Patient information about HUMIRA® (adalimumab)

Treatment for hidradenitis suppurativa (HS) with HUMIRA
Contents

Introduction 5
Structure of the skin 6
What is hidradenitis suppurativa? 7
What is HUMIRA and how does it work? 9
Starting your treatment 10
The effects of HUMIRA 13
During your treatment 14
How to use the HUMIRA injection pen 16
How to use the HUMIRA pre-filled syringe 18
How to store HUMIRA 21
HUMIRA and the environment 23
Living with HS 25
Would you like to know more? 26
This brochure is for patients with hidradenitis suppurativa (HS) who are about to start treatment with HUMIRA.

Here you can read about the structure of the skin, the skin disease HS, what HUMIRA is, how the treatment works and other factors that you might want to consider.

The information in this brochure should be considered a complement to the information you receive from your specialist and clinic nurse. If you have any more questions after reading this brochure, speak to your specialist or clinic nurse.

Good luck!
What is hidradenitis suppurativa?

Hidradenitis suppurativa (HS) is a chronic and often painful disease characterized by recurrent inflammation of the hair follicles in areas of skin containing apocrine sweat glands. The inflammation, which is mostly limited to the armpits, groin, perineum and under the breasts, leads to painful bumps and lumps of pus. The hair follicles are clogged, and blackheads, scar tissue and fistulae can form in the skin. They can leak foul-smelling pus, which may require bandaging.

HS is an inflammatory skin disease, which means that the immune system is involved in some way. It is not yet known why some people are affected. Research shows that HS may be hereditary. In about one-third of all cases, HS runs in families. HS is not contagious, nor is it caused by poor hygiene.

Structure of the skin

The skin is the largest organ in the body, with a surface area of nearly two square meters. The skin has three layers:

**The epidermis** is the outermost layer of skin. It is composed of several layers of tightly packed cells, with thicknesses ranging from 0.1-1 mm.

**The dermis** is the middle layer. It contains blood vessels that provide structure and nourishment for the epidermis.

**The hypodermis** (or subcutis) is the lowermost layer, and often referred to as subcutaneous tissue. It contains lobules of fat that provide thermal insulation and act as a shock absorber.

The skin also contains:

**Hair follicles:** small holes in the epidermis where hairs grow out

**Sweat glands:** glands in the dermis or hypodermis where sweat is formed.

There are two types of sweat glands:

**Eccrine sweat glands:** sweat glands found in virtually all parts of the body, with the highest density in the palms and soles, and on the head. These glands secrete directly onto the surface of the skin and regulate the body’s temperature by releasing water and salt.

**Apocrine sweat glands:** sweat glands that are mainly found in the armpits, groin, perineum and on the breast. These sweat glands develop during puberty and secrete into hair follicles. Apocrine sweat glands are associated with “body odor,” but are not involved in temperature regulation in the same way as eccrine sweat glands.

**Sebaceous glands:** glands that secrete sebum and are found in the dermis all over the body. They become more active after puberty and release sebum into hair follicles.
What is HUMIRA and how does it work?

HUMIRA is a biological drug that is given by injection using an injection pen or syringe.

HUMIRA is a TNF blocker. TNF (tumor necrosis factor) is a proinflammatory cytokine that occurs naturally in the body.

In a normal situation, the function of inflammation is to promote wound healing and to protect the body from damage by killing intruders such as viruses and bacteria.

Many inflammatory diseases produce excessive amounts of TNF, causing the immune system to overreact and trigger an inflammatory response by mistake.

The active ingredient in HUMIRA is adalimumab. Adalimumab is an antibody that binds and inactivates excessive TNF, which modifies the inflammation process.
Dosage for adults
For HS, the normal dosage is an initial dose of 160 mg (4 injections in one day, or 2 injections per day for two consecutive days), followed by 80 mg (2 injections in one day) two weeks later. Two weeks later, the treatment continues with one dose of 40 mg every week.

Dosage for adolescents (12 years and older, and weight 30 kg or more)
The normal dosage is an initial dose of 80 mg (2 injections in one day) followed by 40 mg one week later, and thereafter 40 mg every other week. If the treatment isn’t working, your doctor may consider increasing the dosage to 40 mg every week.

It is also recommended that you apply an antiseptic solution to the affected areas every day.

What if I forget to take HUMIRA at the prescribed time?
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.

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 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.

Open dialog is important
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.
The effects of HUMIRA

Some people experience rapid relief from their symptoms, an improvement may take longer for others. However, you should continue taking your injections.

When the drug begins to work, most people experience relief from the more pronounced symptoms of their disease. The number of lumps and bumps decreases, for example, and the pain eases.

Even if you feel better, you should continue with your HUMIRA injections for as long as the doctor tells you.

After 12 weeks, you should assess the effects of your treatment together with your doctor. If you haven’t noticed any improvement yet, your treatment should be reconsidered.

