Package leaflet: Information for the patient

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

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 Humira and during treatment with Humira. Keep this **Patient Reminder Card** with you.
- If you have any 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 Humira is and what it is used for
2. What you need to know before you use Humira
3. How to use Humira
4. Possible side effects
5 How to store Humira
6. Contents of the pack and other information
7. Injecting Humira

1. What Humira is and what it is used for

Humira contains the active substance adalimumab.

Humira is used to treat
- 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 Humira, adalimumab, is a human monoclonal antibody. Monoclonal antibodies are proteins that attach to a specific target.

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, Humira decreases the process of inflammation in these diseases.

Rheumatoid arthritis

Rheumatoid arthritis is an inflammatory disease of the joints.

Humira 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 Humira.

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

Humira 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 Humira should be used with methotrexate or alone.

Polyarticular juvenile idiopathic arthritis

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

Humira 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 Humira.

Your doctor will decide if Humira 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.

Humira 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 Humira.

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.

Humira 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 Humira.

Psoriatic arthritis

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

Humira is used to treat psoriatic arthritis in adults. Humira 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 Humira.

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.

Humira 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.

Humira is used to treat
- moderate to severe hidradenitis suppurativa in adults and
- moderate to severe hidradenitis suppurativa in adolescents aged 12 to 17 years.

Humira 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 Humira.

Crohn's disease

Crohn's disease is an inflammatory disease of the digestive tract.

Humira 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 Humira.

Ulcerative colitis

Ulcerative colitis is an inflammatory disease of the large intestine.

Humira 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 Humira.

Non-infectious uveitis

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

Humira 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). Humira 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 Humira.

2. What you need to know before you use Humira

Do not use Humira:

- 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 Humira.

Allergic reactions

- If you get allergic reactions with symptoms such as chest tightness, wheezing, dizziness, swelling or rash do not inject more Humira 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 Humira. If you are unsure, contact your doctor.

- You might get infections more easily while you are receiving Humira 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 Humira 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 Humira. You and your doctor should pay special attention to signs of infection while you are being treated with Humira. It is important to tell your doctor if you get symptoms of infections, such as fever, wounds, feeling tired or dental problems.

<u>Tuberculosis</u>

- 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 Humira.

    - As cases of tuberculosis have been reported in patients treated with Humira, your doctor will check you for signs and symptoms of tuberculosis before starting Humira. 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.

<u>Hepatitis B</u>

- 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, Humira 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.

<u>Surgery or dental procedure</u>

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

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 Humira. 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 Humira.
    - 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 Humira.
    - If you received Humira 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 Humira dose you received during pregnancy. It is important that you tell your baby's doctors and other health care professionals about your Humira 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 Humira, 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 Humira.

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 Humira 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 Humira 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 Humira. Some of those patients were also treated with azathioprine or 6-mercaptopurine.

- Tell your doctor if you are taking azathioprine or 6-mercaptopurine with Humira.
- Cases of non-melanoma skin cancer have been observed in patients taking Humira.
- 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 Humira 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 Humira.

Other medicines and Humira

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

You should not take Humira with medicines containing the following active substances due to increased risk of serious infection:
- anakinra
- abatacept.

Humira 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 Humira 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.
- Humira 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 Humira during pregnancy compared with mothers with the same disease who did not receive Humira.
- Humira can be used during breast-feeding.
- If you receive Humira 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 Humira 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

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

Humira contains polysorbate

This medicine contains 0.4 mg of polysorbate 80 in each 40 mg dose. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How to use Humira

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 Humira in each of the approved uses are shown in the following table. Your doctor may prescribe another strength of Humira if you need a different dose.

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 Humira. If your doctor decides that methotrexate is inappropriate, Humira can be given alone. If you have rheumatoid arthritis and you do not receive methotrexate with your Humira therapy, your doctor may decide to give Humira 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
Children and adolescents from 2 years of age weighing 10 kg to less than 30 kg	20 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
Children and adolescents from 6 years of age weighing 15 kg to less than 30 kg	20 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
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

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 Humira 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	First dose of 80 mg (two 40 mg injections in one day), followed by 40 mg two weeks later. 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. Thereafter, the usual dose is 40 mg every other week.	Your 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 (two 40 mg injections in one day), followed by 40 mg two weeks later. Thereafter, the usual dose is 20 mg every other week.	Your doctor may increase the dose frequency to 20 mg every week.

Ulcerative colitis		
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 80 mg (two 40 mg injections in one day) two weeks later. Thereafter, the usual dose is 40 mg every other week.	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 Humira 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 Humira 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 Humira. Humira can also be given alone.
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. Humira is recommended for use in combination with methotrexate.
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. Humira is recommended for use in combination with methotrexate.

Method and route of administration

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

Detailed instructions on how to inject Humira are provided in section 7 'Injecting Humira'.

If you use more Humira than you should

If you accidentally inject Humira 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 Humira

If you forget to give yourself an injection, you should inject the next dose of Humira 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 Humira

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

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 Humira 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 Humira.

