Patient information about HUMIRA® for rheumatic disorders

For people who have been prescribed HUMIRA

abbvie

HUMIRA
adalimumab
destination you
This brochure is for patients who are about to start treatment with HUMIRA for a rheumatic disease, or for non-infectious uveitis* (an eye disease).

You may already have travelled a long and difficult journey with your disease. With the help of your treatment and the information contained in this brochure, the road ahead will hopefully be easier and lead to a more active life, without any symptoms.

Don’t let the disease control your life. You are the one who decides!

Good luck!

*The following rheumatic diseases can now be treated with HUMIRA: rheumatoid arthritis, axial spondyloarthritis and psoriatic arthritis. HUMIRA is also used to treat non-infectious uveitis, an eye disease that can affect the entire, back or middle layer of the eye.
What is HUMIRA and how does it work?

HUMIRA is a biological drug that is given once every other week by injection to inhibit inflammation.

HUMIRA is a TNF inhibitor. TNF (tumor necrosis factor) is an inflammation-stimulating protein that occurs naturally in the body.

Normally, the purpose of inflammations is to protect the body against harmful effects by repelling trespassers such as bacteria and viruses.

However, many inflammatory diseases, such as rheumatic joint diseases, are associated with excessive TNF production. The excess causes the immune system to mistakenly overreact, which then triggers inflammation.

The active ingredient in HUMIRA is adalimumab. Adalimumab is an antibody that binds and inactivates excessive TNF, which modifies the inflammation process.

A human antibody produced by genetic engineering

The drug should behave in the same way as naturally occurring substances when it enters the body. Biological drugs are therefore composed of substances that are almost identical to the body’s own structure.

HUMIRA is a human anti-TNF antibody, produced by recombinant DNA technology (genetic engineering).

Too much TNF creates an imbalance. The immune system overreacts, causing increased disease activity.

HUMIRA reduces the excess, modifies the inflammation process and reduces disease activity.
Who is treated with HUMIRA?

Treatment with HUMIRA has been approved for the following indications. They are all rheumatic diseases that primarily affect joints, except for uveitis. Uveitis affects the eye and may, or may not, be caused by a rheumatic disease. For these conditions, HUMIRA can be used alone or in combination with other drugs.

Rheumatoid Arthritis (RA) causes inflammation of the joints that can lead to permanent disability. RA can also attack other organs, such as the heart, lungs and eyes. When the disease flares up, the inflammation can affect multiple joints simultaneously, particularly the hands and feet. The inflammation tends to be symmetrical, which means both the right and left foot are affected.

In Sweden, about 0.5-1% of the population suffers from RA. The disease is more common in women than men. About 50,000 people in Sweden are living with RA. Every year, about 5,000 people develop the disease. The age of onset is usually 50-60 years, but young people in their twenties can also be affected.

Axial spondyloarthritis is an inflammatory disease that affects the spine. The most common symptoms are nocturnal back pain and early morning stiffness. The pain usually improves with movement. The discomfort may also be similar to sciatic pain that radiates down the leg. The pain is mainly caused by inflammation in the joints, tendons and ligaments attached to the pelvis and spine. Other organs may also be affected. Inflammation of the eyes and gastrointestinal tract is also common.

Some patients with axial spondyloarthritis may also, over time, develop radiographic changes in the spine and/or sacroiliac joints. This condition is known as ankylosing spondylitis (AS), also called Bechterew’s Disease. Axial spondyloarthritis also includes non-radiographic axial spondyloarthritis (nsAxSpA). Patients with nsAxSpA can have similar symptoms to AS patients, but with no evidence of joint damage on x-rays. The age of onset is usually 18-30 years.

Physical therapy is a key component of treatment.

Psoriatic Arthritis (PsA) is a form of rheumatism that affects people with psoriasis. Psoriasis is a disorder that is characterised by a disturbance in the formation of new skin cells, which causes itchiness, flaking and sensitive areas in the skin. In psoriatic arthritis, the extremities of the finger joints and Achilles’ tendon are often attacked, something that is uncommon with RA. In individual cases, the joint pains may make themselves felt before the skin trouble. It is estimated that about 20,000 Swedes are affected.

Between 10 and 30 percent of people with psoriasis also get joint pains, but there is no connection between the extent of the rash and how severe the joint pains are. The disorder occurs in all age groups and is equally common in men and women.

