HUMIRA VIAL

Adalimumab (rch)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Humira.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Read this leaflet carefully before you use Humira and keep it with the medicine.
You may need to read it again.

What Humira is used for

Humira is intended for the treatment of

- Rheumatoid arthritis,
- Polyarticular Juvenile Idiopathic Arthritis,
- Psoriatic arthritis,
- Ankylosing spondylitis,
- Crohn's disease and
- Psoriasis.

The active ingredient in this medicine is adalimumab, a fully human monoclonal antibody. Monoclonal antibodies are proteins that recognise and bind to other unique proteins. Adalimumab binds to a specific protein (tumour necrosis factor or TNFalpha), which is present at increased levels in inflammatory diseases such as rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease and psoriasis.

- **Rheumatoid Arthritis**
  Humira is used to reduce the signs and symptoms of moderately to severely active rheumatoid arthritis, a painful disease of the joints, as well as slow down and protect against damage to joints. Signs and symptoms of rheumatoid arthritis include joint pain, tenderness, swelling and stiffness.
- **Polyarticular Juvenile Idiopathic Arthritis**
  Humira is indicated for reducing the signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis, which is an inflammatory disease, involving the joints, with diagnosis typically occurring in children between the ages of 4 and 17 years.
- **Psoriatic Arthritis**
  Humira is used to reduce the signs and symptoms, as well as inhibit the progression of structural damage of moderately to severely active psoriatic arthritis, a disease of the joints and skin, with some similarities to rheumatoid arthritis, as well as psoriasis and other factors.
- **Ankylosing spondylitis**
  Humira is used to reduce the signs and symptoms in patients with active ankylosing spondylitis, an inflammatory disease of the spine. Signs and symptoms of ankylosing spondylitis include back pain and morning stiffness.
- **Crohn's Disease**
  Humira is used for the treatment of moderate to severe Crohn's disease in adults to reduce the signs and symptoms of the disease and to induce and maintain clinical remission in patients who have had an inadequate response to conventional therapies, or who have lost response to or are intolerant of infliximab.
- **Psoriasis**
  Humira is used to reduce the signs and symptoms of moderate to severe chronic plaque psoriasis, an inflammatory disease of the skin.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.
Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

Before you use Humira

When you must not use it

Do not use Humira if you have:

- An allergy to any medicine containing adalimumab or any of the ingredients listed at the end of this leaflet.
  Symptoms of an allergic reaction may include:
  - chest tightness
  - shortness of breath, wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body
  - hives, itching or skin rash
- A severe infection including infection of the bloodstream, active tuberculosis and other infections that can occur when the body's natural defences are lowered.
- You are already using anakinra (Kineret) – a medicine for rheumatoid arthritis.
- You are already using abatacept (Orencia) – a medicine for rheumatoid arthritis.
- You have moderate to severe heart failure.

Do not use this medicine after the expiry date printed on the label/blister/carton or if the packaging is torn or shows signs of tampering.
If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- an infection, including a long-term or localised infection (for example, leg ulcer)
- a history of recurrent infections or other conditions that increase the risk of infections
- you are a carrier of or you suspect you may be infected with the hepatitis B virus
- a fungal infection
- multiple sclerosis and other demyelinating disease
- heart conditions including congestive heart failure, heart attack or worsening of existing heart conditions
- cancer or autoimmune disease
- kidney or liver problems
- you experience allergic reactions such as chest tightness, wheezing, dizziness, swelling or rash
- tuberculosis, or if you have been in close contact with someone who has had tuberculosis
- a suppressed immune system
- allergy to rubber or latex

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 this medicine. This will include a thorough medical history, a chest x-ray and tuberculin test.

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 contracting HBV. Humira can cause reactivation of HBV in people who carry this virus. In some rare cases, especially if you are taking other medicines that suppress the immune system, reactivation of HBV can be life-threatening.

Tell your doctor if you are scheduled for any vaccines.
It is recommended that children with polyarticular juvenile idiopathic arthritis, if possible, be brought up to date with all immunisations in agreement with current immunisation guidelines prior to initiating Humira therapy.

Patients receiving Humira should not receive live vaccines.

Tell your doctor if you are currently taking or have previously taken any medicine that lowers the body's resistance to disease.

Tell your doctor if you are a psoriasis sufferer who has undergone phototherapy.

Tell your doctor if you are pregnant or plan to become pregnant.
The effects of Humira in pregnant women are not known. Therefore the use of this medicine in pregnant women is not recommended.

