

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

The name of your medicine is Humira 40 mg solution for injection in pre-filled pen but will be referred to as Humira throughout this leaflet. Please note that the leaflet also contains information about other strengths.

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 (TNF), which is involved in the immune (defence) system and is present at increased levels in the inflammatory diseases listed above. By attaching to TNF, 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.

Tuberculosis

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

Hepatitis B

- Tell your doctor if you are a carrier of the hepatitis B virus (HBV), if you have active HBV or if you think you might be at risk of getting HBV.
- Your doctor should test you for HBV. In people who carry HBV, 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.

Surgery or dental procedure

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.

Demylinating 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 check 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 may 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:

- anakirra
- 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 6 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.

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.

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.

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

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

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

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.

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.

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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.

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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.

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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.

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Children and adolescents from 6 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.

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Children and adolescents from 6 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.

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Children and adolescents from 2 years of age weighing less than 20 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 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

