaflet was last revised in 2023/12

**7. Instructions for use**

- The following instructions explain how to give your child a subcutaneous injection of Yuflyma using the pre-filled syringe. 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 injection.
- **Do not** attempt to inject your child until you are sure that you understand how to prepare and give the injection.
- After proper training, the injection can be given by your child or given by another person, for example, a family member or friend.
- Only use each pre-filled syringe for one injection.

**Yuflyma Pre-filled Syringe**



**Figure A**

**Do not use the pre-filled syringe if:**

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

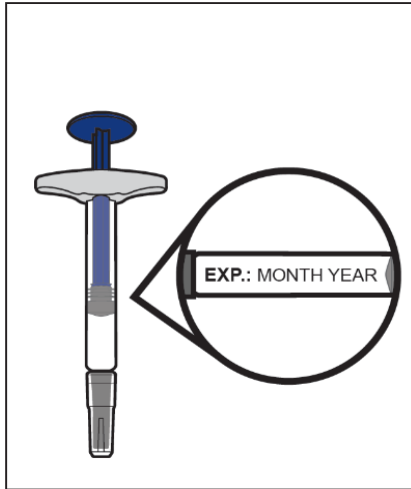
**Do not remove the needle cover until just before injection. Keep Yuflyma out of the sight and reach of children.**

### **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 syringe from the carton stored in your refrigerator.
  - Hold the pre-filled syringe body when removing it from the carton. **Do not** touch the plunger rod and cap.
- c. Make sure you have the following supplies:
  - Pre-filled syringe
  - Alcohol swab

**Not included in the carton:**

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



**Figure B**

### **2. Inspect the pre-filled syringe**

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

**Do not** use the pre-filled syringe if:

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



### 3. Inspect the medicine

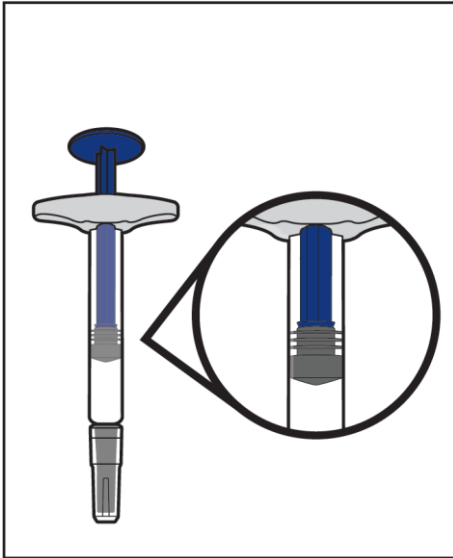


Figure C

- a. Look at the medicine and confirm 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.

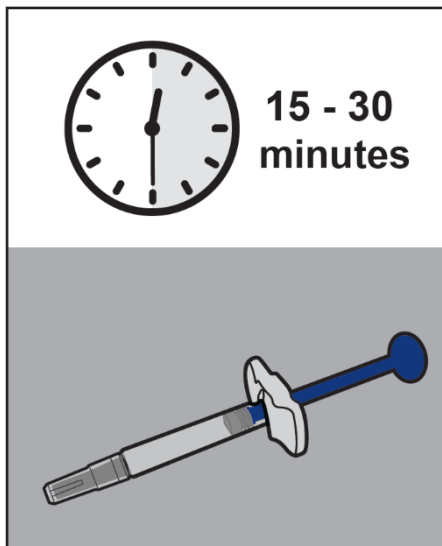
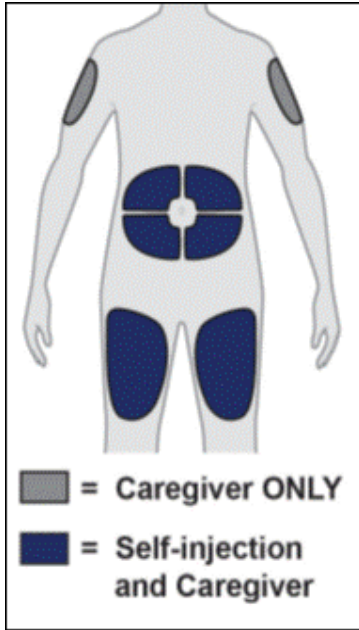


Figure D

### 4. Wait 15 to 30 minutes

- a. Leave the Pre-filled Syringe at room temperature for 15 to 30 minutes to allow it to warm up.
- **Do not** warm the pre-filled syringe using heat sources such as hot water or a microwave.



**5. Choose an appropriate injection site**

**a. You may inject into:**

- the front of your thighs.
- your child's 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).

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 your child has 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.

**Figure E** **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.



**6. Wash your hands**

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

**Figure F**

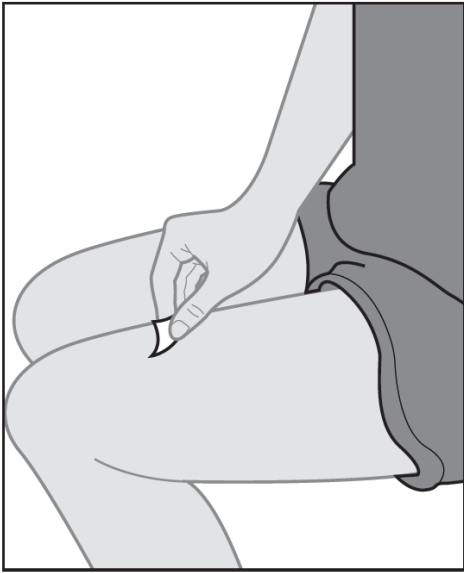


Figure G

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.