Tell your doctor if you are breastfeeding or plan to breastfeed.
It is not known whether Humira passes into breast milk. If you are breastfeeding, your doctor may advise you to stop breastfeeding while you are using this medicine.

Tell your doctor if you live(d) or have travelled to countries where there is more risk for certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, or blastomycosis).
These infections may develop or become more severe if you take Humira.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using Humira.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Humira may interfere with each other. Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

Tell your doctor or pharmacist if you are taking anakinra (Kineret).
Taking the two medicines together may increase the risk of infection.

Humira can be taken together with medicines used to treat arthritis, such as: methotrexate, steroids or pain medications including non-steroidal anti-inflammatory drugs such as ibuprofen.

How to use Humira

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label or in this leaflet, ask your doctor or pharmacist for help.

How much to use

Always use Humira exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose for adults with rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis is one 40mg injection fortnightly.

The usual dose for children with polyarticular juvenile idiopathic arthritis, age 4 to 17 years, with a body weight equal to and above 30 kg is 40 mg given fortnightly as a single dose.

For children below 30 kg body weight the recommended dose is 20 mg fortnightly. A 20 mg pre-filled syringe is available for this patient population.

The usual dose for adults with Crohn's disease is an initial dose of 160mg (given as four injections on one day or two injections a day over two days), followed by 80mg two weeks later (given on one day) then 40mg starting two weeks later and continuing every two weeks.

The usual dose for adults with psoriasis is an initial dose of 80mg, followed by 40mg given fortnightly starting one week after the initial dose.

Your doctor may prescribe other medicines for rheumatoid or psoriatic arthritis to take with this medicine.

How to use it

Humira is injected under the skin. The injection can be self-administered or given by another person, for example a family member or friend after proper training in injection technique, or your doctor or his/her assistant.

Instructions for preparing and giving an injection of Humira:

Read these instructions carefully and follow them step by step.
These instructions explain how to self- inject this medicine.

Do not attempt to self-inject until you are sure that you understand how to prepare and give the injection.
Your doctor or his/her assistant will also show you best how to self-inject.

Do not mix the injection in the vial with any other medicine.

1. Setting up

- Wash your hands thoroughly
- Set up the following items on a clean surface
  - One vial of Humira for injection.
  - One empty syringe.
  - One alcohol pad.
- Look at the expiry date on the vial. Do not use the product after the month and year shown. Check the colour has not changed and that there are no particles in the solution.

2. Choosing an injection site

- Choose a site on your thigh or stomach
- For each injection use a site at least 3 cm from the last spot.
- Rotate between thigh and stomach

3. Preparing an Injection Site

- Do not inject in an area where the skin is tender, reddened, bruised, or hard. This may mean there is an infection.
- Wipe the injection site with the enclosed alcohol pad, using a circular motion.
- Do not touch the area again before injecting.

4. Injecting Humira

- Do not shake the vial
- Remove the cap from syringe needle, being careful not to touch the needle or let it touch any surface.
- Carefully withdraw the contents of the vial into the syringe
- With one hand, gently grasp the cleaned area of skin and hold firmly.
- With the other hand, hold syringe at 90-degree angle to skin, with the grooved side up.
- With one quick, short motion, push needle all the way into skin
- Release the skin with the first hand
- Push plunger to inject solution – it can take from 2 to 5 seconds to empty the syringe.
- When the syringe is empty, remove the needle from skin, being careful to keep it at the same angle as when it was inserted.
- Using cotton wool or pieces of gauze, apply pressure over the injection site for 10 seconds. A little bleeding may occur. Do not rub the injection site. Use a band-aid if you want to.

5. Throwing away supplies

- Never re-use the empty syringe.
- Never re-cap a needle.
- After injecting Humira, immediately throw away the used syringe in a special container as instructed by your doctor, nurse or pharmacist.
- Keep this container out of the reach of children.

How long to use it

Keep using Humira for as long as your doctor tells you.

Humira will not cure your condition but should help control arthritic pain, swelling and stiffness.

If you forget to use it

If you forget to give yourself an injection, you should inject the next dose of Humira as soon as you remember. Then inject your next dose as you would have on your originally scheduled day, had you not forgotten a dose.

Do not give yourself two injections to make up for the injection that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you use too much (overdose)

If you accidentally inject Humira more frequently than told to by your doctor, immediately telephone your doctor or the Poisons Information Centre (Australia: Telephone 13 11 26; New Zealand: Telephone 0800 764 766), or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention. Always take the outer carton of the medicine with you.