Psoriatic arthritis can also cause inflammation in other parts of the body, such as the eyes and gastrointestinal tract. Contact your health care provider if you experience these symptoms.

Uveitis is a form of chronic inflammatory disease that affects parts of the eye. It can sometimes be triggered by rheumatic diseases, but may also be caused by infection. HUMIRA is indicated for the treatment of non-infectious uveitis that affects the back, middle or entire eye.

Although uveitis is rare, the condition can lead to visual impairment or blindness if left untreated.

Uveitis can occur at any age, but usually affects people of working age, from 20–50 years. While 40% of the uveitis cases described above have no known underlying disorder, diseases such as MS, sarcoidosis and Behcet’s Disease can cause uveitis.
What you should consider before and during your treatment

Your safety is a top priority

Previous diseases, current infections and future plans – anything to do with your body – may have significance for your upcoming treatment with HUMIRA. You must always tell your doctor about your health concerns and how you feel.

To ensure you have no active infections when treatment begins, your doctor will perform a number of tests and examinations (including X-rays and blood tests), to rule out latent tuberculosis and hepatitis B or C.

Always tell your doctor:

• If you have an infection – locally on your body (such as an infected sore or dental problems) – or in your body (such as fever, fatigue, influenza, pneumonia or tonsillitis).
• If you have, or have ever had, hepatitis B or problems with prolonged or recurrent infections.
• If you have, or have ever had, tuberculosis or been in contact with anyone who has tuberculosis.
• If you are planning to get vaccinated.
• If you are about to undergo surgery.
• If you have a neurological disease, such as multiple sclerosis (MS).
• If you have, or have ever had, a serious heart disease or heart failure.
• If you are pregnant, or planning to become pregnant.
• If you smoke.
• If you take any other medication, including non-prescription products and/or natural remedies. Bring a list of the medications you take when you visit your doctor or any other health care provider.

Medication used to treat rheumatic diseases

The type of medication used depends on the severity of the disease. Medications used to treat rheumatic diseases can be divided into the following groups:

• Analgesics such as acetaminophen and ibuprofen. Used to supplement the basic treatment.
• Cortisone, also known as steroids. The treatment often has a rapid effect, but may eventually cause side effects. Cortisone is usually given for a short time only and in the lowest-possible doses. Doses and forms can vary, depending on the disease activity. Cortisone can be taken in tablet form, or given topically by injection into the affected joint.
• Immunosuppressive drugs, such as methotrexate, are given as basic first-line therapy to stop the ongoing inflammation.
• TNF inhibitors are biologics used to treat moderate to severe inflammatory joint disease. HUMIRA belongs to this group.
During your treatment
Like all other drugs, HUMIRA can have side effects. While most side effects are temporary and harmless, some can be serious.
At the beginning of your treatment, your skin may become red and swollen at the injection site. This is very common and usually harmless. The swelling will usually disappear within a few days.
You may be more susceptible to colds during your treatment, and if you have a severe infection, you should not take your injection.
Always contact your doctor:
• If you notice any of the following symptoms at the beginning of your treatment:
  – swollen lymph nodes
  – a dry cough that does not improve within a week or two
  – sudden weight loss
  – constant sweating
• If you get:
  – signs of infection, such as fever, nausea, sores
  – dental problems, a burning sensation with urination
  – weakness or fatigue
  – a cough
  – tingling
  – numbness
  – double vision
  – leg or arm weakness
  – a bump or open sore that does not heal
  – signs and symptoms of blood disorders, such as prolonged fever, bruising, bleeding, pallor
• If you have symptoms of heart failure
  – increasing shortness of breath
  – swollen ankles
• If you are planning to become pregnant. Read more under “Pregnancy” below
• If you are about to undergo surgery (including dental surgery)
• If you are going to be treated with antibiotics
• If you are planning to get vaccinated, before travelling abroad, for example

Pregnancy
If you are planning a pregnancy, you should consult your doctor in advance. If you become pregnant during treatment, it is vital that you discuss this with your doctor so that you can decide together how your condition, and your medication, should be managed throughout your pregnancy.

Surgery
Treatment with HUMIRA should end at least 2–4 weeks before elective surgery. Treatment can generally be resumed 1–2 weeks after surgery.

