HUMIRA®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Humira?

Humira contains the active ingredient adalimumab. Humira is used to treat various inflammatory conditions.

For more information, see Section 1. Why am I using Humira? in the full CMI.

2. What should I know before I use Humira?

Check the list of ingredients at the end of the CMI. Do not use Humira if you have ever had an allergic reaction to any of them.

Talk to your doctor before you take this medicine if he/she is not aware that you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Humira? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Humira and affect how it works, or Humira may interfere with other medicines and affect how they work.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Humira?

Humira is injected under the skin (subcutaneous).

More instructions can be found in Section 4. How do I use Humira? in the full CMI.

5. What should I know while using Humira?

Things you should do	• Remind any doctor or dentist or pharmacist you visit that you are using Humira. • Keep all your appointments, including for blood tests. • Tell your doctor if you develop an infection or you notice new or changed spots on your skin. • Tell your doctor if you are scheduled for any vaccines.
Things you should not do	• Do not stop using this medicine or change the dose unless your doctor tells you to.
Driving or using machines	• Be careful before you drive or use any machines until you know how Humira affects you. The effects on your ability to drive or use machines whilst taking Humira are not known.
Drinking alcohol	• There is no information on the effects of taking Humira with alcohol
Looking after your medicine	• Store Humira in the refrigerator (2 °C to 8 °C). Do not freeze. • Keep pens or syringes in the pack to protect your medicine from light.

For more information, see Section 5. What should I know while using Humira? in the full CMI.

6. Are there any side effects?

Side effects that require urgent medical attention include: Signs of an allergic reaction, such as chest tightness, difficulty breathing, swelling of face lips and tongue, rash; signs of heart failure, such as shortness of breath on exertion or lying down, swelling of the feet; signs suggesting a blood disorder, such as persistent fever, bruising, bleeding, paleness.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

HUMIRA® (hue-me-rah)

Active ingredient: *adalimumab (rch)* (a-da-li-mue-mab)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Humira. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Humira.**

Where to find information in this leaflet:

1. Why am I using Humira?

Humira contains the active ingredient adalimumab.

Humira is used to treat rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, enthesitis-related arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease in adults and children aged 6 years and over, ulcerative colitis, psoriasis in adults and children aged 4 years and over, hidradenitis suppurativa in adults and adolescents aged 12 years and over, and uveitis in adults and children aged 2 years and over.

2. What should I know before I use Humira?

Warnings

Do not use Humira if:

1. you are allergic to adalimumab, or any of the ingredients listed at the end of this document
2. you have a severe infection such as sepsis (a serious infection of the blood) or tuberculosis (a serious infection of the lungs caused by bacteria), or other severe infection caused by a virus, fungus, parasite or bacteria
3. you have heart failure considered by your doctor to be moderate or severe.

Check with your doctor if you:

- have or have had an infection that does not go away or keeps coming back, this can include leg ulcers
- you have ever had tuberculosis, or you have been in close contact with someone who has tuberculosis. Tuberculosis can develop during therapy even if you have received treatment for the prevention of tuberculosis.
- you currently have active hepatitis B, have ever had hepatitis B, are a carrier of the hepatitis B virus or you think you may be at risk of contracting hepatitis B
- you have or have had an infection caused by a fungus, or you have lived or travelled in countries where fungal infections are common
- you have or have had uveitis, where the middle layer of the eyeball is inflamed
- you have or have had allergic reactions such as chest tightness, wheezing, dizziness, swelling or rash
- you have a disease that affects the insulating layer of the nerves, e.g. multiple sclerosis (MS)
- you have or have had a blood disorder
- you have or have had low resistance to disease
- you have or have had a heart condition
- you have or have had cancer or autoimmune disease
- you have a lung disease called chronic obstructive pulmonary disease (COPD)
- you have or have had kidney or liver problems
- you have any vaccinations scheduled
- you have or have had psoriasis (a skin disease that produces patches of thickened, scaly skin that is not contagious)
- you have had phototherapy, also known as light therapy, for psoriasis
- you have any surgery planned
- you take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Make sure your doctor is aware that you are pregnant or plan to become pregnant. Humira should only be used in pregnancy if clearly needed.