To ensure that the treatment is working properly, your doctor will schedule regular tests and follow-ups.

Get involved and influence your own treatment

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 advantage 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 online account and prescription refill services. Find out what options are available where you live.
During your treatment

Previous diseases, current infections and future plans – anything to do with your body – may have significance for your upcoming treatment with HUMIRA. 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.

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, you should stop taking HUMIRA well in advance (three months).

Be aware of how you feel
Just as before you started using HUMIRA, you should keep an eye on your health during treatment. During treatment, it may be more difficult to notice infections. You should pay more attention to how you feel. If your children go to kindergarten, you should check with your doctor about what to do when the risk of infection is high. If you notice any abnormal changes to your health, always consult your doctor.

Seek emergency care!
Always call your doctor if you experience severe itching, severe skin rash, swelling in the face, hands or feet, or swallowing or breathing difficulties. This could mean that you have developed an allergic reaction to the drug. Stop taking the drug until your symptoms have been diagnosed.

Dental care or other medical treatment
Since treatment with HUMIRA affects the immune system, you should inform your health care providers, including your dentist, that you are undergoing treatment with HUMIRA. Always show them the patient record card you have received from your doctor or nurse.
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. Do not use the pen if it has been dropped or crushed.

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.
   • You should hand in full and sealed containers to your pharmacy or deposit them at your local recycling station. Note that local guidelines may be in place. Ask your pharmacy about what applies in your area.

Refer also to the section “HUMIRA and the environment.”
How to use the HUMIRA pre-filled syringe

HUMIRA is also available in pre-filled syringes, as an alternative to the HUMIRA injection pen. Injections are normally given every other week. Before leaving the clinic, you should learn everything you can about how to use the syringe because later on, you will have to take care of the injections yourself. Always dispose of used syringes.

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. Do not use the pen if it has been dropped or crushed.

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.”

Remember to let the syringe stand for 15–20 minutes at room temperature before use.
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.

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:
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.

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

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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.
Living with HS

HS is a disease that can be very embarrassing and painful, and have a negative impact on a person’s quality of life. The experience of living with a chronic disease like HS highly individual. You know your body best, and how the disease effects you and your life, and what support you need. The tips below may make your daily life easier.

Regular exercise, a healthy diet, avoiding stress and getting enough sleep are good for everyone’s health and wellbeing. If you suffer from HS, the following could be especially valuable:

Lose weight (if you are overweight): Research has established a link between HS and being overweight. If you are overweight, it might be a good idea to change your eating and exercise habits. The conditions for taking part in physical activity can vary between individuals and the disease may also be physically limiting. A tip for getting started is to find some form of physical activity that you can do every day. Taking walks, for example, can help you to control both your weight and your disease.

Stop smoking (if you smoke): Research has established a link between smoking and HS, and smoking can have a negative prognostic effect.

Avoid tight clothing: There is no special type of clothing to relieve HS, but you can consult your dermatologist about what might work best for you, depending on the severity of your discomfort and where the symptoms are on your body. Loose clothing is often better than tight clothing and cotton “breathes” better than synthetics. Wool can be uncomfortable against sore and painful areas of skin.

Wash with antiseptic soap or bath additives: Washing the area with antiseptic soap or bath additives will help prevent a bacterial skin infection from developing. Deodorants, shaving and similar will not worsen the condition. Topical application of an antiseptic can inhibit the growth of bacteria and minimize the odor from abscesses and sores. Ask your dermatologist for advice.
Would you like to know more?

www.hsonline.se HS online is a Swedish website with information about hidradenitis suppurativa.

www.hs-foundation.org The Hidradenitis Suppurativa Foundation is a global organization dedicated to improving research, education, and the quality of life and care for individuals and families affected by HS.

www.hidrosadenitis.dk Patientforeningen HS is a Danish patient association that offers information and support for people with HS.

www.hstrust.org The Hidradenitis Suppurativa Trust is a charity in the UK dedicated to the raising of awareness, understanding and support for HS.
AbbVie is a research-driven biopharmaceutical company that was founded in 2013 following the division of Abbott. With competent and dedicated employees and a unique innovation strategy, we are dedicated to finding solutions to serious diseases with the goal of improving life for people affected by disease.

We are represented in 170 countries and have about 28,000 employees. In Sweden, we have about 130 employees and a head office in Solna. For more information about the company, visit www.abbvie.se

Read all of the package leaflet carefully before you start taking HUMIRA.

HUMIRA®, (adalimumab), Rx, F, L04AB04 (TNF-alpha inhibitor), SPC July 20, 2017. Therapeutic indication: The treatment of moderate to severe active hidradenitis suppurativa (acne inversa) in adult patients and adolescents (12 years) who have not responded to traditional systemic HS therapy. HUMIRA® is available as a solution for injection, pre-filled injection pen/syringe, 40 mg. For a complete list of indications, contraindications, precautions, side effects, price and dosage, see fass.se.