

PART III: CONSUMER INFORMATION

Pr ORENCIA®
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-abatacept for injection
Intravenous Infusion, 250 mg / vial

Pr ORENCIA®
abatacept injection

Solution for Subcutaneous Injection, 125 mg / mL This leaflet is Part III of a three-part “Product Monograph” published when ORENCIA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ORENCIA. Contact your doctor or pharmacist if you have any questions about this medication.

Do not use ORENCIA for a condition for which it was not prescribed. Do not give ORENCIA to other people, even if they have the same condition.

ABOUT THIS MEDICATION

ORENCIA is a medicine used to treat rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA)/juvenile rheumatoid arthritis (JRA) and psoriatic arthritis (PsA). It is supplied in vials for intravenous (IV) infusions (given through a needle placed in your arm vein), and in prefilled syringes or ClickJect™ prefilled autoinjectors for subcutaneous (SC) injections [given just under the skin of your abdomen (tummy), arms or legs] with the active ingredient called “abatacept”.

The ORENCIA SC Injection syringe or autoinjector cannot be used for IV infusion.

The ORENCIA vial for IV Infusion cannot be used for SC injections.

ORENCIA is a medicine that keeps the immune system from attacking healthy tissues in the body. The immune system is the body's defense against attack, such as infections by bacteria and viruses. A normal immune system leaves healthy body tissues alone.

In people with RA and PsA, the immune system attacks normal body tissues. This can cause damage and inflammation especially in the tissues of your joints. PsA may be accompanied by psoriasis. Psoriasis is an inflammatory disease that affects the skin and can cause raised, thick, red and scaly patches (“psoriatic skin lesions”) that can appear anywhere on the body. Psoriatic arthritis is usually seen in patients with psoriasis and affects both the joints and the skin.

ORENCIA modifies an important step in this attack. By

decreasing the immune system's attack on normal tissues, ORENCIA can reduce pain, joint inflammation, and damage to your bones and cartilage. ORENCIA may also help you with your daily activities (such as getting dressed, walking and climbing stairs).

However, ORENCIA also can lower your body's ability to fight infection. ORENCIA treatment can make you more prone to getting infections or make any infection you have worse. It is important to tell your doctor if you think you have any infections, like a cold, flu, infected cuts, etc.

ORENCIA is used to treat:

- Adults with moderate to severe rheumatoid arthritis (RA). RA is a disease that causes pain and joint inflammation (tenderness and swelling). RA can also cause joint damage. Your doctor has decided to treat you with ORENCIA because your disease is still active even though you have tried other treatments.
- Children and adolescents with moderately to severely active juvenile idiopathic arthritis (JIA)/juvenile rheumatoid arthritis (JRA) with polyarticular course after one or more JIA/JRA medicines have been used and not worked.
- Adults with active psoriatic arthritis (PsA) who failed to respond to other PsA treatments. In adults, ORENCIA can be used alone or with other PsA treatments.

ORENCIA has not been studied in children under 6 years of age.

When it should not be used:

You should not take ORENCIA if you have:

- ever had an allergic reaction to ORENCIA
- an infection that has spread through your body (sepsis)

What the medicinal ingredient is:

Abatacept.

- Each vial for IV infusion contains 250 mg abatacept.
- Each single-dose disposable prefilled syringe or autoinjector for subcutaneous (SC) administration contains 125 mg of abatacept per 1.0 mL of solution.

What the nonmedicinal ingredients are:

Intravenous formulation - inactive ingredients: Maltose, sodium chloride and sodium phosphate.

Subcutaneous formulation - inactive ingredients: Sucrose, poloxamer 188, monobasic sodium phosphate monohydrate, dibasic sodium phosphate anhydrous, water for injection.

What dosage forms it comes in:

Vials for IV use and single-dose disposable prefilled syringes or autoinjectors for SC administration.

How will ORENCIA be given to me and how often will I receive ORENCIA?

ORENCIA may be administered as an intravenous infusion (IV) or a subcutaneous (SC) injection.