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 (localized 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 Humira 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 the Yellow Card Scheme, Website: 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 Humira

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

Do not use this medicine after the expiry date stated on the label/blister/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 Humira pre-filled pen may be stored at room temperature (up to 25°C) for a maximum period of 14 days – be sure to protect it from light. Once removed from the refrigerator for room temperature storage, the pen **must be used within 14 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 Humira contains

The active substance is adalimumab.
The other ingredients are mannitol, polysorbate 80 and water for injections.

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

Humira 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 Humira pre-filled pen is a single-use grey and plum-coloured pen which contains a glass syringe with Humira. There are two caps – one is grey and labelled ‘1’ and the other is plum and labelled ‘2’. There is a window on each side of the pen through which you can see the Humira solution inside the syringe.

The Humira 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.

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

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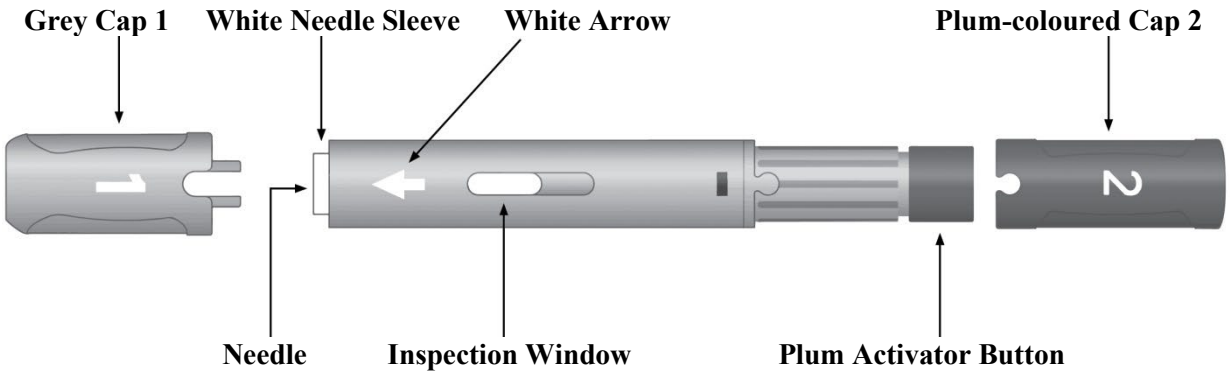
To listen to or request a copy of this leaflet in Braille, large print or audio, please contact the Marketing Authorisation Holder.

7. Injecting Humira

- The following instructions explain how to give yourself a subcutaneous injection of Humira 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.

Humira Pre-filled Pen



Do not use the pre-filled pen 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 pen has been dropped or crushed

Do not remove the caps until just before injection. Keep Humira out of the sight and reach of children.

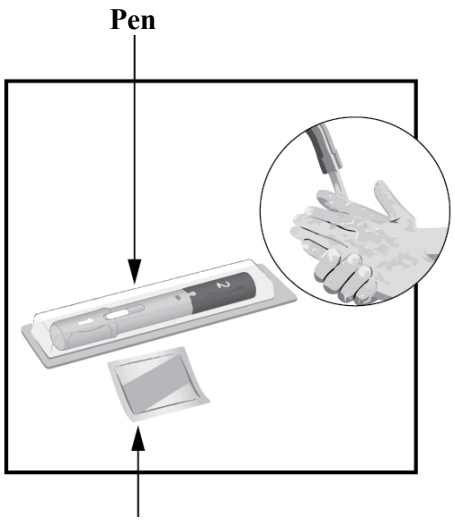
STEP 1

Take Humira out of the refrigerator.

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

- **Do not** remove the Grey or Plum-coloured Caps 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



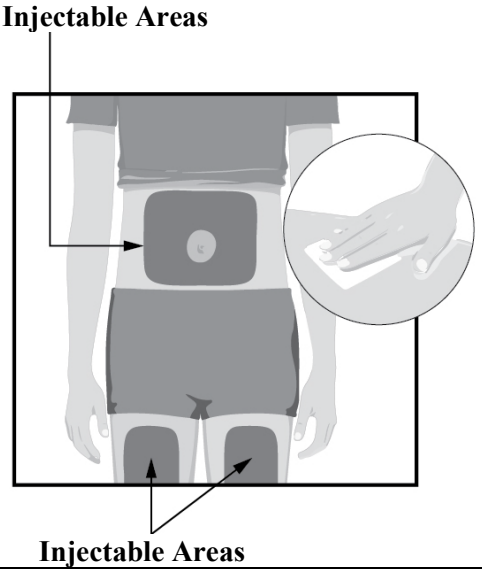
Check expiry (EXP) date. **Do not** use the pre-filled pen if expiry (EXP) date has passed.

Place the following on a clean, flat surface

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

Wash and dry your hands.

