ABRILADA®

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 ABRILADA?

ABRILADA contains the active ingredient adalimumab. ABRILADA is used for the treatment of a number of inflammatory diseases.

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

2. What should I know before I use ABRILADA?

Do not use if you have ever had an allergic reaction to adalimumab or any of the ingredients listed at the end of the CMI; you have a severe infection including an infection of the blood (sepsis), active tuberculosis or other severe infections; you are already using anakinra (Kineret); you have moderate to severe heart failure.

Talk to your doctor if 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 ABRILADA? in the full CMI.

3. What if I am taking other medicines?

Some medicines and ABRILADA may interfere with each other. Tell your doctor or pharmacist if you are taking anakinra (Kineret) or abatacept (Orencia). Tell your doctor if you are taking azathioprine or 6-mercaptopurine with ABRILADA.

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 ABRILADA?

- ABRILADA is given as a subcutaneous injection (under the skin). It may be injected by the patient, family member or carer.
- Your doctor will advise how much ABRILADA to use depending on your medical condition.
- Detailed instructions on how to inject ABRILADA are provided in the 'Instructions for Use' leaflet inside the pack.

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

5. What should I know while using ABRILADA?

Things you should do	• Remind any doctor, pharmacist or dentist you visit that you are using ABRILADA. • Check with your doctor before you receive any vaccines. • Call your doctor straight away if you become pregnant while using ABRILADA. • It is important to tell your doctor if you get symptoms of an infection.
Things you should not do	• Do not stop using ABRILADA, without checking with your doctor. • Do not take ABRILADA and anakinra (Kineret) or ABRILADA and abatacept (Orencia) together.
Driving or using machines	• Be careful before you drive or use any

	machines or tools until you know how ABRILADA affects you. • ABRILADA may have a minor influence on the ability to drive and use machines.
Looking after your medicine	• Keep ABRILADA in a refrigerator (2°C to 8°C). Do not freeze. • Keep your medicine in the pack until it is time to use it in order to protect it from light.

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

6. Are there any side effects?

ABRILADA can make you more likely to get infections or make any infection that you may have worse.

There have been cases of certain kinds of cancer in patients using ABRILADA or similar medicines. 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 ABRILADA your risk for developing cancer may increase. Cases of skin cancer have been observed in patients taking ABRILADA.

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.

ABRILADA®

Active ingredient(s): *adalimumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ABRILADA. 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.

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 ABRILADA.

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

Where to find information in this leaflet:

1. Why am I using ABRILADA?
2. What should I know before I use ABRILADA?
3. What if I am taking other medicines?
4. How do I use ABRILADA?
5. What should I know while using ABRILADA?
6. Are there any side effects?
7. Product details

---

1. Why am I using ABRILADA?

ABRILADA contains the active ingredient adalimumab. Adalimumab is 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 higher levels in some inflammatory diseases.

ABRILADA is used for the treatment of a number of inflammatory diseases:

- Rheumatoid arthritis

Rheumatoid arthritis is an inflammatory disease of the joints. Signs and symptoms of rheumatoid arthritis include joint pain, tenderness, swelling and stiffness. ABRILADA is used to reduce the signs and symptoms of moderate to severely active rheumatoid arthritis, as well as to slow down further damage to the joints, to help them move more freely.

Your doctor will decide if ABRILADA should be used with another medicine called methotrexate, or on its own.

ABRILADA can also be used to treat severe, active and progressive rheumatoid arthritis without previous methotrexate treatment.

- Polyarticular Juvenile Idiopathic Arthritis (pJIA)

pJIA is an inflammatory disease of the joints. ABRILADA is used to reduce the signs and symptoms of moderate to severely active pJIA, in patients 2 years of age and older, who have not responded well enough to

other medicines. Your doctor will decide whether ABRILADA should be used with another medicine called methotrexate or used alone.

- Enthesitis-related arthritis (ERA)

ERA is an inflammatory disease of the joints and the places where tendons join the bone. ABRILADA is used to treat ERA in children.

You will have already been given other medicines to treat your condition. Your doctor has prescribed ABRILADA for you as you haven't responded well enough to these medicines.

