

HADLIMA® PushTouch™ Auto- injector 40 mg

adalimumab

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Hadlima.

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 Hadlima and keep it with the medicine.

You may need to read it again.

What HADLIMA is used for

The active ingredient in this medicine is adalimumab, which 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.

Hadlima 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.

Hadlima is used to reduce the signs and symptoms of moderate to severely active rheumatoid arthritis, as well as to slow down and protect the joints from further damage to help them move more freely.

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

Hadlima 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. Hadlima is used to reduce the signs and symptoms of moderate to severely active pJIA, in patients 2 years of age and older, when other medicines are not appropriate. Your doctor will decide whether Hadlima 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. Hadlima is used to treat ERA in children.

You may have already been given other medicines to treat your

condition. Your doctor has prescribed Hadlima 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. Hadlima is used to reduce the signs and symptoms, of moderate to severely active PsA, as well as to slow down and protect the joints from further damage, to help them move more freely.

You may have already been given other medicines to treat your condition. Your doctor has prescribed Hadlima 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. Hadlima 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. Hadlima 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 may have already been given other medicines to treat your condition. Your doctor has prescribed Hadlima 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).

Hadlima is used to treat moderate to severe ulcerative colitis when other medicines are not appropriate.

- 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. Hadlima is used to treat moderate to severe forms of the disease in adults and severe forms in children and adolescents 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.

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

You may have already been given other medicines to treat your condition. Your doctor has prescribed Hadlima 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). Hadlima is used to treat non-infectious intermediate, posterior and pan-uveitis.

You may have already been given other medicines to treat your condition. Your doctor has prescribed Hadlima 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.

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

The long term effects of adalimumab on the growth and development of children are not known.

Before you use HADLIMA

When you must not use it

Do not use Hadlima 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

Do not use Hadlima if 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.

Do not use Hadlima if 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.

Do not use Hadlima if you have moderate to severe heart failure.

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

Do not use this medicine after the expiry date printed on the label/ carton or if the packaging is torn or shows signs of tampering.

Return out of date or damaged medicines 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:

- 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)
- you 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 Hadlima. It is important that you and your doctor pay special attention to

signs of infection while you are being treated with Hadlima.

- you 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 Hadlima, your doctor will check you for signs and symptoms of tuberculosis before starting this medicine. 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.

- you 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, Hadlima 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.

- you 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 Hadlima.
- you have or have had uveitis, your doctor may check for signs and symptoms of neurologic disease before starting this medicine.
- you have or develop a demyelinating disease (a disease that affects the insulating layer

around the nerves, such as multiple sclerosis).

- you have or have had allergic reactions such as chest tightness, wheezing, dizziness, swelling or rash
- you have or have had a blood disorder.
- you have or have had low resistance to disease
- you have or have had a serious heart condition.
- you have or have had a serious cancer or autoimmune disease
- you have or have had a serious lung disease called chronic obstructive pulmonary disease (COPD).
- you have or have had a serious kidney or liver problems.

Tell your doctor if you are scheduled for any vaccines.

Certain vaccines may cause infections and should not be given while patients are receiving Hadlima.

Wherever possible, it is recommended that children be brought up to date with all immunisations according to current immunisation guidelines prior to starting adalimumab therapy. Patients receiving Hadlima should not receive live vaccines.

Tell your doctor if you have psoriasis and have undergone phototherapy, also known as light therapy.

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 Hadlima treatment.

Hadlima 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 adalimumab during pregnancy,

compared with mothers with the same disease who did not use adalimumab.

If you use Hadlima 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 Hadlima 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 adalimumab 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 Hadlima.

Taking other medicines

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

Some medicines and Hadlima 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 Hadlima may increase the risk of infection.

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

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

Hadlima can be taken together with other medicines such as methotrexate, other disease-modifying anti-rheumatic agents (for example, sulfasalazine, hydroxychloroquine, leflunomide and injectable gold preparations), and steroids or pain medications

including non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen.

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

How to use HADLIMA

Hadlima 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 Hadlima 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 Hadlima without methotrexate, your doctor may change your Hadlima dose to 40 mg every week or 80 mg (as two 40 mg injections) every fortnight, depending on your response.

Other medicines may be prescribed by your doctor to be taken while you are being treated with Hadlima.

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 Hadlima.

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 on 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 (as two 40 mg injections) every fortnight, depending on your response.

Psoriasis in Adults

The usual dose for adults 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 (as two 40 mg injections) 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 (as two 40 mg injections) every fortnight starting at day 29, which then continues (maintenance dose).

Your doctor may prescribe other medicines for your condition to take with Hadlima.

Juvenile Idiopathic Arthritis & Entesitis-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.

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 and above:

- initial dose of 160 mg (day 1) (given as four 40 mg injections on one day OR 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 (as two 40 mg injections) every fortnight, 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 the 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.

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 (as two 40 mg injections) every fortnight, depending on your response.