STEP 3



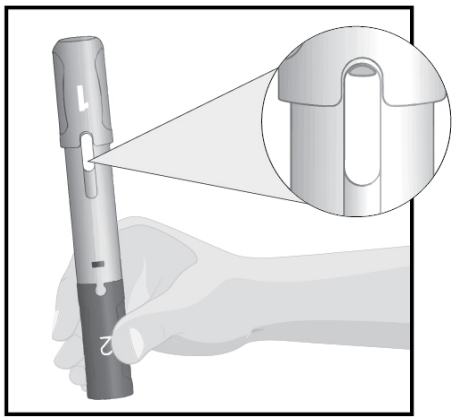
Choose an injection site:

- 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

STEP 4



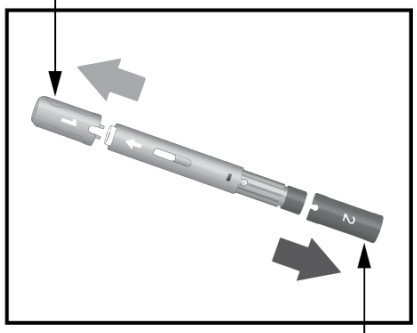
Hold the pre-filled pen with the Grey Cap 1 pointing up.

Check the inspection window.

- It is normal to see 1 or more bubbles in the window
- Make sure the liquid is clear and colourless
- **Do not** use the pre-filled pen if the liquid is cloudy or has particles
- **Do not** use the pre-filled pen if it has been dropped or crushed

STEP 5

Cap 1



Cap 2

Pull the Grey Cap 1 straight off. Throw the cap away. Do not recap.

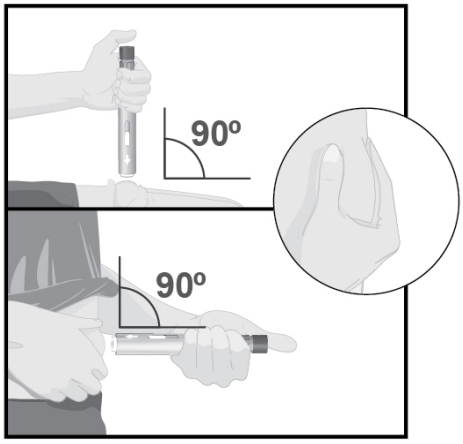
- Check that the small black needle cover of the syringe has been removed with the cap
- It is normal to see a few drops of liquid come out of the needle

Pull the Plum-coloured Cap 2 straight off. Throw the cap away. Do not recap.

The pre-filled pen is now ready to use.

Turn the pre-filled pen so that the white arrow points toward the injection site.

STEP 6



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

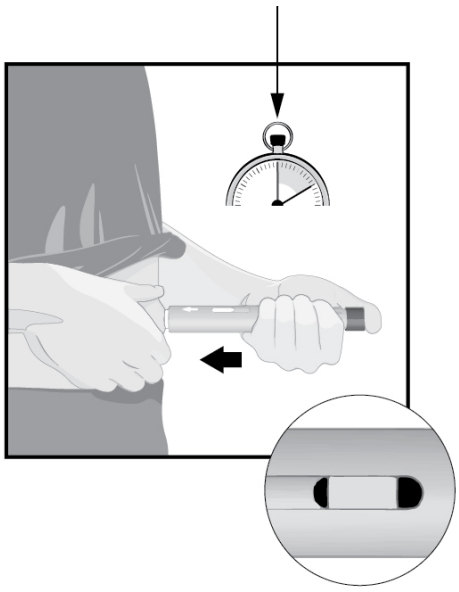
Point the white arrow toward the injection site (thigh or abdomen).

Place the white needle sleeve straight **(90˚ angle)** against the injection site.

Hold the pre-filled pen so that you can see the inspection window.

Do not press the plum activator button until you are ready to inject.

STEP 7



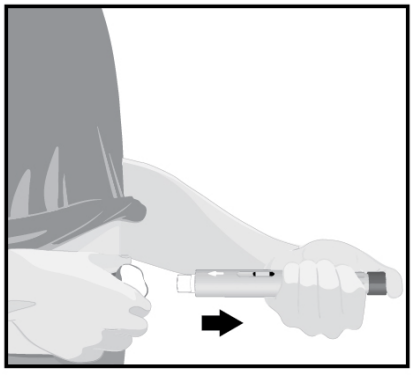
Firmly push the pre-filled pen down against the injection site before starting the injection.
Keep pushing down to prevent the pre-filled pen from moving away from the skin during the injection.

Press the plum activator button and count slowly for **10** seconds.

- A loud **"click"** will signal the start of the injection
- **Keep pushing** the pre-filled pen down **firmly** against the injection site until the injection is complete.

The injection is complete when the yellow indicator has stopped moving.

STEP 8



When the injection is completed, slowly pull the pre-filled pen from the skin. The white needle sleeve will cover the needle tip.

- A small amount of liquid on the injection site is normal

If there are more than a few drops of liquid on the injection site, contact your doctor, nurse or pharmacist.

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

STEP 9

Throw away the used pre-filled pen in a special disposal container as instructed by your doctor, nurse or pharmacist.

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

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