YUFLYMA® 10MG/0.1ML SOLUTION FOR INJECTION IN PRE-FILLED PEN

Adalimumab (40 mg and 80 mg)

What is in this leaflet

1. What Yuflyma is used for
2. How Yuflyma works
3. Before you use Yuflyma
4. How to use Yuflyma
5. While you are using Yuflyma
6. Side effects
7. Storage and Disposal of Yuflyma
8. Product Description
9. Manufacturer and Batch Releaser
10. Product Registration Holder
11. Date of revision
12. Serial Number

What Yuflyma is used for

Yuflyma is intended for treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis aged above 2 years old, axial spondyloarthritis (ankylosing spondylitis and Non-radiographic axial spondyloarthritis), psoriatic arthritis, enthesitis-related arthritis in children aged 6 years and above, psoriasis in adults and children aged 4 years and above, Crohn's disease in adults and children aged 6 years and above, ulcerative colitis in adults and children aged 6 years and above, hidradenitis suppurativa in adults and adolescents, and uveitis in adults and children aged 2 years and above.

How Yuflyma works

It is a medicine that decreases the inflammation process of these diseases.

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

Before you use Yuflyma

– *When you must not use it*

- If you are allergic to adalimumab or any of the other ingredients of this medicine.
- If you have active tuberculosis or other severe infections. 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.

– *Before you start to use it*

Children and adolescents

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

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.

– *Taking other medicines*

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).

How to use Yuflyma

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

Detailed instructions on how to inject Yuflyma are provided in section below:

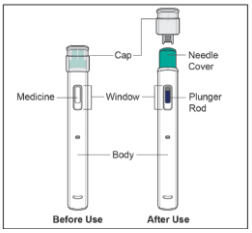


Figure A

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

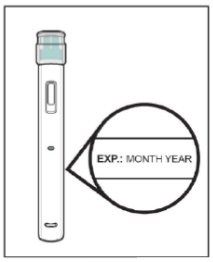


Figure B

2. Inspect the Pre-filled Pen

a) Ensure you have the correct medicine (Yuflyma) and dosage.
b) Look at the 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.

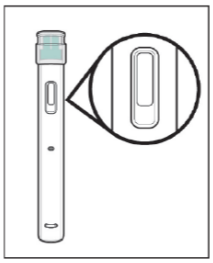


Figure C

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 pen 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.

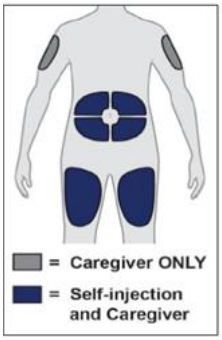


Figure E

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.

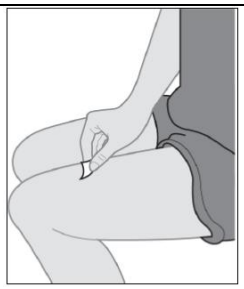


Figure G

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.

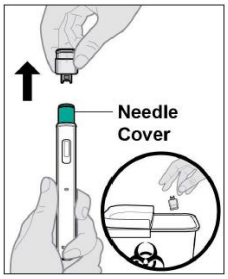


Figure H

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.
- It is normal to see a few drops of liquid come out of the needle.

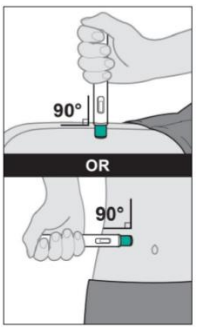


Figure I

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

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

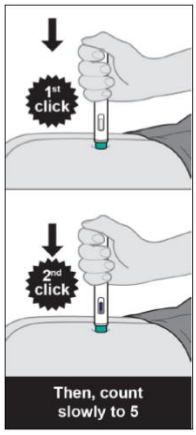


Figure J

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.

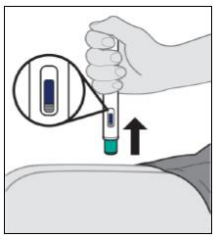


Figure K

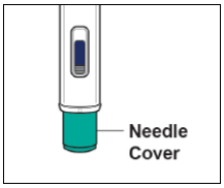


Figure L

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.

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

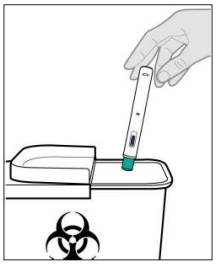


Figure M

12.Dispose of the Pre-filled Pen

a) Throw away the used pre-filled pen in 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.

– *How much to use*

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

– *When to use it*

Use as directed by your doctor or pharmacist.

– *How long to use it*

Continue taking Yuflyma for as long as your doctor recommends.

– *If you forget to use it*

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 use too much (overdose)*

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.

While you are using it

– *Things you must do*

- Read carefully these instructions before using the Yuflyma pen. Consult your healthcare provider if you have questions about using the Yuflyma pen.
- Use the pen ONLY if your healthcare provider has trained you on the right way to prepare for and to give an injection.
- Ask your healthcare provider how often you will need to give an injection.
- Rotate the injection site each time you give an injection. Each new injection site should be at least 3 cm away from the previous injection site.

– *Things you must not do*

- Do not use the pen if it has been dropped or is visibly damaged. A damaged pen may not function properly.
- Do not reuse the pen.
- Do not shake the pen at any time.
- Do not drive or operate machine as 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.

− *Things to be careful of*

Talk to your doctor before or during treatment with Yuflyma if you have:

- Allergic reactions
- Infections
- Tuberculosis
- Hepatitis B
- Surgery or dental procedure
- Demyelinating disease
- Vaccinations
- Heart failure
- Fever, bruising, bleeding or looking pale
- Cancer
- Autoimmune disease

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) side effects include:

- 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

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 may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Yuflyma

− *Storage*

- 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.
- A single Yuflyma may be stored at temperatures up to a maximum of 25°C for a period of up to 31 days. The pre-filled pen must be protected from light, and discarded if not used within the 31-day period.
- 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.

− *Disposal*

After use, place the pre-filled pen into a puncture resistant container and discard as required by local regulations.

Product Description

− *What it looks like*

Yuflyma is a clear to slightly opalescent, colourless to pale brown solution which is supplied as a single use pre-filled pen.

Yuflyma 40 mg solution for injection in pre-filled pen

Packs of:

- 1 pre-filled pen (0.4 ml sterile solution), with 2 alcohol pads.
- 2 pre-filled pens (0.4 ml sterile solution), with 2 alcohol pads.

Yuflyma 80 mg solution for injection in pre-filled pen

Packs of:

- 1 pre-filled pen (0.8 ml sterile solution), with 2 alcohol pads.
- 3 pre-filled pens (0.8 ml sterile solution), with 4 alcohol pads.

− *Ingredients*

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

− *MAL number*

MALXXXXXXXX

Manufacturer

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