What happens if I forget to take HUMIRA?
If you forget to take HUMIRA, take your missed dose as soon as you remember. Then take the next injection at your usual time. If a long time has passed since you forgot to take your dose, contact your doctor.
**Vaccines**
Normal doses of vaccine are sometimes less effective for people undergoing anti-TNF treatment. Your doctor may therefore need to revise or increase your protection if he or she thinks you are at higher risk of infection.
However, live vaccines should not be given during treatment! These include vaccines for measles, mumps, rubella, chickenpox, shingles, tuberculosis and yellow fever. If you need to be vaccinated with any of these vaccines, before travelling abroad for example, your should stop taking HUMIRA well in advance (three months).

**Smoking**
Research shows that smoking can cause or exacerbate inflammation in people with rheumatic diseases. But smoking can also impair the treatment efficacy of a biological medication, such as HUMIRA.

**Alcohol**
There are no particular risks associated with alcohol when you are taking HUMIRA. But, as always, it is important that you take care of yourself.
The effects of HUMIRA

The effects of HUMIRA on rheumatic conditions has been studied for almost ten years. The studies have shown that HUMIRA reduces inflammation and stiffness, and prevents joint damage in rheumatoid arthritis and psoriatic arthritis. You must therefore continue to take your medication as prescribed, to prevent a recurrence of the symptoms or serious damage to your joints.

Unless your doctor tells you otherwise, one dose of HUMIRA is usually taken every other week.

When the medication starts to work, will you notice an immediate improvement in your symptoms, such as less pain and swelling or more flexible joints, and you will be able to move more easily. If you have psoriatic arthritis, the plaques – or inflamed patches of skin – will become smaller or disappear. Exactly how you notice that HUMIRA is working will depend on your own particular symptoms. The treatment also has a documented positive effect on general well-being. Many experience greater well-being, less fatigue and that life is easier.

Some people get relief from their symptoms within a few days; for others it may take longer. You must be patient, and continue taking your injections. After 12 weeks, your doctor usually evaluates the effects together with you, to decide how to proceed.

The overall goal of your treatment is to silence your symptoms and achieve what medical professionals call remission. This means that inflammation is inactive and joint damage has stopped progressing (the latter condition is specific to rheumatoid arthritis and psoriatic arthritis). Other key goals are to avoid long-term complications and the need for hospitalization.

The main goal, however, is that you feel good and can live the life you want to live – with work, friends, family and hobbies.

So, even though you feel better, you must continue with your HUMIRA injections for as long as the doctor tells you. Otherwise the symptoms may return.

Which type of HUMIRA is best for you?

There are two different ways to inject HUMIRA: with a syringe, or an injection pen. You and your doctor can decide which option is best for you.

HUMIRA is currently available in packs of two or six pens. The advantages of the larger pack is that you save trips to the pharmacy, and that you usually have the medication on hand at home. Some pharmacies also offer prescription refill, home delivery or online subscription services. Find out what options are available to you where you live.

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HUMIRA pre-filled syringe 6-pack and 2-pack HUMIRA injection pen 6-pack and 2-pack There are two different ways to inject HUMIRA: with a syringe, or an injection pen. Both are latex-free, with ultra-thin wall needles. The injection pen is designed to make self-injection easier.
How to use the HUMIRA injection pen

HUMIRA is injected by means of an injection pen. HUMIRA is also available as a pre-filled syringe. It is important that you learn everything about how the pen is to be used before you leave the surgery, as you will then take care of the injections yourself. At the clinic, you can even let someone you know train in giving you injections as support. Once the pen has been used, it should always be discarded.

1. Bring out everything you need
   • Take out the injection pen from the fridge 15–20 minutes before an injection.
   • Take out an alcohol swab (found in the packaging) and an ice bag if necessary.
   **Important!** Check the expiration date. Do not use the pen after the stated month and year.

2. Prepare the injection site
   • Choose a new injection site on the thigh or stomach, more than 3 cm from the site where HUMIRA was last injected and at least 5 cm from the navel.
   **Important!** Never inject into an area that is red, bruised or feels hard, as this could be a sign of local infection.
   • Wash your hands thoroughly with soap.
   • Wipe the area with the alcohol swab and then avoid touching the area.

3. Prepare the injection pen
   • Hold the HUMIRA pen upright with the grey cap marked 1 pointing up.
   • Study the injection fluid in the window, it should be clear and colourless.
   **Important!** Do not use the pen if the liquid is cloudy, discolored, contains particles, has been frozen or left in direct sunlight.