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

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

Tell your baby's doctors if you have taken Humira while you are pregnant, especially before your baby receives any vaccinations.

Make sure your doctor is aware that you are breastfeeding, or you plan to do so.

Use in children

- Wherever possible, it is recommended that children are up to date with all vaccinations, according to current immunisation guidelines, before they are started on Humira treatment.
- Treatment of Crohn's disease in children should be supported by good nutrition to allow appropriate growth.
- The long-term effects of Humira on the growth and development of children is not known.

Use in the elderly

If you are over 65, you may be more likely to get an infection while taking Humira.

3. What if I am taking other medicines?

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

Some medicines may interfere with Humira and affect how it works, while Humira may affect how other medicines work.

Do not take Humira if you are taking the following medicine:

- anakinra, a medicine used to treat rheumatoid arthritis, juvenile idiopathic arthritis and conditions associated with a defect in a protein called cryoprin.

Medicines that may <u>increase</u> the risk of infection when taken with Humira include:

- anakinra, a medicine used to treat rheumatoid arthritis, juvenile idiopathic arthritis and conditions associated with a defect in a protein called cryoprin
- abatacept, a medicine used to treat rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis
- azathioprine, a medicine used for suppressing the immune system to treat various conditions
- 6-mercaptopurine, a medicine used to treat certain types of leukaemia, a blood disorder.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Humira.

4. How do I use Humira?

How much to use

- **<u>Rheumatoid arthritis in adults</u>**

  Inject one 40 mg dose every fortnight.

  If you are **<u>not</u>** taking methotrexate, your doctor may change this dose to 40 mg every week, or 80 mg every fortnight, depending on your response.

- **<u>Psoriatic arthritis and ankylosing spondylitis in adults</u>**

  Inject one 40 mg dose every fortnight.

- **<u>Crohn's disease and ulcerative colitis in adults</u>**

  Inject 160 mg on day 1, followed by 80 mg on day 15 and 40 mg on day 29. Then, continue to inject 40 mg every fortnight (maintenance dose).

  Your doctor may change this maintenance dose to 40 mg every week, or 80 mg every fortnight, depending on your response.

  (See **<u>Special dosing instructions</u>** at the end of this section.)

- **<u>Crohn's disease in children</u>**

  If the patient's body weight is at least 40 kg, inject 160 mg on day 1, followed by 80 mg on day 15 and 40 mg on day 29. Then, continue to inject 40 mg every fortnight (maintenance dose).

  Your doctor may change this maintenance dose to 40 mg every week, or 80 mg every fortnight, depending on your response.

  (See **<u>Special dosing instructions</u>** at the end of this section.)

  If the patient's body weight is less than 40 kg, inject 80 mg on day 1, followed by 40 mg on day 15, and 20 mg on day 29. Then, continue to inject 20 mg every fortnight.

  Your doctor may change this maintenance dose to 20 mg every week, depending on your response.

  (See **<u>Special dosing instructions</u>** at the end of this section.)

- **<u>Psoriasis in adults</u>**

  Inject 80 mg on day 1, followed by 40 mg on day 8 and 40 mg on day 22. Then, continue to inject 40 mg every fortnight (maintenance dose).

  Your doctor may change this maintenance dose to 40 mg every week, or 80 mg every fortnight, depending on your response.

  (See **<u>Special dosing instructions</u>** at the end of this section.)

- **<u>Psoriasis in children</u>**

  If the patient's body weight is at least 40 kg, inject 40 mg on day 1, followed by 40 mg on day 8 and 40 mg on day 22. Then continue to inject 40 mg every fortnight (maintenance dose).

  If the patient's body weight is less than 40 kg, inject 20 mg on day 1, inject 20 mg on day 8, then 20 mg on day 22. Then continue to inject 20 mg every fortnight (maintenance dose).

- **<u>Uveitis in adults</u>**

  Inject 80 mg on day 1, followed by 40 mg on day 8 and 40 mg on day 22. Then continue to inject 40 mg every fortnight (maintenance dose).

  (See **<u>Special dosing instructions</u>** at the end of this section.)

- **<u>Uveitis in children</u>**

  The usual dose for children aged 2 years or older with non-infectious anterior uveitis, depends on body weight.

