

ORENCIA®

(or-en-see-ah)

Abatacept (ab-ah-ta-sept) (rch) Powder for intravenous infusion; Abatacept (rch) solution for Injection (pre-filled syringe, pre-filled autoinjector)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ORENCIA. It does not contain all of 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 receiving ORENCIA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor.

You should read this leaflet carefully and keep it in a safe place to refer to it later.

What ORENCIA is used for

ORENCIA contains abatacept; a medicine which is used to treat:

- moderate to severe rheumatoid arthritis in adults;
- severe, active and progressive rheumatoid arthritis,
- psoriatic arthritis in adults, and
- polyarticular juvenile idiopathic arthritis.

Rheumatoid Arthritis

Rheumatoid arthritis is a disease that causes pain and joint inflammation (tenderness and swelling). It can also cause joint damage.

You may be given ORENCIA and methotrexate to:

- Reduce the signs and symptoms of your disease.
- Slow down the damage to your bones and joints.
- Improve your physical function and your ability to do normal daily activities.

Psoriatic Arthritis

Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis, an inflammatory disease of the skin. If you have active psoriatic arthritis you will first be given other medicines. If you do not respond well enough to these medicines, you may be given ORENCIA.

Polyarticular juvenile idiopathic arthritis

ORENCIA infused intravenously is also used to treat moderate to severe polyarticular juvenile idiopathic arthritis in children and adolescents 6 years of age and older who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs.

It is not recommended to use the subcutaneous formulation of ORENCIA in children.

ORENCIA is available in two formulations:

- ORENCIA powder for infusion **MUST ONLY BE GIVEN BY YOUR DOCTOR OR NURSE.**
- ORENCIA solution for injection is injected under the skin and can be injected by your doctor, nurse, carer or yourself.

The first dose should be done under medical supervision.

Patients can self inject after the doctor/ healthcare practitioner is assured that the patient's and/or carer's injection technique is satisfactory, and while providing medical follow-up as necessary.

ORENCIA is a medicine that keeps the immune system from attacking healthy tissues in the body. The immune system is the body's defence against attack by infections caused by bacteria and viruses. A normal immune system leaves healthy body tissues alone. In adults with rheumatoid arthritis or psoriatic arthritis and in children and adolescents (more than or equal to 6 years of age) with polyarticular juvenile idiopathic arthritis, the immune system attacks normal body tissues. This can cause damage and inflammation especially in the tissues of your joints. ORENCIA interferes with an important step in this attack; it decreases the immune system's attack on normal tissues. ORENCIA can reduce pain, joint inflammation, and damage to your bones and cartilage.

ORENCIA can also reduce your body's ability to fight infection, so treatment with ORENCIA may make you more prone to getting infections, or make any infection that you might have worse. It is important to tell your doctor if you think you have any infections.

Ask your doctor if you have any questions about why ORENCIA has been prescribed for you.

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

ORENCIA is not recommended for use in children under 6 years of age, as there have been no formal studies of its effects in children under 6 years of age.

Before you are given ORENCIA

When you must not be given ORENCIA

Do not use ORENCIA if you have:

- **An allergy to any medicine containing abatacept or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction to ORENCIA may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- **A severe infection, as ORENCIA can affect your body's ability to fight serious infection.**

You should be screened for certain infections prior to treatment with ORENCIA.

If you develop symptoms suggestive of infections, such as fever, persistent cough, weight loss, or listlessness, seek medical attention immediately.

Do not take this medicine/it after the expiry date printed on the pack 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.

If you are not sure whether you should be given ORENCIA, talk to your doctor.

Before you are given ORENCIA

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 medical conditions, especially the following:

- have any kind of infection including an infection that is in only one place in your body (such as an open cut or sore), or an infection that is in your whole body (such as the flu). Having an infection could put you at risk for serious side effects from ORENCIA. If you are unsure, please ask your doctor;
- have an infection that won't go away or a history of infections that keep coming back;
- have had tuberculosis, or if you recently have been in close contact with someone who has had tuberculosis. If you develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats) call your doctor right away. Before you start ORENCIA, your doctor may examine you for tuberculosis or perform a skin test;
- have chronic obstructive pulmonary (lung) disease (COPD). You may develop certain respiratory problems more often if you receive ORENCIA, including: worsened COPD, pneumonia, cough or trouble breathing;
- have multiple sclerosis;
- are scheduled to have surgery;
- recently received a vaccination or are scheduled for any vaccination. You should not be given ORENCIA if you have recently received a live vaccine. All vaccines should be brought up-to-date before starting ORENCIA. Talk with your doctor about your vaccination plans prior to receiving ORENCIA. If your child is to receive ORENCIA,

discuss your child's vaccination history and plans with their doctor;

- are a carrier of the hepatitis B virus (HBV), if you have active HBV or if you think you might be at risk of contracting HBV.

