

PART III: CONSUMER INFORMATION

PrORENCIA* (abatacept)

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 an intravenous (IV) medicine used to treat rheumatoid arthritis (RA). It is supplied in 15 mL vials containing 250 mg of the active ingredient called “abatacept”; each pack contains 1 vial.

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, the immune system attacks normal body tissues. This can cause damage and inflammation especially in the tissues of your joints. 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.

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 infusion contains 250 mg abatacept.

What the nonmedicinal ingredients are:

Maltose, sodium chloride and sodium phosphate.

What dosage forms it comes in:

Vials for IV use.

How will ORENCIA be given to me?

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.

How often will I receive ORENCIA?

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.

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

IMPORTANT: PLEASE READ

ORENCIA or other RA biologic treatment, your risk may increase. The role of ORENCIA in the development of cancer is not known.

Allergic reactions: If you develop a severe rash, chest pain, swollen face or difficulty breathing during or after receiving ORENCIA, call your doctor immediately. 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.

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 (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 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.
- Are scheduled to have surgery.

Recently received a vaccination or are scheduled for any vaccination. 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.
- 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.

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PROPER USE OF THIS MEDICATION

Dose of ORENCIA in 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.

Dose of ORENCIA in 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.

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 serious.

IMPORTANT: PLEASE READ

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

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345
By toll-free fax: 866-678-6789
Online: www.healthcanada.gc.ca/medeffect
By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:
Canada Vigilance National Office
Marketed Health Products Safety
and Effectiveness Information Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. 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

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