- Psoriatic arthritis (PsA)

PsA is an inflammatory disease of the joints that is usually associated with psoriasis. Signs and symptoms include joint pain, tenderness and swelling. ABRILADA is used to reduce the signs and symptoms of moderate to severely active PsA, as well as to slow down further damage to the joints, to help them move more freely.

You will have already been given other medicines to treat your condition. Your doctor has prescribed ABRILADA for you as you haven't responded well enough to these medicines.

- Ankylosing spondylitis

Ankylosing spondylitis is an inflammatory disease of the spine. Signs and symptoms of ankylosing spondylitis include back pain and stiffness. ABRILADA is used to reduce the signs and symptoms in patients with active disease.

- Crohn's Disease

Crohn's disease is an inflammatory disease of the digestive tract. ABRILADA is used to treat moderate to severe Crohn's disease in adults and children aged 6 years and over to reduce the signs and symptoms of the disease and to induce and maintain periods where the symptoms are no longer present (remission).

You will have already been given other medicines to treat your condition. Your doctor has prescribed ABRILADA for you as you may either have not responded well enough, or you may have lost response or cannot tolerate these medicines.

- Ulcerative Colitis

Ulcerative colitis is an inflammatory disease of the large intestine (bowel). ABRILADA is used to treat moderate to severe ulcerative colitis in adults when other medicines have not worked well enough or when other medicines are not suitable.

- Psoriasis

Psoriasis is an inflammatory disease of the skin. Plaque psoriasis, the most common form, is a skin condition that causes red, flaky, crusty patches of the skin covered with silvery scales. Plaque psoriasis can also affect nails, causing them to crumble, thicken and lift away from the nail bed which can be painful.

ABRILADA is used to treat moderate to severe forms of the disease in adults and severe forms in adolescents and children from 4 years of age for whom topical therapy (such as creams, lotions and ointments) and phototherapy (also known as light therapy) have either not worked very well, or are not suitable.

- Hidradenitis suppurativa (HS)

HS (sometimes called acne inversa) is a chronic and often painful inflammatory skin disease.

Symptoms may include tender nodules (lumps) and abscesses (boils) that may leak pus, which can have an unpleasant odour. 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

ABRILADA is used for the treatment of adults and adolescents from 12 years of age with active moderate to severe HS, ABRILADA can reduce the number of nodules and abscesses caused by the disease, and the pain that is often associated with it.

You will have already been given other medicines to treat your condition. Your doctor has prescribed ABRILADA for you as you haven't responded well enough to these medicines.

Your doctor will schedule follow-up appointments to check on your progress to determine whether you should continue treatment.

- Uveitis

Uveitis is an inflammatory disease affecting certain parts of the eye. This 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). ABRILADA is used to treat non-infectious intermediate, posterior and pan-uveitis in adult patients.

You may have already been given other medicines to treat your condition. Your doctor has prescribed ABRILADA for you as you may either have not responded well enough, or you have lost response or cannot tolerate these medicines.

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.

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

2. What should I know before I use ABRILADA?

Warnings

Do not use ABRILADA if:

1. you are allergic to 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.

2. Always check the ingredients to make sure you can use this medicine.
3. you have a severe infection including an infection of the blood (sepsis), active tuberculosis or other severe infections that can be caused by viruses, fungi, parasites or bacteria.
   Infections can occur when the body's natural defences are lowered.
4. you are already using anakinra (Kineret).
   Anakinra is a medicine for rheumatoid arthritis, JIA and conditions associated with a defect in a protein called cryoprin.
5. you have moderate to severe heart failure.
6. particulates or discolourations are noted. ABRILADA is a clear, colourless to very light brown solution.

If you are not sure whether any of the above conditions apply to you, ask your doctor.

Check with your doctor if you:

- have or have had an infection, including a long-term infection or an infection in one part of the body (for example, leg ulcer).
- have had infections which keep coming back or other conditions that increase the risk of infections.
  If you are over 65, you may be more likely to get an infection while taking ABRILADA. It is important that you and your doctor pay special attention to signs of infection while you are being treated with ABRILADA
- have ever had tuberculosis, or if you have been in close contact with someone who has had tuberculosis.