Intravenous Infusion

- ORENCIA will be given to you by a healthcare professional using an IV. This is called an infusion. This means the medicine will be given to you through a needle placed in a vein in your arm. It will take about 30 minutes to give you the full dose of medicine.
- You will receive your first dose of ORENCIA followed by additional doses at 2 and 4 weeks after the first dose. You will then receive a dose every 4 weeks.

Subcutaneous injection

- ORENCIA, as a subcutaneous injection (injected under the skin), is administered every week.
- If you have rheumatoid arthritis, you may start with one IV dose (see above) then you will get weekly SC injections.
- Your first SC dose should be given by your healthcare provider. If your healthcare provider decides that you or a caregiver may be able to give your injections of ORENCIA at home, you should receive training on the right way to prepare and inject ORENCIA. Do not try to inject ORENCIA yourself until you have been shown the right way to give the injections by your healthcare provider. ORENCIA for subcutaneous injection should be injected one time each week.
- See the detailed Patient/Caregiver Instructions for use instructions about the right way to prepare and administer your ORENCIA subcutaneous injections at home.

If you miss your appointment or if you forget to receive your ORENCIA injection, ask your doctor when to schedule your next dose or take your next subcutaneous injection.

WARNINGS AND PRECAUTIONS

Information to know about serious side effects with ORENCIA

Serious infections: There have been some cases where patients receiving ORENCIA, or other RA biologic treatment, have developed serious infections, including tuberculosis (TB) and infections caused by viruses,

bacteria, or fungi.

Malignancies: During the clinical trials, certain kinds of cancer have been reported in patients treated with ORENCIA, these case reports are regarded as uncommon. Lung cancer and cancer of the lymph glands were reported more often in patients treated with ORENCIA than in patients treated with placebo. The current number of reported cancer cases in the ORENCIA studies appears to be consistent with the expected number of cancer cases reported in the RA population. People with more serious RA that have had the disease for a long time may have a higher than average risk of getting a kind of cancer that affects the lymph system, called lymphoma. If you take ORENCIA or other RA biologic treatment, your risk may increase. The role of ORENCIA in the development of cancer is not known.

There have been reports of certain kinds of skin cancer in patients taking ORENCIA. Some patients receiving ORENCIA have developed types of cancer called non-melanoma skin cancer. If any changes in the healing or the appearance of your skin or growths on your skin occur during or after your treatment with ORENCIA, tell your doctor.

Allergic reactions: If you develop a severe rash, chest pain, swollen face or difficulty breathing during or after receiving ORENCIA, call your doctor immediately. The prefilled syringe or autoinjector components do not contain any latex or dry natural rubber.

ORENCIA has not been studied in pregnant women or nursing mothers, so we don't know what the effects are on pregnant women or nursing babies. You should tell your doctor if you are pregnant, or are planning to become pregnant. If you took ORENCIA during pregnancy, talk to your doctor before your baby receives any vaccines.

You can take other medicines with ORENCIA if your doctor has prescribed them or has told you it is okay to take them while you are receiving ORENCIA. It is important to tell your doctor if you are taking any other medicines including hormones, over the counter medicines, vitamins, supplements, or herbal products before you are treated with ORENCIA. If you start taking or plan to start taking any new medicine while you are receiving ORENCIA, tell your doctor.

ORENCIA should not be taken with other biologic medications for RA such as Enbrel®, Humira®, Remicade®, or Kineret®.

Before you receive treatment with ORENCIA you should tell 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

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(such as the flu). Having an infection could put you at risk for serious side effects from ORENCIA. If you are not sure, please ask your doctor.