4. Inject
   • Hold the pen with a steady grip around the middle.
   • Remove the safety caps, the grey cap marked 1 first, then the plum-coloured cap marked 2. **Never replace the caps.**
   • Press together the cleaned skin and position the injection pen at a right angle against the skin with the window facing upwards.
   • Press the plum-coloured button.
   • Once you hear the click, you should count to ten slowly and keep the injection pen in the same position.
   • Once you have finished counting, check that the entire yellow indicator is visible in the window and that it has stopped moving.
   • Pull the injection pen straight out at the same right angle from the skin.
   • Hold a cotton swab to the injection site for 10–15 seconds. A drop of blood or fluid may come out, which is entirely normal. Do not rub on the injection site. Apply a plaster if you like.

5. Dispose of the used material
   • Dispose of used injection pens according to the instructions from your nurse or doctor.
   • The safety cap can be separated and disposed of as hard plastic. Refer also to the section “HUMIRA and the environment.”
Remember to let the syringe stand for 15–20 minutes at room temperature before use.

How to use the HUMIRA pre-filled syringe

As an alternative to the HUMIRA injection pen, HUMIRA is also available as a pre-filled syringe. It is important that you learn everything about how the syringe is to be used before you leave the surgery, as you will then take care of the injections yourself.

At the clinic, you can even let someone you know train in giving you injections as support. Once the syringe has been used, it should always be discarded.

1. Bring out everything you need
   • Take out the syringe from the fridge 15–20 minutes before an injection.
   • Take out an alcohol swab (found in the packaging).
   **Important!** Check the expiration date. Do not use the syringe after the stated month and year.

2. Prepare the injection site
   • Choose a new injection site on the thigh or stomach, more than 3 cm from the site where HUMIRA was last injected and at least 5 cm from the navel.
   **Important!** Never inject into an area that is red, bruised or feels hard, as this could be a sign of local infection.
   • Wash your hands thoroughly with soap.
   • Wipe the area with the alcohol swab and then avoid touching the area.
   **Important!** HUMIRA is a liquid that should be transparent and colorless. Do not use the syringe if the liquid is cloudy, discolored, contains particles, has been frozen or left in direct sunlight.

3. Inject
   • Remove the protective cap from the needle. Do **not** shake the syringe.
   • Press together the cleaned skin with one hand and hold steadily.
   • Take the syringe in the other hand and hold it at a 45 degree angle to the skin.
   • Insert the needle all the way into the skin with a quick, concise movement.
   • Let go of the skin.
   • Press in the syringe’s plunger to inject HUMIRA. It takes 2–5 seconds to empty the syringe.
   • Pull out the syringe from the skin. Be careful to pull at the same angle.
   • Hold a cotton swab to the injection site for 10–15 seconds. A drop of blood or fluid may come out, which is entirely normal. Do not rub on the injection site. Apply a plaster if you like.

4. Throw away the used materials
   • Do not replace the protective cap for the needle.
   • Clip off the needle using Safe-Clip, which you will be given at the surgery.
   • Discard syringes and needles according to the instructions you have been given by your nurse or doctor.

Refer also to the section “HUMIRA and the environment.”
How to store HUMIRA

At home:
Do not remove the pen/syringe from its original carton, because HUMIRA is light-sensitive. Keep HUMIRA in the refrigerator (2–8 °C). HUMIRA must not be frozen.

If necessary (when travelling, for example), a HUMIRA pre-filled syringe/pen can be kept at room temperature (up to 25°C) for a maximum of 14 days. Make sure it is kept out of direct sunlight. If the syringe/pen has been taken out of the refrigerator and kept at room temperature, it must be used within 14 days or discarded, even when it has been returned to the refrigerator. Write down the date when the syringe/pen is first taken out of the refrigerator, and the date when it should be discarded.

When travelling:
HUMIRA is available in packs of both two and six doses. Consult your doctor or pharmacist about the best option for you.

Keep HUMIRA in a cooler filled with ice packs. Do not remove HUMIRA from its original carton in the cooler.

When travelling abroad with HUMIRA, you will also need a letter from your doctor to confirm that you are being treated with HUMIRA. The letter must be signed by your doctor.