As cases of tuberculosis have been reported in patients treated with ABRILADA, your doctor will check you for signs and symptoms of tuberculosis before starting ABRILADA. This will include a thorough medical evaluation, including your medical history, and appropriate screening tests (for example a chest x-ray and tuberculin test).
Tuberculosis can develop during therapy even if you have received treatment for the prevention of tuberculosis.
If symptoms of tuberculosis (for example a cough that doesn't go away, weight loss, lack of energy, mild fever), or any other infections appear during or after therapy, tell your doctor immediately.

- are a carrier of the hepatitis B virus (HBV), or you have active HBV or you think you might be at risk of contracting HBV.
  In people who carry HBV, ABRILADA can cause the virus to become active again. In some rare cases, especially if you are taking other medicines that suppress the immune system, reactivation of HBV can be life threatening.
- have or have had 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 ABRILADA.
- have or have had uveitis, your doctor may check for signs and symptoms of neurologic disease before starting this medicine.

- have or develop a demyelinating disease (a disease that affects the insulating layer around the nerves, such as multiple sclerosis).
- have or have had allergic reactions such as chest tightness, wheezing, dizziness, swelling or rash.
- have or have had a blood disorder.
- have or have had low resistance to disease.
- have or have had a serious heart condition.
- have or have had cancer or autoimmune disease.
- have a lung disease called chronic obstructive pulmonary disease (COPD).
- have or have had kidney or liver problems.
- are scheduled for any vaccines.
  Certain vaccines may cause infections and should not be given while patients are receiving ABRILADA. Wherever possible, it is recommended that children, be brought up to date with all immunisations according to current immunisation guidelines prior to starting on ABRILADA therapy. Patients receiving ABRILADA should not receive live vaccines.
- have psoriasis and have undergone phototherapy, also known as light therapy.
- have allergies to any other medicines, foods, preservatives or dyes.

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

Check with your doctor if you are pregnant or intend 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 ABRILADA treatment.

ABRILADA should only be used during pregnancy if clearly needed.

If you use ABRILADA 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 ABRILADA use during your pregnancy before the baby receives any vaccine.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known whether ABRILADA passes into breast milk. If you are breastfeeding, your doctor may advise you to stop breastfeeding while you are using this medicine.

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 and ABRILADA may interfere with each other.

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

Tell your doctor if you are taking azathioprine or 6-mercaptopurine with ABRILADA.

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

ABRILADA can be taken together with other medicines such as: methotrexate, and other disease-modifying anti-rheumatic agents, steroids or pain medications including non-steroidal anti-inflammatory drugs (NSAIDS).

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

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

4. How do I use ABRILADA?

ABRILADA is given as a subcutaneous injection (under the skin). It may be injected by the patient, family member or carer.

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 ABRILADA exactly as your doctor has instructed you.

Check with your doctor or pharmacist if you are not sure.

How much to use

Rheumatoid Arthritis in Adults

- The usual dose for adults with rheumatoid arthritis is one 40 mg injection every fortnight.
- If you are receiving ABRILADA without methotrexate, your doctor may change your ABRILADA dose to 40 mg every week or 80 mg every fortnight, depending on your response.
- Other medicines may be prescribed by your doctor to be taken while you are being treated with ABRILADA.

Psoriatic Arthritis & Ankylosing Spondylitis in Adults

- The usual dose for patients with psoriatic arthritis and ankylosing spondylitis is one 40 mg injection every fortnight.
- Other medicines may be prescribed by your doctor to be taken while you are being treated with ABRILADA.

Crohn's disease & Ulcerative Colitis in Adults

- The usual dose for adults with Crohn's disease or ulcerative colitis is as follows:
  - initial dose of 160 mg (day 1) (given as four 40 mg injections in one day OR as two 40 mg injections per day over two consecutive days)
  - 80 mg at day 15 (given as two 40 mg injections in one day).
  - 40 mg starting at day 29, which then continues once every fortnight (maintenance dose).
- Your doctor may change this ongoing (maintenance) dose to 40 mg every week or 80 mg every fortnight, depending on your response.

Psoriasis in Adults

- The usual dose for adult patients with psoriasis is as follows:
  - initial dose of 80 mg (day 1) (given as two 40 mg injections in one day)
  - 40 mg given one week later (day 8), then
  - 40 mg every fortnight from day 22 (maintenance dose).
- Your doctor may change this ongoing (maintenance) dose to 40 mg every week or 80 mg every fortnight, depending on your response.