While you are using Humira

Things you must do

Check with your doctor before you receive any vaccines.
It is recommended that polyarticular juvenile idiopathic arthritis patients, if possible, be brought up to date with all immunisations in agreement with current immunisation guidelines prior to initiating Humira therapy.

Some vaccines, such as oral polio vaccine, should not be given while receiving Humira.

If you become pregnant while using Humira, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor you are using Humira.

Tell all doctors, dentists, and pharmacists who are treating you that you are using Humira.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using Humira.
Your doctor may recommend temporary discontinuation of Humira.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not give Humira to anyone else, even if they have the same condition as you.

Do not use Humira to treat any other complaints unless your doctor tells you to.

Do not take Humira and anakinra (Kineret) together.

Do not take Humira and abatacept (Orencia) together.

Things to be careful of

The needle cover of the syringe contains natural rubber (latex). This may cause severe allergic reactions in patients sensitive to latex. Patients who have a known sensitivity to latex should be advised to avoid touching the inner shield.

You might get infections more easily while you are receiving Humira treatment. These infections may be serious and include

tuberculosis, infections caused by viruses, fungi or bacteria, or other opportunistic infections and sepsis that may, in rare cases, 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 recommend temporary discontinuation of Humira.

Be careful driving or operating machinery until you know how Humira affects you. The effects on your ability to drive and use machines whilst taking this medicine are not known.

The long term effect of Humira on the growth and development of children is not known.

Side effects

Check with your doctor as soon as possible if you have any problems while using Humira, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like all medicines, this medicine can cause some side effects.

Ask your doctor or pharmacist any questions you may have.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

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

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor immediately if you notice any of the following:

- Persistent cough, weight loss, listlessness, fever
- Signs of infection such as fever, malaise, wounds, dental problems, burning on urination
- Signs of nervous system disorders such as numbness or tingling throughout your body, arm or leg weakness, double vision
- A bump or open sore that doesn't heal

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor if you notice any of the following:

- Injection site reactions (including pain, swelling, redness or itching)
- Upper respiratory tract infections (including cold, runny nose, sinus infection, sore throat)
- Lower respiratory tract infections (such as bronchitis, pneumonia)
- Headache, dizziness, vertigo, sensation disorders
- Increased cough, sore throat
- Abdominal symptoms such as nausea, diarrhoea, abdominal pain,
- Rash, itching
- Fatigue
- Mouth inflammation and ulcers
- Elevated liver enzymes
- Musculoskeletal pain
- Viral infections (including influenza, cold sore blisters, chicken pox and shingles)
- Bacterial infections (including Urinary Tract Infection)
- Fungal Infections

These are the more common side effects of Humira.

Other side effects not listed above may occur in some people.

There have been cases of certain kinds of cancer in 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 chance of getting a kind of cancer that affects the lymph system, called lymphoma, or that affects the blood, called leukaemia. If you take Humira your risk may increase. On rare occasions, a specific and severe type of lymphoma has been observed in patients taking Humira. Some of those patients were also treated with azathioprine or 6-mercaptopurine. In addition very rare 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.

Do not be alarmed by this list of possible side effects.
You may not get any of them.

Tell your doctor if you notice anything that is making you feel unwell, even if it is not on this list.

After using Humira

Storage

Keep your vial in the pack until it is time to use it.

Keep Humira in a refrigerator (2°C-8°C). Do not freeze.

Keep Humira in the refrigerator in a way children cannot get to it.

Do not leave Humira in the car especially in hot weather.

If you need to travel, make sure the medicine is kept at the right temperature. This is important whether travelling by car, bus, train, plane or any other form of transport.

Disposal

After injecting Humira, immediately throw away the used syringe in a special container as instructed by your doctor, nurse or pharmacist.

If your doctor tells you to stop using Humira or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Humira is a clear, colourless, sterile solution of

- 40mg adalimumab in 0.8mL water in a vial (AUST R 95779)

The following packs are available:

- 1 vial with 1 empty syringe and 1 alcohol pad

Ingredients

Active ingredient:
adalimumab

Other ingredients:

- Mannitol
- Citric acid monohydrate
- Sodium citrate
- Monobasic sodium phosphate dihydrate
- Dibasic sodium phosphate dihydrate
- Sodium chloride
- Polysorbate 80
- Water for injections

Distributor

Humira is distributed in Australia by:

Abbott Australasia Pty Ltd
ABN 95 000 180 389
32-34 Lord St
Botany NSW 2019

Humira is distributed in New Zealand by:

Abbott Laboratories (NZ) Ltd
4 Pacific Rise
Mt Wellington
NEW ZEALAND

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