

ORENCIA®

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 ORENCIA?

ORENCIA contains the active ingredient abatacept. ORENCIA 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.

For more information, see Section [1. Why am I using ORENCIA?](#) in the full CMI.

2. What should I know before I use ORENCIA?

Do not use if you have ever had an allergic reaction to abatacept or any of the ingredients listed at the end of the CMI.

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 ORENCIA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ORENCIA and affect how it works.

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 ORENCIA?

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.

More instructions can be found in Section [4. How do I use ORENCIA?](#) in the full CMI.

5. What should I know while using ORENCIA?

Things you should do	<ul style="list-style-type: none">• Tell any other doctors, dentists, and pharmacists who are treating you that you are being given ORENCIA, especially if you are about to be started on any new medicine.• Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">• 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.

<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● ORENCIA 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.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> ● ORENCIA must be refrigerated at 2°C to 8°C. ● Do not Freeze. ● It must be protected from light.

For more information, see Section [5. What should I know while using ORENCIA?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, ORENCIA can cause side effects. Your doctor will discuss potential side effects with you and will explain the risks and benefits of your treatment. Some side effects can be serious and you may require medical attention.

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.

ORENCIA[®] (or-en-see-ah)

Active ingredient: abatacept (ab-ah-ta-sept) (rch)

Consumer Medicine Information (CMI)

This leaflet provides important information about using ORENCIA. **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 ORENCIA.**

Where to find information in this leaflet:

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

1. Why am I using ORENCIA?

ORENCIA contains the active ingredient abatacept.

ORENCIA 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 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 (6 years of age or older) 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.

2. What should I know before I use ORENCIA?

Warnings

Do not use ORENCIA if:

- you are allergic to abatacept, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

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
- you have a severe infection, as ORENCIA can affect your body's ability to fight serious infections.
- 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.

Check with your doctor if you:

- 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.
- 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.

- 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.
- have weakness, visual changes, memory loss, trouble thinking or difficulty walking. There have been reports of a rare brain infection called Progressive Multifocal Leukoencephalopathy (PML), developing in patients using ORENCIA, mostly when used in combination with other medicines that suppress the immune system.
- 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.

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.

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.

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.

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

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.

Use in children or adolescents

- ORENCIA is not recommended for use in children under 6 years of age.

Diabetes and blood glucose monitoring

- 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).

Sodium restriction diet

- 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.

3. What if I am taking other medicines?

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

Some medicines may interfere with abatacept and affect how it works.

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, etanercept, infliximab; you may have a higher chance of getting a serious infection.

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

4. How do I use ORENCIA?

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.

Powder for intravenous infusion only

How ORENCIA 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 Orencia 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.

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

Never inject more than the dose recommended.

If you forget to use ORENCIA

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 ORENCIA

If you accidentally inject ORENCIA more frequently than advised by your doctor, 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.

5. What should I know while using Orenzia?

Things you should 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.

Call your doctor straight away if you:

- Have any signs or symptoms of possible side effects or if they get worse. See Section [6. Are there any side effects?](#)
- Develop symptoms of an allergic reaction. These symptoms 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.

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

Things you should 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.

Driving or using machines

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

ORENCIA 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.

Looking after your medicine

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date.

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.

Serious side effects

Serious side effects	What to do
Symptoms of allergic reaction: <ul style="list-style-type: none">• shortness of breath, wheezing or difficulty breathing	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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 	<p>notice any of these serious side effects.</p>
<p>Infections</p> <p>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.</p> <p>Symptoms of an infection may include:</p> <ul style="list-style-type: none"> ● fever ● feeling very tired ● have a cough ● have flu-like symptoms ● warm, red, or painful skin <p>Infusion-related reactions</p>	<p>Call your doctor as soon as possible</p>

Serious side effects	What to do
<p>Some patients may experience reactions related to the infusion of ORENCIA. Most of these reactions are mild to moderate and may include:</p> <ul style="list-style-type: none"> ● dizziness ● headache ● increase in blood pressure <p>In rare cases, infusion-related reactions may be severe and require that you discontinue treatment.</p> <p>Hypersensitivity reactions</p> <p>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:</p> <ul style="list-style-type: none"> ● low blood pressure ● rash 	

Serious side effects	What to do
<ul style="list-style-type: none"> ● shortness of breath <p>Serious hypersensitivity reactions are rarely reported.</p>	

Other side effects - Adults

Other side effects	What to do
<p>Very common</p> <ul style="list-style-type: none"> ● infections of the upper airway (including infections of the nose, throat and sinuses) <p>Common</p> <ul style="list-style-type: none"> ● lower respiratory tract infection, such as bronchitis ● urinary tract infection ● herpes (cold sores) ● pneumonia ● headache, dizziness ● increase in blood pressure ● cough 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Other side effects	What to do
<ul style="list-style-type: none"> ● abdominal pain, diarrhoea, mouth ulcers, nausea or indigestion ● rash, dermatitis ● fatigue, weakness, local injection site reaction (subcutaneous injection only) ● changes to liver function test 	

Other side effects - Children and adolescents (more than 6 years of age)

Other side effects	What to do
<ul style="list-style-type: none"> ● headache ● nausea ● diarrhoea ● cough ● infections of nose and throat ● fever ● upper abdominal pain 	<p>Speak to the doctor if your child has any of these side effects and they worry you.</p>

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 ORENCIA contains

Powder for intravenous infusion only

Active ingredient (main ingredient)	Abatacept (rch)
Other ingredients (inactive ingredients)	maltose, monobasic sodium phosphate and sodium chloride

ORENCIA powder for intravenous infusion does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Solution for injection subcutaneous administration - Adults only

Active ingredient (main ingredient)	Abatacept (rch)
Other ingredients (inactive ingredients)	sucrose, poloxamer, monobasic sodium phosphate, dibasic sodium phosphate and water for injection

ORENCIA solution for injection does not contain maltose.

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

What ORENCIA looks like

Powder for intravenous infusion

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

AUST R 130100

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.

Pre-filled syringe:

AUST R 206764 (with needle guard and flange extender)

AUST R 177174 (with needle guard, not marketed)

AUST R 177176 (with flange extender, not marketed)

Pre-filled autoinjector:

AUST R 236039

Who distributes ORENCIA

Bristol-Myers Squibb Australia Pty Ltd

4 Nexus Court, Mulgrave,

Victoria 3170, Australia.

Toll free number: 1800 067 567

Email: MedInfo.Australia@bms.com

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