  If the patient's body weight is less than 30 kg, inject 20 mg every fortnight. An initial dose of 40 mg may be administered by your child's doctor 1 week before starting maintenance treatment.

  If the patient's body weight is at least 30 kg, inject 40 mg every fortnight. An initial dose of 80 mg may be administered by your child's doctor 1 week before starting maintenance treatment.

- **Hidradenitis suppurativa in adults**

  Inject 160 mg on day 1, followed by 80 mg on day 15. Then continue to inject 40 mg every week or 80mg every fortnight from day 29 (maintenance dose).

  (See **Special dosing instructions** at the end of this section.)

- **Hidradenitis suppurativa (HS) in adolescents**

  Inject 80 mg on day 1, followed by 40 mg on day 8, and 40 mg on day 22. Then continue to inject 40 mg every fortnight (maintenance dose)

  Your doctor may change this maintenance dose to 40 mg every week, or 80 mg every fortnight depending on your response.

  (See **Special dosing instructions** at the end of this section.)

- **Polyarticular juvenile idiopathic arthritis and enthesitis-related arthritis**

  If the patient's body weight is at least 30 kg, inject one 40 mg dose every fortnight.

  If the patient's body weight is between 10 and 30 kg, inject one 20 mg dose every fortnight.

Use an antiseptic face wash on the affected areas.

Special dosing instructions

- When a dose of 160 mg is required, this can be given as two 80 mg OR four 40 mg injections in one day, or one 80 mg or two 40 mg injections per day over two consecutive days.
- When a dose of 80 mg is required, this can be given as one 80 mg injection or two 40 mg injections in one day.

In some instances, Humira needs to be taken with other medicines. Your doctor will let you know which medicines, how to take them and how long to take them.

Follow all instructions given to you and use Humira until your doctor tells you to stop.

How to use Humira

- Humira is injected under the skin (sub-cutaneous injection).
- It can be injected by the patient, or by someone else, such as a family member, friend or carer.
- An injection should not be attempted until proper training has been received on the correct injection technique.
- Do not mix the injection with any other medicine.
- Read the instructions for preparing and giving a Humira injection that are supplied with the product. These instructions are also available via the following hyperlinks:

  Humira syringe:

  https://www.medsinfo.com.au/media/veihumis

  Humira 40mg/0.8mL pen:

  https://www.medsinfo.com.au/media/veihumip

  Humira 40mg/0.4mL pen:

  https://www.medsinfo.com.au/media/veihu40p

  Humira 80mg/0.8mL pen:

  https://www.medsinfo.com.au/media/veihu80p

If you forget to inject Humira

It is important that you use your medicine as prescribed by your doctor.

If you miss your dose at the usual time, inject Humira as soon as you remember, and continue injecting the next dose at the usual time on your scheduled day.

Do not take a double dose to make up for the dose you missed.

If you inject too much Humira

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there appear to be no signs of discomfort or poisoning.

5. What should I know while using Humira?

Things you should do

- Keep all your doctor's appointments so your progress can be tracked.
- Keep your appointments for blood tests. Some side effects are seen in blood results before you have any symptoms.
- Remind any doctor, dentist or pharmacist you visit that you are using Humira, especially if you are scheduled for surgery or to receive any live vaccines (e.g. Bacille Calmette-Guerin or oral polio vaccine).

Call your doctor straight away if you:

- get symptoms of an infection, such as a fever, skin sores, feeling tired, any problems with your teeth or gums or pain when passing urine or blood in your urine.
- become pregnant while using Humira.
- notice new skin lesions (skin spots or sores), or if existing lesions change appearance.

Things you should not do

- Do not stop using this medicine or change the dose without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Humira affects you.

Drinking alcohol

There is no information on the use of alcohol with Humira.

Looking after your medicine

Follow the instructions on the carton on how to take care of your medicine properly.

- Keep Humira in the carton protected from light.
- Keep Humira in a refrigerator (at 2°C to 8°C). Do not freeze.

Keep it where young children cannot reach it.

When to discard your medicine

- When necessary, a single Humira pen or syringe may be stored at room temperature (25°C) for a maximum of 14 days, protected from light.
- Once removed from the refrigerator, the pen or syringe must be used within 14 days or discarded, even if it has been returned to the refrigerator.
- After injecting Humira, immediately throw away the used pen or syringe in a special sharps container as instructed by your doctor, nurse or pharmacist.

