Humira Pre-filled Syringe

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 used for the treatment of:

- Rheumatoid arthritis

Humira is used to reduce the signs and symptoms of moderate 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 used for reducing the signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis, which is an inflammatory disease involving multiple joints, in patients 2 years of age and older.

- Enthesitis-related arthritis

Humira is used to treat enthesitis-related arthritis, an inflammatory disease of the joints in children.

- Psoriatic arthritis

Humira is used to reduce the signs and symptoms, as well as inhibit the progression of joint damage of moderate 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, an inflammatory disease of the digestive tract, in adults and children aged 6 years and above to reduce the signs and symptoms of the disease and to induce and maintain periods where the symptoms are no longer present. Humira can be given to patients who have not responded well enough to conventional therapies, or who have lost response to or are intolerant to infliximab (another medicine used to treat Crohn's disease).

- Ulcerative Colitis

Humira is used for the treatment of moderate to severe ulcerative colitis an inflammatory bowel disease, in patients who have not responded well enough to conventional therapy or who are intolerant to or have medical contraindications for such therapies. Patients should show a response within 8 weeks to continue treatment.

- Psoriasis

Humira is used to treat chronic plaque psoriasis, an inflammatory disease of the skin. Plaque psoriasis can also affect nails, causing them to crumble, thicken and lift away from the nail bed which can be painful. Humira is used for moderate to severe forms of the disease in adults and severe forms in children and adolescents from 4 years of age who have not responded well enough to topical therapy and phototherapy, or who cannot be given those treatments.

- Hidradenitis suppurativa

Humira is used for the treatment of adult and adolescents from 12 years of age with active moderate to severe hidradenitis suppurativa (acne inversa), 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. Your doctor will schedule follow-up appointments to check on your progress to continue treatment.

- Uveitis

Humira is used to treat non-infectious intermediate, posterior and pan-uveitis, an inflammatory disease of the uveal tract of the eye. Humira is used in adults who have not responded well to corticosteroids or whose disease flares when they taper off corticosteroids. Signs and symptoms include inflammation, vision impairment and pain.

The active ingredient in this medicine is adalimumab, a fully human monoclonal antibody. Monoclonal antibodies are proteins made by a type of blood cell to fight a foreign protein in the body. Adalimumab recognises and binds to a specific protein (tumour necrosis factor or TNF-alpha), which is present at increased levels in inflammatory diseases such as rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, enthesitis-related arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, hidradenitis suppurativa, psoriasis and uveitis.

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 not addictive.

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

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

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
- You have 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 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.

Return it to your pharmacist for disposal.

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
- a history of tuberculosis, or if you have been in close contact with someone who has had tuberculosis

  If symptoms of tuberculosis (persistent-cough, weight loss, listlessness, mild fever), or any other infection appear during or after therapy, tell your doctor immediately.

  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.
- the hepatitis B virus (HBV) if you are a carrier of, or you have active HBV or 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 in you are taking other medicines that suppress the immune system, reactivation of HBV can be life threatening.
- a fungal infection, or have lived or travelled in countries where some fungal infections are common. These infections may develop or become more severe if you take Humira.
- If you suffer from uveitis, your doctor may check for signs and symptoms of neurologic disease before starting this medicine.
- multiple sclerosis a disease of the nervous system or other demyelinating disease
- allergic reactions such as chest tightness, wheezing, dizziness, swelling or rash
- blood disorders
- low resistance to disease
- heart conditions including congestive heart failure, heart attack or worsening of existing heart conditions
- cancer or autoimmune disease
- a lung disease called chronic obstructive pulmonary disease
- kidney or liver problems

  Tell your doctor if you are scheduled for any vaccines

It is recommended that children, 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 a psoriasis sufferer who has undergone phototherapy.

Tell your doctor if you are pregnant or plan to become pregnant.

You should consider the use of adequate contraception to prevent pregnancy and continue its use for at least 5 months after the last Humira treatment.

Humira should only be used during pregnancy if clearly needed.

A pregnancy study found that there was no higher risk of birth defects when the mother had used Humira during pregnancy, compared with mothers with the same disease who did not use Humira.

If you use Humira during pregnancy, your baby may have a higher risk of getting an infection.

It is important that you tell your baby's doctors and other healthcare professionals about your Humira use during your pregnancy before the baby receives any vaccine.