Uveitis in Adults

- The usual dose for adults with uveitis is as follows:
  - initial dose of 80 mg (day 1) (given as two 40 mg injections in one day),
  - 40 mg one week later (day 8), then

- 40 mg every fortnight, starting at day 22, which then continues (maintenance dose).

Hidradenitis suppurativa in Adults

- The usual dose for adults with HS is as follows:
  - initial dose of 160 mg (day 1) (given as four 40 mg injections in one day OR as two 40 mg injections per day over two consecutive days)
  - 80 mg (day 15) (given as two 40 mg injections in one day)
  - 40 mg every week or 80 mg every fortnight starting at day 29, which then continues (maintenance dose).
- Your doctor may prescribe other medicines for your condition to take with ABRILADA.
- It is recommended you use an antiseptic wash daily on the affected areas.

Juvenile Idiopathic Arthritis & Enthesitis-related Arthritis

- The usual dose for children with pJIA or ERA depends on body weight.
- **For a body weight of 30 kg and above:**
  - The usual dose is 40 mg given every fortnight.
- **For a body weight between 10 kg and less than 30 kg:**
  - The usual dose is 20 mg given every fortnight.

Crohn's Disease in Children

- The usual dose for children with Crohn's disease depends on body weight.

- **For a body weight of 40 kg or above:**
  - initial dose 160 mg (day 1) (given as four 40 mg injections in one day OR as two 40 mg injections per day over two consecutive days)
  - 80 mg two weeks later (day 15) (given as two 40 mg injections in one day)
  - 40 mg every fortnight starting at day 29, which then continues (maintenance dose).
- Your doctor may change this ongoing (maintenance) dose to 40 mg every week or 80 mg every fortnight, depending on your response.
- **For a body weight of less than 40 kg:**
  - initial dose of 80 mg (day 1) (given as two 40 mg injections in one day)
  - 40 mg two weeks later (day 15)
  - 20 mg every fortnight, starting at day 29, which then continues (maintenance dose).
- Your doctor may change this ongoing (maintenance) dose to 20 mg every week, depending on your response.
- Treatment of Crohn's disease in children should be supported by good nutrition to allow appropriate growth.

Psoriasis in Children

- The usual dose for children with psoriasis depends on body weight:
- **For a body weight of 40 kg and above:**
  - The usual dose is 40 mg given once every week for the first two weeks, then once every fortnight.

- **For a body weight of less than 40 kg:**
  - The usual dose is 20 mg given once every week for the first two weeks, then once every fortnight.

Hidradenitis suppurativa in Adolescents

- The usual dose for adolescents with HS, (from 12 years of age, weighing at least 30 kg) is as follows:
  - initial dose of 80 mg (day 1) (given as two 40 mg injections in one day)
  - 40 mg starting one week later (day 8)
  - 40 mg every fortnight starting at day 22, which then continues (maintenance dose).
- Your doctor may change this ongoing (maintenance) dose to 40 mg every week or 80 mg every fortnight, depending on your response.
- It is recommended you use an antiseptic wash daily on the affected areas.

How to use ABRILADA

- ABRILADA is administered by injection under the skin (by subcutaneous injection).
- **Detailed instructions on how to inject ABRILADA are provided in the 'Instructions for Use' leaflet inside the pack.**

How long to use ABRILADA

- Keep using ABRILADA for as long as your doctor tells you.
- ABRILADA 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 ABRILADA

If you forget to give yourself an injection, you should inject the next dose of ABRILADA as soon as you remember. Then inject your next dose as you would have on your originally scheduled day.

Do not try to make up for missed doses by injecting more than one dose at a time.

If you use too much ABRILADA

If you think that you have used too much ABRILADA, you may need urgent medical attention.

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 are no signs of discomfort or poisoning.

Always take the outer carton of the medicine with you.

5. What should I know while using ABRILADA?

Things you should do

Check with your doctor before you receive any vaccines.

Wherever possible, it is recommended that children be brought up to date with all immunisations according to current immunisation guidelines prior to starting ABRILADA therapy.

Patients receiving ABRILADA should not receive live vaccines (for example, BCG or oral polio vaccine).