Getting rid of any unwanted medicine

If your doctor advises that you no longer need to use this medicine or it is out of date, follow local guidelines for safe disposal.

6. Are there any side effects?

All medicines can have side effects. Most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Injection site: • pain • swelling • redness • itching **Lungs and upper airways** • cold • flu • runny nose • cough • sore throat • sinus infection • asthma or worsening asthma • bronchitis or pneumonia (congestions on the chest) **Ears, eyes and mouth** • pain in the ear • pain, redness or swelling of the eye or eye lid • changes to vision • mouth ulcers • pain in the gums • excessive bleeding from the gums **Brain and nerves** • headache or migraine • dizziness • muscle weakness • muscle, bone or joint pain • numbness • difficulty balancing **Gut and digestion** • nausea • vomiting • tummy pain • reflux or heartburn **Skin and nails** • rash • itching • redness • scaly skin patches • problems with your fingernails or toenails • hair loss • cold sore blisters • chicken pox. **Blood** • bleeding • bruising more easily than usual **Body as a whole** • tiredness • chest pain • lack of energy • increased heart rate • feeling overwhelmed or sad, lacking motivation (depression) • feeling especially fearful or worried (anxiety)	**Speak to your doctor if you have any of these side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Signs of tuberculosis, such as: • persistent cough • weight loss • listlessness • fever. **Signs of an infection, such as:** • fever • lack of energy • skin bump or sore that doesn't heal • problems with your teeth or gums	**Speak to your doctor as soon as possible if you have any of these side effects.**

Serious side effects	What to do
• pain when passing urine or blood in the urine. **Signs of problems with your nervous system, such as:** • numbness • tingling throughout your body • arm or leg weakness • double or blurred vision. **Signs suggesting a blood clot, such as:** • swelling, tenderness, redness and a warm feeling of an area of the arm or leg	

Very serious side effects

Very serious side effects	What to do
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 of heart failure, such as:** • shortness of breath on exertion or lying down, • swelling of the feet. **Signs suggesting a blood disorder, such as:** • persistent fever, • bruising, • bleeding very easily • paleness.	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

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

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Humira contains

Humira 40 mg in 0.8 mL; 20 mg in 0.4 mL

Humira is a clear, colourless, sterile solution containing:

- 40 mg adalimumab in 0.8 mL solution in a prefilled pen (AUST R 199410)
- 40 mg adalimumab in 0.8 mL solution in a prefilled syringe (AUST R 199412)
- 20 mg adalimumab in 0.4 mL solution in a prefilled syringe (AUST R 199411)

Active ingredient (main ingredient)	adalimumab
Other ingredients (inactive ingredients)	mannitol citric acid monohydrate sodium citrate dihydrate monobasic sodium phosphate dihydrate dibasic sodium phosphate dihydrate sodium chloride Polysorbate 80 Water for injections

Humira 80 mg in 0.8mL; 40 mg in 0.4 mL,

20 mg in 0.2 mL

Humira is a clear, colourless, sterile solution containing:

- 80 mg adalimumab in 0.8 mL solution in a prefilled pen (AUST R 285904)
- 80 mg adalimumab in 0.8 mL solution in a prefilled syringe (AUST R 292934)
- 40 mg adalimumab in 0.4 mL solution in a prefilled pen (AUST R 281509)
- 40 mg adalimumab in 0.4 mL solution in a prefilled syringe (AUST R 281470)
- 20 mg adalimumab in 0.2 mL solution in a prefilled syringe (AUST R 289104).

Active ingredient (main ingredient)	adalimumab
Other ingredients (inactive ingredients)	mannitol Polysorbate 80 Water for injections

What Humira looks like

Prefilled pens and prefilled syringes are available for patient use in packs of 1,2, 4 or 6 units with alcohol pads, although not all presentations may be available or marketed in all pack sizes.

Who distributes Humira?

Humira is distributed in Australia by:

AbbVie Pty Ltd

ABN 48 156 384 262

241 O'Riordan Street

Mascot NSW 2020

This leaflet was prepared in October 2024.

Version 3