

HUMIRA® SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE

Adalimumab

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What Humira® is used for

Humira® 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 Humira® works

It is a medicine that decreases the inflammation process of these diseases. The active ingredient, adalimumab, is a human monoclonal antibody produced by cultured cells. Monoclonal antibodies are proteins that recognise and bind to other unique proteins. Adalimumab binds to a specific protein (tumour necrosis factor or TNFα), which is present at increased levels in inflammatory diseases such as rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, axial spondyloarthritis (ankylosing spondylitis and Non-radiographic axial spondyloarthritis), psoriatic arthritis, psoriasis, ulcerative colitis, hidradenitis suppurativa, Crohn's disease, Uveitis and Enthesitis-Related Arthritis.

Before you use Humira®

- When you must not use it

- If you are allergic(hypersensitive) to adalimumab or any of the other ingredients of Humira®.
- If you have a severe infection, including active tuberculosis. It is important that you tell your doctor if you have symptoms of infections, e.g. 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.

Pregnancy and lactation

You should talk to your doctor if you become pregnant or are planning to have a baby.

According to a pregnancy study, there was no higher risk of birth defects when the mother had received Humira® during pregnancy compared with mothers with the same disease who did not receive Humira®.

You should talk to your doctor if you are breastfeeding or plan to breastfeed.

If you received Humira® during pregnancy, your baby may have a higher risk of getting an infection.

It is important that you tell your baby's doctors and other health care professionals about your Humira® use during your pregnancy before the baby receives any vaccine.

- Before you start use it

- If you have an infection, including long-term or localized infection (for example, leg ulcer) consult your doctor before starting Humira®.
- As cases of tuberculosis have been reported in patients treated with Humira®, your doctors will check you for sign and

symptoms of tuberculosis before starting Humira®.

- Advise your doctor if you reside or travel in regions where fungal infections such as histoplasmosis coccidioidomycosis or blastomycosis are epidemic.
- Advise 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 contracting HBV. Your doctor should test you for HBV. Humira® can cause reactivation of HBV in people who carry this virus. In some rare cases, especially if you are taking other medicines that suppress the immune system, reactivation of HBV can be life-threatening.
- Advise your doctor if you have a history of recurrent infections or other conditions that increase the risk of infections.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Live vaccines may cause infections and should not be given while receiving Humira®.

You should not take Humira® with medicines containing the active substance, anakinra or abatacept. If you have questions, please ask your doctor.

How to use Humira®

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

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- How long to use it

Continue taking Humira[®] for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

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

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Humira[®].

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Humira[®] to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Humira[®] may have a minor influence on your ability to drive and use machines. Room spinning sensation and vision disturbances may occur after taking Humira[®].

Side effects

Like all medicines, Humira[®] can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine:

- Severe rash, hives or other signs of allergic reaction;
- Swollen face, hands, feet;
- Trouble breathing, swallowing;
- Shortness of breath with exertion or upon lying down or swelling of the feet;
- Signs and symptoms suggestive of blood disorders such as persistent fever, bruising, bleeding, paleness;

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 of liver problems such as yellowing of skin and/or eyes, severe tiredness, nausea and/ or vomiting, bleeding or bruising, dark urine, or stomach pain.

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 Humira[®]

- Storage

Keep out of the reach and sight of children.

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

Keep the pre-filled syringe/pen in the outer carton.

A Humira pre-filled syringe or Pen may be stored at temperatures up to a maximum of 25°C (77°F) for a single period of up to 14 days. The syringe or Pen must be protected from light, and discarded if not used within the 14-day period.

Do not use the Humira[®] pre- filled syringe/pen after the expiry date stated on the label/blister/carton after EXP:.. The expiry date refers to the last day of that month.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Humira[®] 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.

Humira[®] 40 mg solution for injection is supplied as a sterile solution of 40 mg adalimumab dissolved in 0.4 ml solution.

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Humira[®] 80 mg solution for injection in pre-filled syringe is supplied as a sterile solution of 80 mg adalimumab dissolved in 0.8 ml solution.

- Ingredients

- Active ingredient
Adalimumab
- Inactive ingredients
Mannitol, polysorbate 80 and water for injections.

- MAL number:

Humira[®] Solution for Injection in Pre-filled Syringe 20mg/0.2ml
MAL19116042ACRZ
Humira[®] Solution for Injection in Pre-filled Syringe 40mg/0.4ml:
MAL17107005ACRZ
Humira[®] Solution for Injection in Pre-filled Syringe 80mg/0.8ml
MAL19116043ACRZ

Batch released by:
AbbVie Biotechnology GmbH
Knollstrasse
67061 Ludwigshafen, Germany

Product Registration Holder

AbbVie Sdn Bhd
Level 9 Menara Lien Hoe,
No.8 Persiaran Tropicana, Tropicana
Golf & Country Resort, 47410 Petaling
Jaya, Selangor Darul Ehsan, Malaysia.

