

Humira Pen

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

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 to 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, with diagnosis typically occurring in children 2 years of age and older.

- Enthesitis-related arthritis

Humira is used to treat enthesitis-related arthritis, an inflammatory disease of the joints that begins before the 16th birthday, in patients from 6 years of age.

- Psoriatic arthritis

Humira is used to reduce the signs and symptoms, as well as inhibit the progression of joint 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.

- Non-radiographic axial spondyloarthritis

Humira is used for the treatment of adult patients with severe axial spondyloarthritis without radiographic evidence of ankylosing spondylitis, an inflammatory disease of the spine. Your doctor will check that you have objective signs of inflammation via a blood test or scan, and will prescribe Humira only if you have not responded well enough to anti-inflammatory medicines.

- 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.

- 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.

- Uveitis

Humira is used to treat adults with non-infectious intermediate, posterior or pan-uveitis, with inflammation affecting the back of the eye and children from 2 years of age with chronic non-infectious anterior uveitis with inflammation affecting. Inflammation may lead to a decrease of vision and/or the presence of floaters in the eye (black dots or wispy lines that move across the field of vision). Humira works by reducing this inflammation. Signs and symptoms include inflammation, vision impairment and pain.

- 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.

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, non-radiographic axial spondyloarthritis, Crohn's disease, ulcerative colitis, psoriasis, hidradenitis suppurativa 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 available only 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.

If it has expired or is damaged, 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 if you are taking other medicines that suppress the immune system, reactivation of HBV can be life-threatening.

- If you suffer from uveitis, your doctor may check for signs and symptoms of neurologic disease before starting this medicine.
- 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.
- 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.

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.

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

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 other 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 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. You should check with your doctor or pharmacist if you are unsure.

How much to use

Adults

The usual dose for adults with rheumatoid arthritis, psoriatic arthritis and axial spondyloarthritis (ankylosing spondylitis and non-radiographic axial spondyloarthritis) is one 40 mg injection fortnightly.

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

The usual dose for adults with psoriasis or uveitis is an initial dose of 80 mg, 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.

The usual dose for adults with hidradenitis suppurativa is an initial dose of 160 mg (given as 4 injections in one day or 2 injections per day for two consecutive days), followed by an 80 mg dose (as 2 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 to take with this medicine.

Children

For children with polyarticular juvenile idiopathic arthritis, 2 years and older, or

enthesitis-related arthritis, 6 years and older

- with a body weight of 30 kg or above, the usual dose is 40 mg given fortnightly as a single dose.
- with a body weight of 15 kg to below 30 kg, the recommended dose is 20 mg fortnightly.
- With a body weight of 10 kg to below 15 kg the recommended dose is 10 mg fortnightly.

The usual dose for children with Crohn's disease depends on body weight and the severity of disease. Treatment will begin with a larger dose on day 1 and continue with a smaller dose every two weeks. Your doctor will tell you what dose to take and when.

The usual dose for children with psoriasis depends on body weight.

- With a body weight of 30 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 30 kg, the usual dose is 20 mg given once weekly for the first two weeks, then fortnightly.

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

For children with non-infectious anterior uveitis aged 2 years or older, the dose depends on body weight.

- With a body weight of 30 kg or more, the usual dose is 40 mg fortnightly with methotrexate. Your child's doctor may also prescribe an initial dose of 80 mg which may be administered one week prior to the start of the usual dose.
- With a body weight of less than 30 kg, the usual dose is 20 mg fortnightly with methotrexate. Your child's doctor may also prescribe an initial dose of 40 mg which may be administered one week prior to the start of the usual dose.

Your doctor may prescribe other medicines for your child's condition to take with this medicine.

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

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

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 pen, instructions for preparing and giving an injection of Humira 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 how best to self-inject.

Keep Humira out of the sight and reach of children.

1. What should I do before I give myself a Humira injection?

- Take one dose tray containing a pre-filled pen of Humira from the refrigerator

- Do not shake or drop the pre-filled pen
- Leave Humira at room temperature for 15 to 30 minutes before injecting

Do not remove the grey cap or plum cap while allowing Humira to reach room temperature.

Do not warm Humira in any other way.

For example, do not warm it in a microwave or in hot water.

Do not use it if the solution has been frozen.

- Check the expiry date on the pre-filled pen label. Do not use the product after the month and year shown.