Travelling with HUMIRA
You are at greater risk of bacterial infection (including Tuberculosis, Legionella, Salmonella and Listeria) when undergoing treatment with HUMIRA. The incidence of these diseases is higher in some countries. Always consult your doctor about the risks that exist in the country you plan to visit, the symptoms you should look for, and how you can find medical care if you need it.

Remember that vaccinations with a live vaccine, such as tuberculosis vaccine, should not be given with three months of receiving HUMIRA treatment.

For up-to-date information about the vaccines recommended for travel, visit 1177.se.

If you have any questions or concerns, contact the infectious disease clinic.

The doctor’s note can be issued in both Swedish and English.
HUMIRA and the environment

HUMIRA consists of a protein that is quickly broken down when it comes out into nature. The actual drug does not, therefore, cause any harm to animals, plants or the ecosystem.

Dispose of used injection pens and pre-filled syringes according to the instructions from your nurse or doctor.

The lid of the pens can be disposed of as hard plastic. If you are unable to sort your waste, dispose of the lids in your normal combustible waste.

The plastic in the HUMIRA pens consists of polypropylene plastic. During combustion, only water and carbon dioxide are produced.

Never flush unused HUMIRA pens or pre-filled syringes down the toilet, or throw them in your household waste. Ask your pharmacist how you should dispose of your medication.

Be environmentally friendly!

HUMIRA does not harm the environment if you follow the instructions for dealing with used injection pens and pre-filled syringes.
Why check-ups?

The goal of your treatment is to help you live your life without symptoms, and to stop the disease from moving through its stages.

Your treatment and disease activity will be assessed at regular intervals, more frequently in the beginning. You and your doctor can agree on a plan for your check-ups.

Check-ups are important because they help to determine the specific stage of your condition and prevent any progression. Even if you start to feel better, regular monitoring is important.

Always contact your doctor if your condition worsens, or if something else doesn’t feel right.

Normal examinations for rheumatic diseases are:

• Joint assessment (“applying pressure and bending”)
• Blood tests
• X-ray, ultrasound or MRI of the affected joints

Regular check-ups will help track your progress toward a symptom-free life.
If you would like to find out more

www.reumatikerförbundet.org The Swedish Rheumatism Association is a patient and co-operative association for people with different rheumatic diagnoses. On the website, you will find information about this and also the association's activities. The Swedish Rheumatism Association supports both research and individuals and is also involved in related social issues.

www.reumatikerlinjen.se Reumatikerlinjen, the Rheumatics Line, is a website and knowledge base for people living with a rheumatic disorder. Here, you will find, among other things, articles, films, training tips and questions and answers on most things concerning your treatment.

www.ungareumatiker.org The Swedish Rheumatism Association’s Youth Organisation works for the rights of young rheumatics and also works in the area of information, camp activities and various other activities.

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www.1177.se 1177 Vårdguiden offers medical advice online and over the phone.

www.fass.se On this page you can search for information about different drugs, how they work and are used and also what side effects they have.

www.abbvie.se The pharmaceutical company, AbbVie’s, Swedish website contains information about the company and its different drugs.
What is HUMIRA? What is meant by a biological drug? What does the treatment involve and how long does it take before you feel better?

This brochure is for people who will be starting treatment with HUMIRA. As well as teaching you more about HUMIRA and what you can expect from your treatment, you can find out more here about the rheumatic disorders HUMIRA is used against, how the drug is used and what you should think about in connection with the treatment.

Read the leaflet carefully before you start taking HUMIRA.

**HUMIRA®, (adalimumab), Rx, F, L04AB04 (TNF-α-inhibitor), SmPC 2016-09-15.**
Therapeutic indications: Treatment of moderate to severe (including severe progressive), active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drugs (DMARDS) including methotrexate has been inadequate. Treatment of active polyarticular juvenile idiopathic arthritis, in patients from the age of 2 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDS). Active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy. Severe active ankylosing spondylitis in adults who have had an inadequate response to conventional therapy. Treatment of adults with severe axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs. Active and progressive psoriatic arthritis in adults when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate. Non-infectious intermediate, posterior uveitis and panuveitis in adult patients who do not respond adequately to corticosteroids, in patients who need corticosteroid-sparing, or patients in whom corticosteroid treatment is inappropriate. HUMIRA® 40 mg solution for injection in vial, single use pre-filled pen/syringe. For full prescribing information, please refer to HUMIRA SmPC at www.EMA.europa.eu.