Date of revision

14/01/2025

Serial number:

NPRA (R3/01)24052023/0252

HUMIRA[®] SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE

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Instructions on preparing and giving an injection of Humira[®]

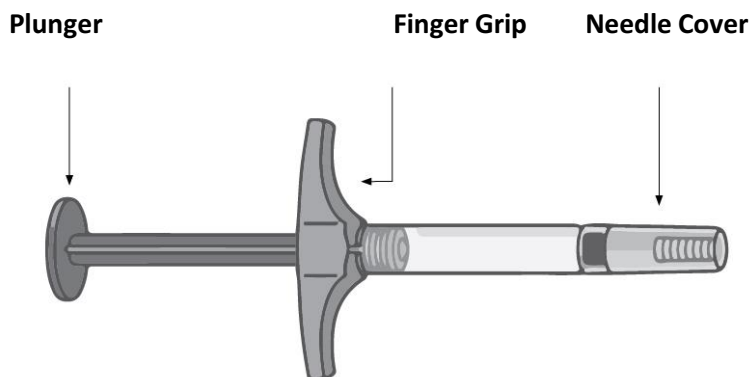
Method and route of administration

Humira[®] is administered by injection under the skin (by subcutaneous injection)

Instructions for use

- The following instructions explain how to give yourself a subcutaneous injection of Humira[®] 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 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 syringe for one injection.

Humira[®] Pre-filled Syringe



Do not use the pre-filled syringe and call your doctor or pharmacist if the

- liquid is cloudy, discoloured, or has flakes or particles in it
- expiry (EXP) date has passed
- liquid has been frozen or left in direct sunlight
- pre-filled syringe has been dropped or crushed

Do not remove the needle cover until just before injection. Keep Humira[®] out of the sight and reach of children.

STEP 1

Take Humira[®] out of the refrigerator.

Leave Humira[®] at room temperature for **15 to 30 minutes** before injecting.

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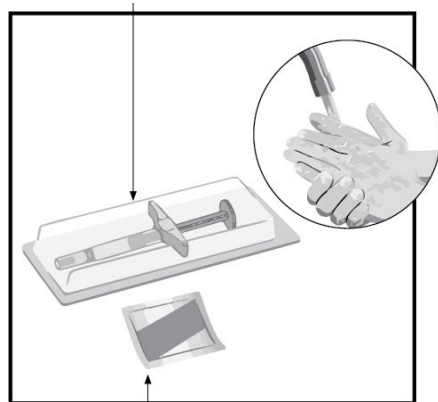
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- **Do not** remove the needle cover while allowing Humira[®] to reach room temperature
- **Do not** warm Humira[®] in any other way. For example, **do not** warm it in a microwave or in hot water

STEP 2

Check the expiry (EXP) date. **Do not** use the pre-filled syringe if expiry (EXP) date has passed.

Syringe



Pad

Place the following on a clean, flat surface

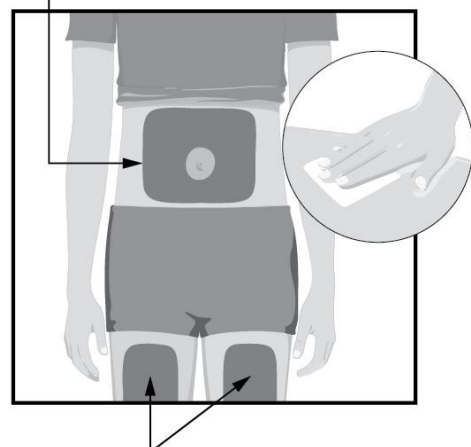
- 1 single-use pre-filled syringe and
- 1 alcohol pad

Wash and dry your hands.

STEP 3

Choose an injection site:

Injectable Areas



Injectable Areas

- On the front of your thighs or
- Your belly (abdomen) at least 5 cm from your belly button (navel)
- At least 3 cm from your last injection site

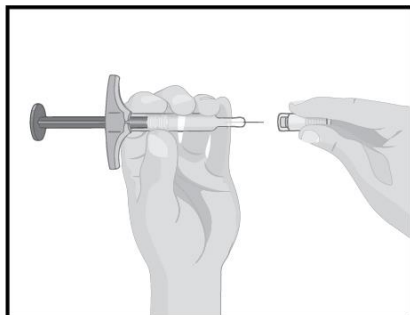
Wipe the injection site in a circular motion with the alcohol pad.