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.

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 naturopath 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) or abatacept (Orencia), other medicines used to treat some forms of arthritis.

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 (NSAIDS) such as ibuprofen.

Tell your doctor or if you are taking any other medicines to treat your condition.

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.

Always use Humira exactly as your doctor has instructed you.

Check with your doctor or pharmacist if you are unsure.

How much to use

Adults

Rheumatoid Arthritis & Psoriatic Arthritis & Ankylosing spondylitis

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

Crohn's disease & Ulcerative Colitis

The usual dose for adults with Crohn's disease or ulcerative colitis is an initial dose of 160 mg (given as two 80 mg injections in one day OR as one 80 mg injection per day over two days OR as four 40 mg injections in one day OR as two 40 mg injections per day over two days), followed by 80 mg two weeks later (given as one 80 mg injection on one day OR two 40 mg injections). After a further two weeks, continue with a dose of 40 mg every fortnight.

Psoriasis & Uveitis

The usual dose for adults with psoriasis or uveitis is an initial dose of 80 mg (given as one 80 mg injection OR two 40 mg injections), followed by 40 mg given fortnightly starting one week after the initial dose.

For adults with psoriasis, depending on your response, your doctor may increase the dose frequency to 40 mg every week.

Hidradenitis suppurativa

The usual dose for adults with hidradenitis suppurativa is an initial dose of 160 mg (given as two 80 mg injections in one day, OR as one 80 mg injection per day for two consecutive days OR as four 40 mg injections in one day OR as two 40 mg injections per day for two consecutive days), followed by an 80

mg dose (as one 80 mg injection OR two 40 mg injections on the same day) two weeks later. After a further two weeks, continue with a dose of 40 mg every week.

Your doctor may prescribe other medicines for your condition arthritis to take with this medicine.

Children

Juvenile Idiopathic Arthritis

The usual dose for children with polyarticular juvenile idiopathic arthritis or enthesitis-related arthritis depends on body weight:

- with a body weight of 30 kg or above, the usual dose is 40 mg given fortnightly.
- with a body weight of 15 kg to less than 30 kg, the recommended dose is 20 mg fortnightly.
- with a body weight between 10 kg to less than 15 kg, the usual dose is 10 mg fortnightly.

Crohn's Disease

The usual dose for children with Crohn's disease depends on body weight and the severity of disease.

-with a body weight of 40 kg or above, the starting dose is 160 mg (given as two 80 mg injections on one day OR one 80 mg injection a day over two days OR as four 40 mg injections in one day OR as two 40 mg injections per day for two consecutive days), followed by 80 mg two weeks later (given as one 80 mg injection in one day OR two 40 mg injections). After a further two weeks, continue with 20 mg or 40 mg every two weeks, depending on severity of disease).

-with a body weight of less than 40 kg, the starting dose is 80 mg (given as one 80 mg injection on one day OR two 40 mg injections), followed by 40 mg two weeks later. After a further two weeks, continue with 10 mg or 20 mg every two weeks, depending on severity of disease).

Treatment of Crohn's disease in children should be supported by good nutrition to allow appropriate growth.

Psoriasis

The usual dose for children with psoriasis depends on the body weight:

- with a body weight between 40 kg or above, the usual dose is 40 mg given once weekly for the first two weeks, then fortnightly.
- with a body weight of less than 40 kg, the usual dose is 20 mg given once weekly for the first two weeks, then fortnightly.

Hidradenitis suppurativa

The usual dose for adolescents (from 12 years, weighing at least 30 kg) with hidradenitis suppurativa is an initial dose of 80 mg (one 80 mg injection in one day OR two 40 mg injections), followed by 40 mg fortnightly starting one week later. If you have an inadequate response, your doctor may increase the dose to 40 mg every week.

It is recommended you use an antiseptic wash daily on the affected areas.

If Humira has no effect on the child's condition after 16 weeks, your doctor may tell you to stop using Humira.

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.

If you are using the Humira pre-filled syringe, instructions for preparing and giving an injection are provided in the Injecting Instructions supplied with the product.

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 same syringe or vial with any other medicine.

Keep out of the sight and reach of children.

STEP 1

Take Humira out of the refrigerator.

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

- **Do not remove the needle cover while allowing Humira to reach room temperature**
- **Do not warm Humira in any other way. For example, do not warm it in the microwave or in hot water.**
- **Do not use the syringe if liquid has been frozen (even if thawed).**

STEP 2

Check the expiry date on the syringe label.