- Have an infection that won't go away or a history of infections that keep coming back.
- Have had tuberculosis (TB), or if you recently have been in close contact with someone who has had TB. If you develop any of the symptoms of TB (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 TB or perform a skin test.
- Have or have had viral hepatitis. Before you use ORENCIA your doctor may examine you for hepatitis.
- Have diabetes and are using a blood glucose monitor to check your blood glucose levels. ORENCIA for intravenous infusion (given through a needle placed in a vein) contains maltose, which is a type of sugar that can give falsely high blood glucose readings with certain types of blood glucose monitors on the day of ORENCIA infusion. Your doctor may recommend a different method for monitoring your blood glucose levels. ORENCIA for subcutaneous administration (injected under the skin) does not contain maltose; therefore, you do not need to change your glucose monitoring.
- Are scheduled to have surgery.
- Recently received a vaccination or are scheduled for any vaccination. Some vaccines should not be given while you are receiving ORENCIA. If your child is to receive ORENCIA, discuss your child's vaccination history and plans with your doctor. All vaccines should be brought up-to-date before starting ORENCIA and patients taking ORENCIA should not receive live vaccines.
- Have a history of chronic obstructive pulmonary (lung) disease (COPD).
- Are pregnant or are planning to become pregnant. If you took ORENCIA during pregnancy, talk to your doctor before your baby receives any vaccines.
- Are breastfeeding.

If you are not sure or have any questions about any of this information, ask your doctor.

INTERACTIONS WITH THIS MEDICATION

No special studies were done to look at whether ORENCIA interferes with blood levels of common RA medications; nor were they done to look at whether common RA medications interfere with blood levels of ORENCIA. Information from clinical studies so far have not suggested a problem like this.

ORENCIA should not be taken with other biologic medications for RA such as Enbrel®, Humira®,

Remicade®, or Kineret®.

PROPER USE OF THIS MEDICATION

Dose of ORENCIA

INTRAVENOUS INFUSION

Adults

Depending on how much you weigh, you will receive 2 - 4 vials of ORENCIA at a time.

Body Weight of Patient	Dose	Number of Vials ^a
< 60 kg (132 lbs)	500 mg	2
60 to 100 kg (132 - 220 lbs)	750 mg	3
> 100 kg (220 lbs)	1 gram	4

^a Each vial provides 250 mg of abatacept for administration.

Children above 6 years of age

The dose for children who weigh less than 75 kg will be determined by the child's weight. The dose for children weighing 75 kg or more will be determined as outlined above for adults.

SUBCUTANEOUS ADMINISTRATION

Adults

If your first dose of ORENCIA is given IV (through a needle placed in your arm), it will be administered according to your weight then your next doses will be given as an injection under the skin of your abdomen (tummy), arms or legs.

ORENCIA subcutaneous injection (injected under the skin) is administered one time each week as a 125 mg injection (full amount contained in the syringe or autoinjector) regardless of how much you weigh. (See "Patient/Caregiver Instructions" for details.)

Overdose

In case of drug overdose, contact a healthcare practitioner (e.g. doctor), hospital emergency department or regional poison control centre, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines that affect your immune system, ORENCIA can cause side effects, some of which may be

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serious.

The more common side effects with ORENCIA are headache, upper respiratory tract infection, sore throat, and nausea. Infusion related reactions were infrequent during the clinical studies with ORENCIA.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM		
Frequency	Side Effect	
Uncommon [happens to 1 in every 100 to 1000 patients (less than 1%)]	<ul style="list-style-type: none"> ▪ Pneumonia (lung infection) ▪ Cellulitis (skin infection) ▪ Urinary tract infection ▪ Bronchitis (lung infection) ▪ Diverticulitis (infection of large intestine) ▪ Pyelonephritis (kidney infection) 	Talk with your healthcare provider if you have any symptoms of an infection.

This is not a complete list of side effects. If you have any unexpected effects while taking ORENCIA, contact your doctor or pharmacist.

HOW TO STORE IT

Your ORENCIA intravenous vials should be stored under refrigeration (2°C - 8°C) and protected from light. Your healthcare professional will prepare the solution for intravenous (IV) infusion.

Your ORENCIA subcutaneous syringes or autoinjectors should be stored under refrigeration (2°C-8°C) and protected from light. Do not allow the prefilled syringe or autoinjector to freeze and do not use beyond the expiration date on the syringe or autoinjector. If frozen, do not use.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reactions reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

Note: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice

MORE INFORMATION

Pregnancy Registry: To monitor for outcomes of pregnant women exposed to ORENCIA, information is being collected about this. Speak to your healthcare professional for more information.

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting the sponsor, Bristol-Myers Squibb Canada at 1-866-463-6267.

This leaflet was prepared by Bristol-Myers Squibb Canada

Last revised: 9 September 2019

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