Call your doctor straight away if you:

- become pregnant while using ABRILADA

Tell your doctor that you are using ABRILADA if you:

- are about to be started on any new medicine.
- are going to have surgery. Your doctor may recommend you discontinue using ABRILADA temporarily.

Remind any doctor, pharmacist or dentist you visit that you are using ABRILADA.

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

Things you should not do

- Do not give ABRILADA to anyone else, even if they have the same condition as you.
- Do not use ABRILADA to treat any other complaints unless your doctor tells you to.
- Do not stop using ABRILADA, without checking with your doctor.
- Do not take ABRILADA and anakinra (Kineret) or ABRILADA and abatacept (Orencia) together.

  Taking either of these two medicines with ABRILADA may lead to an increased risk of developing a serious infection.

Things to be careful of

- It is important to tell your doctor if you get symptoms of an infection, such as a fever, skin sores, feeling tired or any problems with your teeth and gums.
- You might get infections more easily while you are receiving ABRILADA treatment. These infections may be serious and include tuberculosis, infections caused by viruses, fungi, parasites or bacteria, or other infections. Sepsis, an infection of the blood, may, in rare cases, be life-threatening.
- Your doctor may recommend you discontinue ABRILADA if you develop an infection.

Driving or using machines

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

The effects on your ability to drive and use machines whilst taking this medicine are not known.

However, based on side effects observed, ABRILADA may have a minor influence on the ability to drive and use machines. Vertigo and visual impairment may occur whilst taking this medicine.

Looking after your medicine

Keep away from children.

Keep your medicine in the pack until it is time to use it in order to protect it from light.

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

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.

When needed, you can store a single ABRILADA syringe, pen or vial at room temperature up to 30°C for a maximum period of 30 days. Be sure to protect it from light.

Once removed from the refrigerator and stored at room temperature (up to 30°C), the syringe, pen or vial must be used within 30 days or discarded. Do this even if it has been returned to the refrigerator.

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

Do not use this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

When to discard your medicine

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date or damaged, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any 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.

Common side effects

Common side effects	What to do
Blood related issues • Bleeding or bruising more easily than usual • Mouth ulcers, pain or excessive bleeding from the gums **Eye disorders** • Pain or inflammation of the eye or eye lid or changes to your vision **General disorders and administration site conditions** • Pain, swelling, redness or itching at the site of injection • Fatigue, tiredness, lack of energy **Muscle or Bone related issues** • Muscle weakness or numbness, difficulty balancing	**Speak to your doctor if you have any of these more common side effects and they worry you.** They are usually mild and short- lived.

Common side effects	What to do
• Muscle, joint or bone pain **Nervous system** • Headache or migraine, dizziness, vertigo **Psychiatric** • Feeling overwhelmed or sad, or lacking motivation (depression) • Feeling anxious, especially fearful or worried (anxiety) **Heart related issues** • Chest pain • Increased heart rate **Infections** • Cold, runny nose, sinus infection, sore throat cough, congestion on the chest, asthma or worsening of asthma symptoms • Lower respiratory tract infections (such as bronchitis, pneumonia)	

Common side effects	What to do
• Pain in the ear which could suggest an ear infection • Fever, flushing, increased sweating • Viral infections (including the flu, cold sore blisters, chicken pox and shingles) • Bacterial infections (including Urinary Tract Infection) • Fungal Infections **Renal and Urinary related issues** • Burning or pain when passing urine, or blood in the urine **Skin related issues** • Skin bumps or sores that don't heal • Rash, itching, redness or scaly patches • Problems with your finger or toe nails • Hair loss **Stomach related issues**	

Common side effects	What to do
• Nausea, vomiting, abdominal pain • Reflux or heartburn	

Serious side effects

Serious side effects	What to do
Allergic type reactions • 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. **Heart related issues** • Signs and symptoms suggestive of heart failure such as shortness of breath with exertion or upon lying down or swelling of the feet. **Blood related issues**	**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.**

Serious side effects	What to do
• Signs and symptoms suggestive of a blood disorder such as persistent fever, bruising, bleeding very easily, paleness. **Blood clots** • Signs suggesting a blood clot such as swelling, tenderness, redness and a warm feeling of an area of the arm or leg. **Infections** • Signs of tuberculosis such as persistent cough, weight loss, listlessness, fever • Signs of infection such as fever, lack of energy, skin sores, problems with your teeth or gums, burning when you pass urine. You might get infections more easily while you are receiving ABRILADA treatment.	