- **Do not** inject through clothes
- **Do not** inject into skin that is sore, bruised, red, hard, scarred, has stretch marks, or areas with psoriasis plaques

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STEP 4



Hold the pre-filled syringe in one hand.

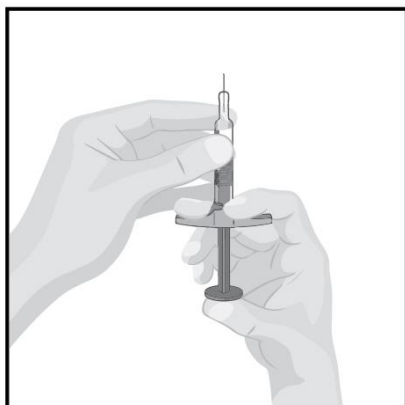
Check the liquid in the pre-filled syringe.

- Make sure the liquid is clear and colourless
- **Do not** use the pre-filled syringe if the liquid is cloudy or has particles
- **Do not** use the pre-filled syringe if it has been dropped or crushed

Gently pull the needle cover straight off with the other hand.
Throw the needle cover away. Do not recap.

- **Do not** touch the needle with your fingers or let the needle touch anything

STEP 5



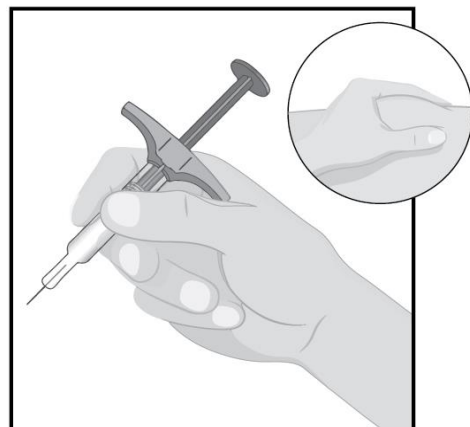
Hold the pre-filled syringe with the needle facing up.

- Hold the pre-filled syringe at eye level with one hand so you can see the air in the pre-filled syringe

Slowly push the plunger in to push the air out through the needle.

- It is normal to see a drop of liquid at the end of the needle

STEP 6



Hold the body of the pre-filled syringe in one hand between the thumb and index fingers, like you would a pencil.

Squeeze the skin at your injection site with your other hand to make a raised area and hold it firmly.

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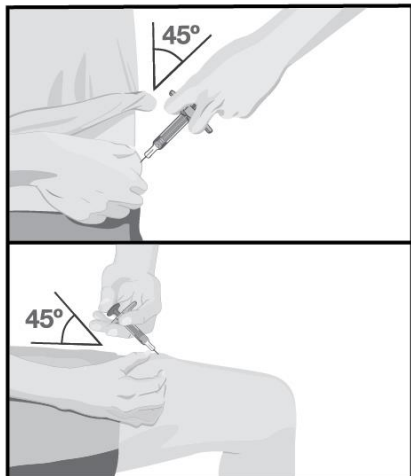
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STEP 7

Insert the needle all the way into the skin at about a 45-degree angle with one quick, short motion.

- After the needle is in, let go of the skin you are holding

Slowly push the plunger all the way in until all of the liquid is injected and the pre-filled syringe is empty.

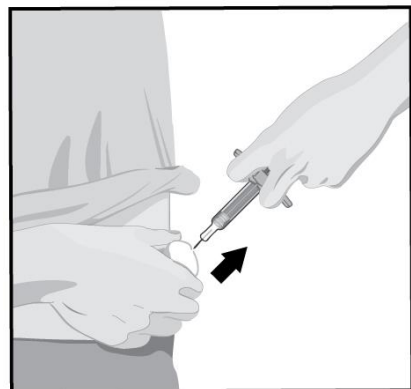


STEP 8

When the injection is completed, slowly pull the needle out of the skin while keeping the pre-filled syringe at the same angle.

After completing the injection, place a cotton ball or gauze pad on the skin over the injection site.

- **Do not rub**
- Slight bleeding at the injection site is normal



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STEP 9

Throw away the used pre-filled syringe in a special disposal container as instructed by your doctor, nurse or pharmacist. **Never** recap a needle.

- **Do not** recycle or throw the pre-filled syringe in the household waste
- **Always** keep the pre-filled syringe and the special disposal container out of the sight and reach of children

The needle cover, alcohol pad, cotton ball or gauze pad, blister and packaging may be put in your household waste.