Do not use the syringe if the expiry date has passed.

Place the following on a clean, flat surface:

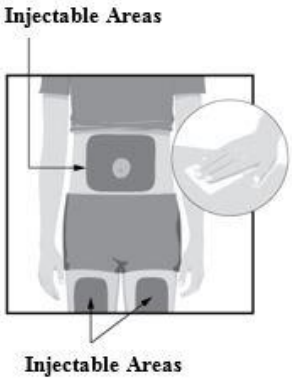
– One Humira single-use syringe and alcohol pad.

– One cotton ball or gauze pad (not included)

– Puncture-resistant sharps disposal container (not included)

Wash and dry your hands

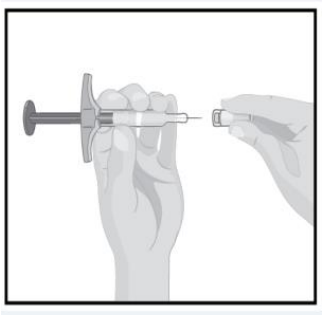
STEP 3



Choose an injection site:

- On the front of your thighs or, your abdomen (belly) at least 5 cm from your navel (belly button)
- Different from and at least 3 cm from your last injection site
- **Wipe the injection site in a circular motion with the alcohol pad**
- **Do not inject into skin that is sore, bruised, red, hard, scarred, has stretch marks, or areas with psoriasis plaques**

STEP 4



Hold the syringe in one hand.

Check the liquid in the pre-filled syringe.

– Make sure the liquid is clear and colourless

– **Do not use the pre-filled syringe if the liquid is cloudy or has particles**

Gently pull the needle cover straight off with the other hand.

- Throw the needle cover away
- **Do not touch the needle with your fingers or let the needle touch anything**

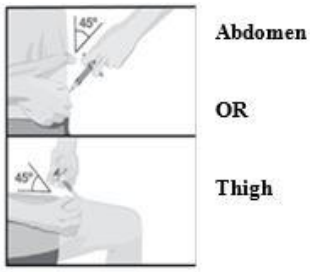
You may see a drop of liquid at the end of the needle. This is normal.

STEP 5

Hold the body of the syringe in one hand between the thumb and index fingers, like you would a pencil.

Gently squeeze the area of cleaned skin with your other hand and hold it firmly.

STEP 6

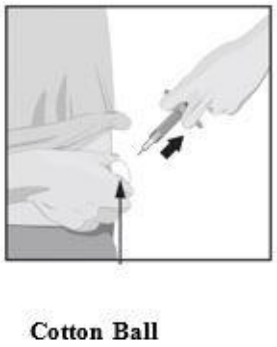


Insert the needle into the skin at about a 45-degree angle using a 'dart-like' motion.

- After the needle is in, let go of the skin you are holding

Slowly push the plunger all the way in until all of the liquid is injected and the syringe is empty.

STEP 7



When the injection is completed, slowly pull the needle out of the skin while keeping the syringe at the same angle.

After completing the injection, place a cotton ball or gauze pad on the skin of the injection site.

- **Do not rub**
- Slight bleeding at the injection site is normal

STEP 8

The Humira syringe should never be reused. Never recap a needle.

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

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

For more information:

Australia: Call us on 1800 043 460 or visit www.abbviecare.com.au

New Zealand: Call us on 0800 900 030 or visit www.abbviecare.co.nz

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 your symptoms.

Ask your doctor if you are not sure how long to take this medicine for.

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 try to make up for missed doses by taking more than one dose at a time.

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), 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 children, 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 stop taking Humira, without checking with your doctor.

Do not take Humira and anakinra (Kineret) together.

Do not take Humira and abatacept (Orencia) together.

Anakinra and abatacept are other medicines used to treat certain forms of arthritis.

Things to be careful of

It is important to tell your doctor if you get symptoms such as fever, wounds, feeling tired or dental problems.

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. 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.

Side effects

Tell 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.

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. You may need medical attention if you get some of the side-effects.

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

Ask your doctor or pharmacist any questions you may have.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you experience any of the following:

- Signs of an allergic reaction such as:
- 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
- Signs and symptoms suggestive of heart failure such as 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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are uncommon.