Serious side effects	What to do
• Signs of soft tissue infection, such as a bump or open sore that doesn't heal **Liver related issues** • Yellow skin and eyes • Abdominal pain • Fatigue, fever and joint pain • Dark urine and pale stool • Loss of appetite and unexplained weight loss **Nervous system** • Signs of nervous system disorders such as numbness or tingling throughout your body, arm or leg weakness, double vision.	

Weight gain has been observed in some patients using ABRILADA.

There have been cases of certain kinds of cancer in patients using ABRILADA or similar medicines. 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 ABRILADA your risk for developing cancer may increase.

On rare occasions, a specific and severe type of lymphoma called hepatosplenic T-cell lymphoma (HSTCL) has been observed in patients taking ABRILADA.

Tell your doctor if new skin lesions (skin spots or sores) appear, or if existing lesions change appearance during or after ABRILADA treatment.

Cases of skin cancer have been observed in patients taking ABRILADA.

If you have COPD, or are a heavy smoker, you should discuss with your doctor whether treatment with a TNF blocker (such as ABRILADA) is right for you.

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 a medicine that is similar to ABRILADA.

Laboratory results

Some side effects observed with ABRILADA may not have symptoms and may only be discovered through blood tests. These include, most commonly, increased lipids, elevated liver enzymes, and low levels of white blood cells and red blood cells in the blood.

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 ABRILADA contains

Active ingredient **(main ingredient)**	Adalimumab
Other ingredients **(inactive ingredients)**	Histidine Histidine hydrochloride monohydrate Disodium edetate

	Sucrose Methionine Polysorbate 80 Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What ABRILADA looks like

ABRILADA 20 mg Pre-filled Syringe (Solution for injection)

ABRILADA 20 mg solution for injection in pre-filled syringe (AUST R 334496) is supplied as a sterile solution of 20 mg adalimumab dissolved in 0.4 mL solution.

The ABRILADA pre-filled syringe is a glass syringe containing a clear, colourless to very light brown solution of adalimumab.

- 2 pre-filled syringes with 2 alcohol swabs

ABRILADA 40 mg Pre-filled Syringe (Solution for injection)

ABRILADA 40 mg solution for injection in pre-filled syringe (AUST R 334498) is supplied as a sterile solution of 40 mg adalimumab dissolved in 0.8 mL solution.

The ABRILADA pre-filled syringe is a glass syringe containing a clear, colourless to very light brown solution of adalimumab.

- 1 pre-filled syringe with 2 (1 spare) alcohol swabs
- 2 pre-filled syringes with 2 alcohol swabs
- 4 pre-filled syringes with 4 alcohol swabs
- 6 pre-filled syringes with 6 alcohol swabs

ABRILADA 40 mg Pre-filled Pen (Solution for injection)

ABRILADA 40 mg solution for injection in pre-filled pen (AUST R 334497) is supplied as a sterile solution of 40 mg adalimumab dissolved in 0.8 mL solution.

The ABRILADA pre-filled pen contains a clear, colourless to very light brown solution of adalimumab.

- 1 pre-filled pen with 2 (1 spare) alcohol swabs
- 2 pre-filled pens with 2 alcohol swabs
- 4 pre-filled pens with 4 alcohol swabs
- 6 pre-filled pens with 6 alcohol swabs

ABRILADA 40 mg/0.8 mL Vial (Solution for injection)

ABRILADA 40 mg solution for injection in vials (AUST R 334499) is supplied as a sterile solution of 40 mg adalimumab dissolved in 0.8 mL solution.

The ABRILADA vial is a glass vial containing a clear, colourless to very light brown solution of adalimumab.

One pack contains 2 boxes, each containing 1 vial, 1 empty sterile syringe, 1 needle, 1 vial adapter and 2 alcohol swabs.

**Not all presentations and pack sizes are marketed.

Who distributes ABRILADA

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

This leaflet was prepared in July 2025.

® = Registered Trademark