There have been rare reports of some types of cancer, including skin cancer, developing in patients using ORENCIA. The role of ORENCIA in the development of cancer is not known. Regular skin examinations are recommended while you are receiving ORENCIA.

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

The effects of ORENCIA in pregnant women are not known. Your doctor will discuss the possible risks and benefits of using ORENCIA during pregnancy.

If you have received ORENCIA while you were pregnant, it is important that you inform the baby's doctor before any vaccinations are given to your baby. Your baby may be at risk of severe infection caused by live vaccines for 5 months since your last ORENCIA administration.

Tell your doctor if you are breastfeeding.

The effects of ORENCIA are not known in nursing babies. Your doctor will discuss the possible risks and benefits of using ORENCIA during breast-feeding.

Tell your doctor if you have diabetes and are using a blood glucose monitor to check your blood glucose levels.

ORENCIA contains maltose, which is a type of sugar that can give falsely high blood glucose readings with certain types of blood glucose monitors. Your doctor may recommend a different method for monitoring your blood glucose levels (intravenous formulation only).

Tell your doctor if you are on a diet that restricts your sodium (salt) intake.

ORENCIA contains sodium chloride and your doctor will advise you how the use of ORENCIA should be considered in your overall dietary intake of sodium.

If you have not told your doctor about any of the above, tell him/her before you are given ORENCIA.

Taking other medicines

Tell your doctor if you are taking any other medication, including any that you get without a prescription from your pharmacy medication, supermarket or health food shop.

Some medicines and ORENCIA may interfere with each other.

You should not be given ORENCIA if you are currently being treated with certain medicines such as biological disease-modifying anti-rheumatic drugs, for example adalimumab (Humira™), etanercept (Enbrel™), infliximab (Remicade™); you may have a higher chance of getting a serious infection.

It is important that you tell your doctor or pharmacist about the medicines you are taking, even if they are not listed in this leaflet.

They will be able to provide you with more information on the medicines you need to be careful with, or should avoid while taking ORENCIA.

How ORENCIA is given

Powder for intravenous infusion only:

How it is given

ORENCIA is given as a slow infusion into a vein over 30 minutes. ORENCIA must only be given by a doctor or nurse.

How much is given

Your doctor will decide what dose you will be given. Your dose will depend on factors such as your weight.

Solution for injection subcutaneous administration - adults only:

There is no clinical trial data for the use of ORENCIA subcutaneous formulation in children, therefore its use in children cannot be recommended.

How it is given

ORENCIA is injected under the skin. It is available in pre-filled syringe or pre-filled autoinjector.

Follow all directions given to you by your doctor/healthcare practitioner carefully.

They may differ from the information contained in this leaflet.

If you are injecting ORENCIA yourself, there are detailed instructions provided in the leaflet inside the pack to assist you.

ORENCIA can be injected by your doctor, nurse, carer or by yourself. The first dose should be done under medical supervision. Patients can self inject after the doctor/healthcare practitioner is assured that the patient's and/or carer's injection technique is satisfactory, and while providing medical follow-up as necessary.

Pre-filled syringe

Take one pre-filled syringe out of the fridge 30 minutes before the injection and allow it to slowly warm up to room temperature, immediate use is recommended.

When using ORENCIA pre-filled syringe, it is important that you do not pull back on the plunger at any time. Do not remove the needle cover until you are ready to inject.

Each syringe of ORENCIA is for single use only, in one patient only. Discard any residue.

When you have finished injecting ORENCIA, discard the syringe into a sharps container.

Pre-filled autoinjector

Take one pre-filled autoinjector out of the fridge 30 minutes before the injection and allow it to slowly warm up to room temperature, immediate use is recommended.

When using ORENCIA pre-filled autoinjector, it is important that you do not remove the orange needle cover until you are ready to inject.

Each autoinjector of ORENCIA is for single use only, in one patient only. Discard any residue.

When you have finished injecting ORENCIA, discard the autoinjector into a sharps container.

If you do not understand the instructions for injecting ORENCIA found in the pack, ask your doctor/healthcare practitioner for help.

To help you remember, use a diary to write in the day of the week you should have your ORENCIA injection.