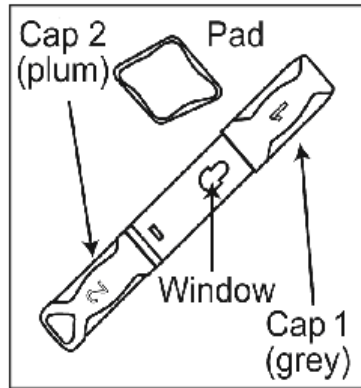


Figure 1

- Hold the pre-filled pen with the grey cap (labelled '1') pointing up. Check the appearance of Humira solution through the windows on the sides of the pre-filled pen.

It must be clear and colourless. If it is cloudy or has particles in it, you must not use it.

Do not remove either the grey cap or the plum cap, until immediately before the injection.

- Set up the following items on a clean surface
 - One Humira pre-filled Pen.
 - One alcohol pad.
- Wash your hands thoroughly

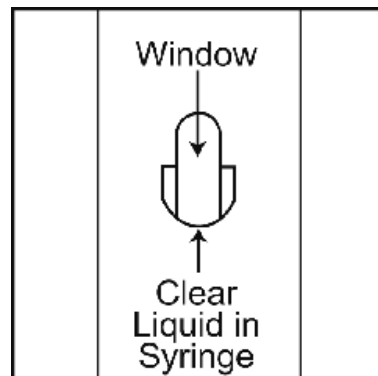


Figure 2

2. Where should I give my injections?

Choose a site on your thigh or stomach (at least 5 cm from your belly button (navel)). Please see the shaded area in Figure 3.

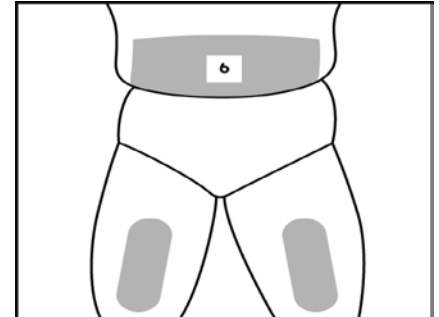


Figure 3

- Change the place that you inject each time so that you do not become sore in one area. Each new injection should be given at least 3 cm from the last injection site.
- **Do not inject into skin that is sore, bruised, red, hard, scarred, has stretch marks or areas with psoriasis plaques.**

3. How do I give my injection?

- Wipe your skin by using the enclosed alcohol pad, using a circular motion.
- Only remove both the grey cap and the plum cap **immediately** before injection.
- Hold the grey body of the pre-filled pen with one hand by placing this hand in the middle of the pen so that neither the grey cap nor the plum cap is covered. Hold the pre-filled pen with the grey cap pointing up.
- With your other hand, pull the grey cap straight off and discard cap.
- Check that the small grey needle cover of the syringe has been removed with the cap. If a few small drops of liquid come out of the needle, that is okay. The white needle sleeve will now be exposed
- **Do not try to touch the needle housed in the barrel.**
- **DO NOT RECAP** the pen as you may damage the needle inside

- Pull the plum safety cap (labelled '2') straight off to expose the plum coloured activation button.
- The pre-filled pen is now ready to use. Do not press the plum activation button until properly positioned as this will result in discharge of medication.

DO NOT RECAP as this could cause the unit to discharge and could potentially cause needle stick injury.

- Do not place the pen down as this could cause the unit to discharge.

4. Giving the injection

- With your free hand, gently grasp or pinch a sizable area of the cleaned skin at the injection site and hold firmly for the entire injection procedure (see Figure 4).
- Position the white end of the pre-filled pen at a right angle (90 degrees) to the skin, so that you can see the window. The presence of one or more bubbles in the window is normal.
- Holding the barrel of the pre-filled pen, press down slightly onto the injection site (holding in place without moving), but do not press plum end until ready for injection.
- With your index finger or your thumb, press the plum coloured button on top once you are ready to begin the injection. You will hear a loud 'click' as the needle is released, and you will feel a small prick as the needle advances.