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

How to use it

Hadlima is injected under the skin. The injection can be self-administered or given by another person, for example a family member or friend or carer, but only after proper training in injection technique.

If you are using the Hadlima PushTouch™ auto-injector, instructions for preparing and giving an injection are provided on

the Product Information/ Instruction for use leaflet 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.

Keep out of the sight and reach of children.

How long to use it

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

Hadlima 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 Hadlima 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? (overdose)

If you accidentally inject Hadlima more frequently than prescribed 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 HADLIMA

Things you must 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 adalimumab therapy.

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

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

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

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

If you are going to have surgery, tell all doctors that you are using Hadlima. Your doctor may recommend you discontinue using Hadlima temporarily.

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

Things you must not do

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

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

Do not stop taking Hadlima, without checking with your doctor.

Do not take Hadlima and anakinra (Kineret) or Hadlima and abatacept (Orencia) together.

Taking either of these two medicines with Hadlima 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 Hadlima treatment. These infections may be serious and include tuberculosis, infections caused by viruses, fungi, parasites or bacteria, or other. Sepsis, an infection of the blood, may, in rare cases, be life-threatening.

Your doctor may recommend you discontinue Hadlima if you develop an infection.

Be careful driving or operating machinery until you know how Hadlima 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 do not feel well while using Hadlima or you have any problems using it.

Do this even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

All medicines can have unwanted side effects. Sometimes they are serious, but most of the time they are not. You may need medical attention if you get some 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 a blood disorder such as persistent fever, bruising, bleeding very easily, paleness

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

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, 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 Hadlima 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:

- Pain, swelling, redness or itching at the site of injection
- 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)

- Pain in the ear which could suggest an ear infection
- Pain or inflammation of the eye or eye lid or changes to your vision
- Mouth ulcers, pain or excessive bleeding from the gums
- Burning or pain when passing urine, or blood in the urine
- Skin bumps or sores that don't heal
- Headache or migraine, dizziness, vertigo
- Muscle weakness or numbness, difficulty balancing
- Fever, flushing, increased sweating
- Nausea, vomiting, abdominal pain
- Reflux or heartburn
- Chest pain
- Rash, itching redness or scaly patches
- Problems with your finger or toe nails
- Hair loss
- Fatigue, tiredness, lack of energy
- Muscle, joint or bone pain
- Bleeding or bruising more easily than usual
- Feeling overwhelmed or sad, or lacking motivation (depression)
- Feeling anxious, especially fearful or worried (anxiety)
- Increased heart rate
- Viral infections (including the flu, cold sore blisters, chicken pox and shingles)
- Bacterial infections (including Urinary Tract Infection)
- Fungal Infections.

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

There have been cases of certain kinds of cancer in patients using adalimumab 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 Hadlima your risk may increase.

On rare occasions, a specific and severe type of lymphoma has been observed in patients taking adalimumab.

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

Very rare cases of skin cancer have been observed in patients taking adalimumab.

If you have COPD, or are a heavy smoker, you should discuss with your doctor whether treatment with a TNF blocker 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 another TNF blocker.

Laboratory results

Some side effects observed with Hadlima 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 is making you feel unwell.

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

After using HADLIMA

Storage

Keep your PushTouch™ auto-injector in the pack until it is time

to use it in order to protect it from light.

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

Keep Hadlima 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.

When needed, you can store a PushTouch™ auto-injector at room temperature (below 25°C) for a maximum period of 14 days. Be sure to protect it from light.

Once removed from the refrigerator and stored at room temperature, the PushTouch™ auto-injector must be used within 14 days or discarded. Do this even if it has been returned to the refrigerator.

These storage instructions are also important when you are travelling.

Write down the date you first remove the PushTouch™ auto-injector from the refrigerator on the label, so you can check how long it has been.

Disposal

After injecting Hadlima, immediately throw away the used PushTouch™ auto-injector in a special 'sharps' container as instructed by your doctor, nurse or pharmacist.

If your doctor tells you to stop using Hadlima 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

Hadlima is a clear, colourless, sterile solution of 40 mg adalimumab in 0.8 mL solution in a syringe available in a PushTouch™ auto-injector for patient use in packs

containing 2 PushTouch™ auto-injectors.

Ingredients

Hadlima contains adalimumab as the active ingredient:

For Hadlima 40 mg/0.8 mL PushTouch™ auto-injector, it also contains other ingredients including:

- Sodium citrate dihydrate
- Citric acid monohydrate
- L-histidine
- L-histidine hydrochloride monohydrate
- Sorbitol
- Polysorbate 20
- Water for injections

Distributor

Hadlima is distributed in Australia by:

Sponsor:

Samsung Bioepis AU Pty Ltd
Level 16, 201 Elizabeth Street,
Sydney NSW 2000, Australia

Distributor:

Merck Sharp & Dohme (Australia)
Pty Limited
Level 1, Building A,
26 Talavera Road,
Macquarie Park NSW 2113,
Australia

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