How much is given

Your doctor/healthcare practitioner will tell you how to inject ORENCIA.

A different site should be used for each new injection. Each new injection site should be approximately 1 inch (2.5cm) from where you last injected ORENCIA.

The recommended dose is 125mg per week regardless of your weight and ORENCIA should be injected under the skin.

The subcutaneous injection can be given with or without an intravenous loading dose. Your doctor will determine whether you will receive an intravenous loading dose prior to using your solution for injection.

How long to use it

You should continue to inject ORENCIA for as long as your doctor recommends.

Never inject more than the dose recommended.

If you miss a dose

If you miss a dose, contact your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

If you accidentally inject ORENCIA more frequently than told to by your doctor, immediately telephone your doctor or the Poisons Information Centre (Australia: Telephone 13 11 26; 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 being treated with ORENCIA

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given ORENCIA.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given ORENCIA.

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

Things you must not do

Do not take ORENCIA to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how ORENCIA affects you.

This medicines may cause dizziness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given ORENCIA.

Like other medicines, ORENCIA can help people with rheumatoid arthritis, psoriatic arthritis and polyarticular juvenile idiopathic arthritis, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

Adults:

- lower respiratory tract infection such as bronchitis
- urinary tract infection
- herpes (cold sores)
- pneumonia
- upper respiratory tract infection such as sore throat, runny or blocked nose
- headache, dizziness
- increase in blood pressure
- cough
- abdominal pain, diarrhoea, mouth ulcers, nausea or indigestion
- rash, dermatitis
- fatigue, weakness, local injection site reaction (subcutaneous injection only)
- changes to liver function test

Children and adolescents (more than 6 years of age):

- headache
- nausea
- diarrhoea
- cough
- infections of nose and throat
- fever
- upper abdominal pain

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

Infections

Serious infections have been reported in patients given ORENCIA. These infections are rare and include tuberculosis, pneumonia and other infections caused by viruses, bacteria and fungi.

Symptoms of an infection may include:

- fever
- feeling very tired
- have a cough
- have flu-like symptoms
- warm, red, or painful skin

Infusion-related reactions

Some patients may experience reactions related to the infusion of ORENCIA. Most of these reactions

are mild to moderate and may include:

- dizziness
- headache
- increase in blood pressure

In rare cases, infusion-related reactions may be severe and require that you discontinue treatment.

Hypersensitivity reactions

Although it is uncommon, some patients may experience hypersensitivity reactions within 24 hours of treatment with ORENCIA. Most of these reactions are mild to moderate and may include:

- low blood pressure
- rash
- shortness of breath

Serious hypersensitivity reactions are rarely reported.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

Symptoms of allergic reaction:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- chills, fever, fast heart beat, dizziness
- flushing, sweating

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

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

Product description

What it looks like

Powder for intravenous infusion only:

ORENCIA is provided as a sterile white powder, it is supplied with a silicone-free disposable syringe.

Ingredients

Active Ingredient: Abatacept (rch) 250mg in a 15mL vial.

Other Ingredients: 500mg maltose, 17.2mg monobasic sodium phosphate and 14.6mg sodium chloride.

ORENCIA does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Storage

ORENCIA must be refrigerated at 2°C to 8°C. It must be protected from light.

Solution for injection subcutaneous administration - adults only:

ORENCIA solution for injection is provided as a 1mL single-dose, disposable pre-filled syringe, or as a 1mL single-dose disposable pre-filled autoinjector. There are four single-dose pre-filled syringes or autoinjectors in a pack containing ORENCIA solution. Each syringe or autoinjector contains 125mg of abatacept.

Ingredients

Active ingredient: Abatacept (rch) 125mg per pre-filled syringe or autoinjector.

Other Ingredients: 170mg sucrose, 8mg poloxamer, 0.286mg monobasic sodium phosphate, 0.838mg dibasic sodium phosphate and up to 1 mL water for injection.

ORENCIA solution does not contain maltose.

Storage

ORENCIA must be refrigerated at 2°C to 8°C. Do not Freeze. It must be protected from light.

Sponsored by

Bristol-Myers Squibb Australia Pty Ltd,
4 Nexus Court, Mulgrave,
Victoria 3170, Australia

Registration Numbers:

Powder for intravenous infusion
AUST R 130100

Solution for injection subcutaneous administration - adults only

Pre-filled syringe

AUST R 177176 (with flange extender, not marketed)

AUST R 206764 (with needle guard and flange extender)

AUST R 177174 (with needle guard, not marketed)

Pre-filled autoinjector

AUST R 236039

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