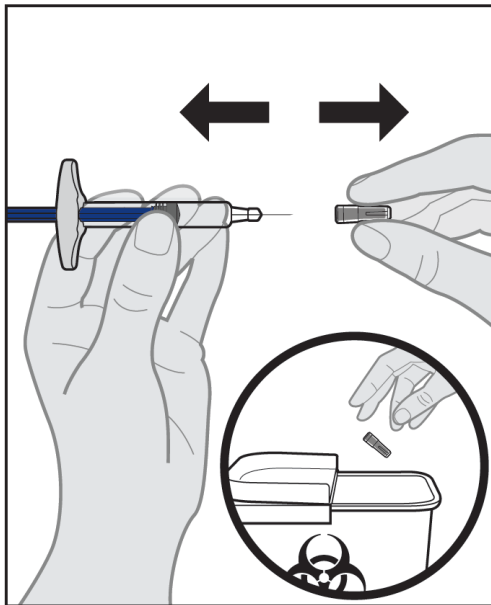


Figure H

8. **Remove the cap**

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

- **Do not** pull back on the plunger rod at any time
- **Do not** remove the cap until you are ready to inject
- **Do not** touch the needle. Doing so may result in a needle stick injury.
- **Do not** recap the pre-filled syringe. Dispose the cap immediately into the sharps disposal container.
- It is normal to see a few drops of liquid come out of the needle.

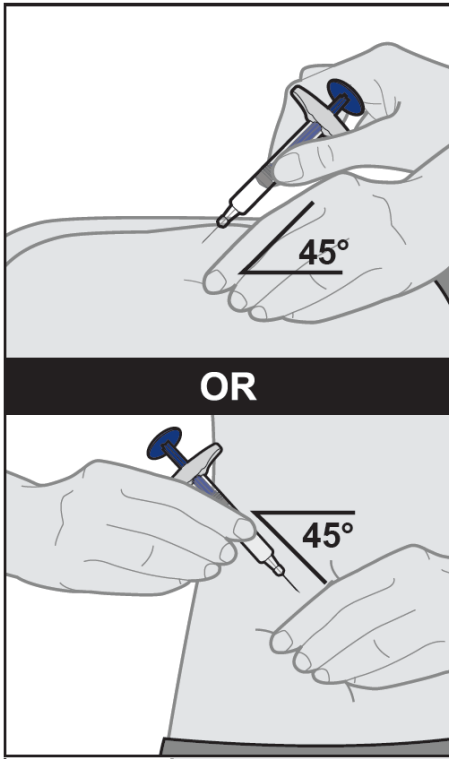


Figure I

**9. Insert the pre-filled syringe into the injection site**

- a. Gently pinch a fold of skin at the injection site with one hand.
- b. Holding the pre-filled syringe by its body, insert the needle completely into the fold of the skin at a 45-degree angle using a quick and “dart-like” motion.

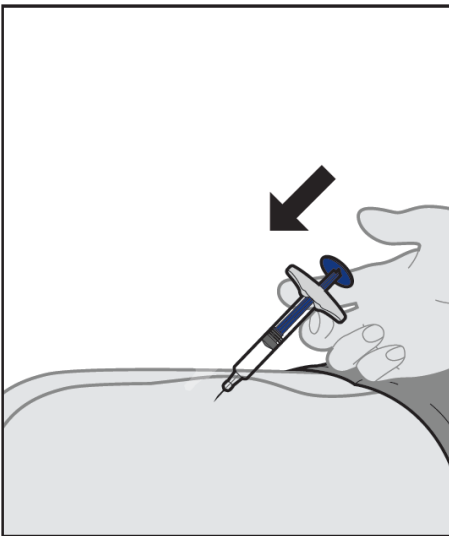


Figure J

**10. Give the injection**

- a. After the needle is inserted, let go of the pinched skin
  - b. Slowly push the plunger all the way down until all of the liquid is injected and the syringe is empty.
- **Do not** change the position of the pre-filled syringe after the injection has started.

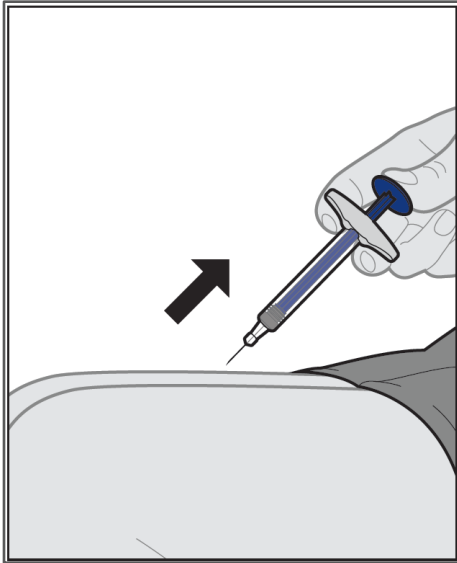


Figure K

**11. Remove the pre-filled syringe from the injection site and care for the injection site**

- a. After the pre-filled syringe is empty, remove the pre-filled syringe from your skin at the same angle it was inserted.
- b. 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.

- **Do not** reuse the pre-filled syringe.
- **Do not** touch or recap the needle.
- **Do not** rub the injection site.



**12. Dispose of the pre-filled syringe**

- **Do not** recap the pre-filled syringe.
  - a. Throw away the used pre-filled syringe 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 syringe and the special sharps disposal container out of the sight and reach of children.