Tell your doctor as soon as possible if you notice any of the following:

- Signs of tuberculosis such as persistent cough, weight loss, listlessness, fever
- Signs of infection such as fever, malaise, wounds, dental problems, burning on urination

  You might get infections more easily while you are receiving Humira treatment.
- Signs of nervous system disorders such as numbness or tingling

throughout your body, arm or leg weakness, double vision

- Signs of soft tissue infection, such as a bump or open sore that doesn't heal

The above list includes serious side effects. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor if you notice any of the following and they worry you:

- 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)
- Ear infections
- Eye inflammation, inflammation of the eye lid or changes to your vision
- Headache, dizziness, vertigo, sensation disorders
- Increased cough, sore throat
- Abdominal symptoms such as nausea, vomiting, abdominal pain,
- Rash, itching
- Fatigue
- Mouth inflammation and ulcers
- Muscle or bone pain
- Elevated lipids
- Depression, anxiety
- Increased heart rate
- Viral infections (including the flu, cold sore blisters, chicken pox and shingles)
- Bacterial infections (including Urinary Tract Infection)
- Fungal Infections
- Changes in mood, feeling low or anxious

The above list includes the more common side effects of Humira. They are usually mild and short-lived.

Laboratory results

Some side effects observed with Humira may not have symptoms and may only be discovered through blood tests. These include increased lipids in the blood, elevated liver enzymes, and increased uric acid in the blood.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

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 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.

After using Humira

Storage

Keep your pre-filled syringe in the pack until it is time to use it.

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

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

Keep the medicine at the right temperature when you travel.

This is important when travelling by car, bus, train, plane or any other form of transport.

Store a pre-filled syringe at room temperature (below 25°C) for a maximum period of 14 days, protected from light.

Once removed from the refrigerator and stored at room temperature, the syringe must be used within 14 days or discarded, even if it is returned to the refrigerator.

Write down the date you first remove the syringe from the refrigerator on the label, so you can check how long it has been.

Disposal

After injecting Humira, immediately throw away the used pre-filled syringe in a special 'sharps' 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 (50mg/mL) is a clear, colourless, sterile solution of:

- 40 mg adalimumab in 0.8 mL solution in a syringe (AUST R 199412) and
- 20 mg adalimumab in 0.4 mL solution in a syringe (AUST R 199411)
- 10 mg adalimumab in 0.2 mL solution in a syringe (AUST R 216038)

The following Pre-filled syringe packs are available:

- 2 pre-filled syringes with 2 alcohol pads (Humira 20 mg/0.4 mL and Humira 40 mg/0.8 mL pre-filled syringe)
- 6 pre-filled syringes with 6 alcohol pads (Humira 40 mg/0.8 mL pre-filled syringe)

Humira (100mg/mL) is a clear, colourless, sterile solution of:

- 20 mg adalimumab in 0.2 mL solution in a syringe (AUST R 289104)
- 40 mg adalimumab in 0.4 mL solution in a syringe (AUST R 281470)
- 80 mg adalimumab in 0.8 mL solution in a syringe (AUST R 292934)

The following Pre-filled syringe packs are available:

- 2 pre-filled syringes with 2 alcohol pads (Humira 20 mg/0.2 mL pre-filled syringe)
- 2 pre-filled syringes with 2 alcohol pads (Humira 40 mg/0.4 mL pre-filled syringe)
- 6 pre-filled syringes with 6 alcohol pads (Humira 40 mg/0.4 mL pre-filled syringe)
- 1 pre-filled syringe with 2 alcohol pads (Humira 80 mg/0.8 mL pre-filled syringe)

Ingredients

Humira contains adalimumab as the active ingredient:

For Humira 10 mg/0.2 mL, 20 mg/0.4 mL and 40 mg/0.8 mL pre-filled syringe, it also contains other ingredients including:

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

For Humira 20 mg/0.2 mL, 40 mg/0.4 mL and 80 mg/0.8 mL pre-filled syringe, it also contains other ingredients including:

- Mannitol
- Polysorbate 80
- Water for injections

Not all presentations may be marketed.

Distributor

Humira is distributed in Australia by:

AbbVie Pty Ltd

ABN 48 156 384 262

241 O'Riordan Street

Mascot NSW 2020

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AUST R 216038

AUST R 281470

AUST R 292934

AUST R 289104

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