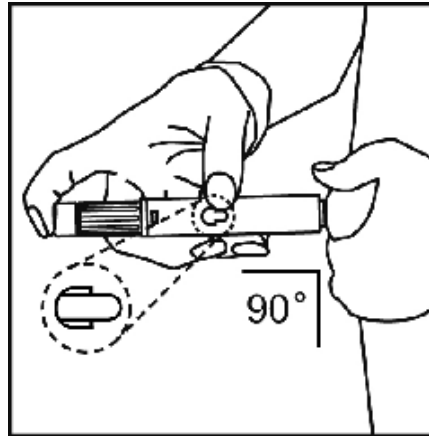
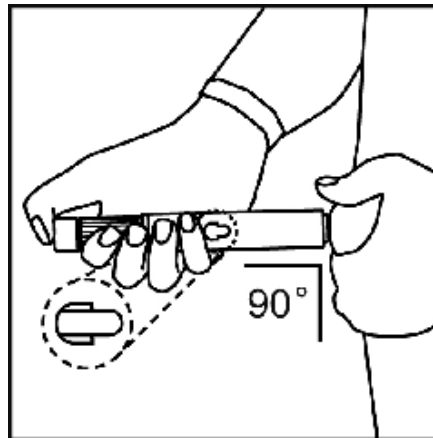


Figure 4



- Keep pressing and continue to hold the pen with steady pressure for about 10 seconds to ensure a complete injection. Do not remove the pen while the injection is being given.
- You will see a yellow indicator move into the window during the injection. The injection is complete when the yellow indicator stops moving (see Figure 5).

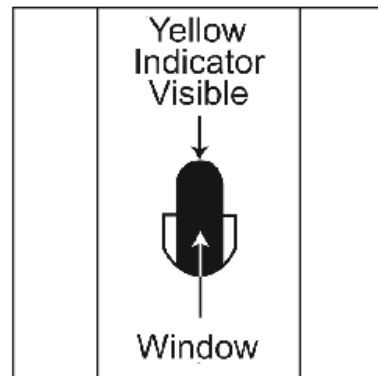


Figure 5

- Lift the pen straight up from the injection site. The white needle

sleeve will move down over the needle and lock into place over the needle tip. Do not try to touch the needle. The white needle sleeve is there to protect you from touching the needle (see Figure 6).

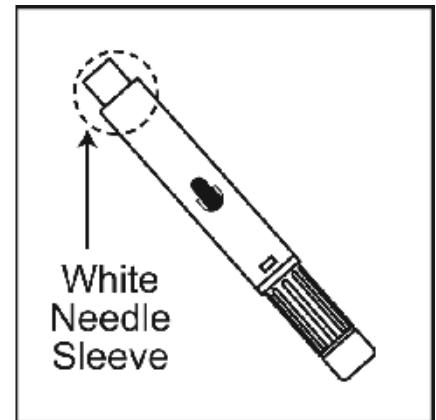


Figure 6

- You may notice a spot of blood at the injection site. You can press a cotton ball or a piece of gauze over the injection site for 10 seconds.

Do NOT rub the injection site.

5. Throwing away supplies

- Only use each pen for one injection. Do not put either of the caps back on the Pen.
- After injecting Humira, immediately throw away the used pen in a special 'sharps' container as instructed by your doctor, nurse or pharmacist.
- Keep this container out of 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 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.

This may increase the chance of getting an unwanted side effect.

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

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 (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 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 yellow fever vaccine, should not be given while you are 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

Tell your doctor if you get symptoms such as fever, wounds, feeling tired or have 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 infections or poisoning of the blood (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
- 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)
- Headache, dizziness, vertigo, sensation disorders
- Increased cough, sore throat
- Abdominal symptoms such as nausea, diarrhoea, abdominal pain,
- Rash, itching
- Fatigue
- Mouth inflammation and ulcers
- Muscle or bone pain
- 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.

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 medicines that stop your body's immune system defence mechanism. In addition 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 pen 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 whether travelling by car, bus, train, plane or any other form of transport.

When required a single Humira pre-filled pen may be stored at room

temperature (below 25°C) for a maximum period of 14 days, but must be protected from light. Once removed from the refrigerator and stored at room temperature, the pen 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 pen 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 is a clear, colourless, sterile solution of:

- 40mg adalimumab in 0.8mL water in a syringe

Available in a Pre-filled pen for patient use in packs containing 2 or 6 pre-filled pens with 2 or 6 alcohol pads

Ingredients

Humira contains 40mg of adalimumab as the active ingredient.

It also contains other ingredients including:

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

Patient Support Programme

The AbbVie Care support programme is available to people prescribed Humira in New Zealand and offers the following:

- Nurse support
- Welcome Kit
- Online Community
- Email and SMS reminders
- Sharps Disposal
- Travel Wallet

For further information:

Call 0800 848 243 or visit
www.abbviecare.co.nz

Distributor

Humira is distributed in New Zealand by:

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6th Floor, 156-158 Victoria St
Wellington, 6011
New Zealand

This leaflet was prepared in:

March 2019

Version 26