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2. Orencia

# Orencia 🖘

Pronunciation: oh-REN-see-ah Generic name: abatacept

Dosage form: Injectable IV infusion, single-dose prefilled syringe for SC use, single-dose prefilled ClickJect SC autoinjector

Drug classes: Antirheumatics, Selective immunosuppressants

Medically reviewed by Carmen Pope, BPharm. Last updated on Nov 1, 2023.

Uses Warnings Before taking Dosage Side effects Interactions FAQ

# What is Orencia?

Orencia (abatacept) is a type of biologic that is given by intravenous infusion or subcutaneous (under the skin) injection which helps prevent your body's immune system from attacking healthy joints and other tissues and is approved for:

- · adults with moderately to severely active rheumatoid arthritis
- patients aged 2 years and older with moderately to severely active polyarticular juvenile idiopathic arthritis
- patients aged 2 years and older with active psoriatic arthritis
- the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and children aged 2 years and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor.

Orencia works by helping to block T-cell activation in the immune system and belongs to the class of medicines known as selective T-cell costimulation modulators. Blocking T-cell activation interrupts the cycle that can lead to joint inflammation, pain, and destruction in certain forms of arthritis and acute graft versus host disease. T-cells are part of the immune system that helps to protect you from certain infections and cancers. It is not a cure for any autoimmune disorder and will only treat the symptoms of your condition.

Orencia was first FDA-approved on 23 December 2005.

# Warnings

Hypersensitivity reactions, including anaphylaxis, have occurred.

Orencia carries a risk of serious infections. People with a history of recurrent infections or with underlying conditions that predispose them to infections (such as a weakened immune system, COPD, or diabetes) are more at risk. Using Orencia with a TNF antagonist can increase your infection risk.

Your doctor should screen you for viral hepatitis and latent TB infection before starting treatment with Orencia. If you test

positive for TB your doctor will initiate TB treatment.

All your childhood vaccinations and other age-appropriate vaccinations should be up to date before starting Orencia. Live vaccines should not be given concurrently or within 3 months of discontinuation. Orencia may blunt the effectiveness of some immunizations.

The risk of respiratory side effects may be more common in patients with COPD (Chronic Obstructive Pulmonary Disease). There is a risk of cytomegalovirus (CMV) and Epstein-Barr Virus (EBV) reactivation in patients treated for aGVHD prophylaxis.

It is not known if Orencia is safe and effective in children less than two years of age.

# Before taking

You should not use Orencia if you are allergic to Orencia, abatacept, or any of the components of the intravenous or subcutaneous injection.

Before you receive or use Orencia, tell your healthcare provider about all of your medical conditions, including if you have:

- any kind of infection even if it is small (such as an open cut or sore), or an infection that is in your whole body (such as the flu)
- an infection that will not go away, an infection that keeps coming back, or inflammation of your liver due to an infection (viral hepatitis)
- had a lung infection called tuberculosis (TB), a positive skin test for TB, or you recently have been in close contact with someone who has had TB. Symptoms of TB may include:
  - a cough that does not go away
  - o fever
  - · weight loss
  - o night sweats.
- a history of Epstein-Barr Virus (EBV) or Cytomegalovirus (CMV) if you are receiving Orencia for the preventative treatment of aGVHD during HSCT from an unrelated donor
- · been scheduled to have surgery
- · recently received a vaccination or are scheduled for a vaccination
- a history of a breathing problem called chronic obstructive pulmonary disease (COPD)
- have diabetes and use a blood glucose monitor to check your blood sugar (blood glucose) levels
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed.

Some people treated with Orencia have developed skin cancer. Tell your healthcare provider if you have a family or personal history of skin cancer, or if you see any growths or changes in the appearance of your skin during or after treatment.

# Pregnancy and breastfeeding

It is not known if Orencia can harm an unborn baby. If you inadvertently become pregnant while taking Orencia, register with the pregnancy registry by calling 1-877-311-8972. When your baby is born talk to your healthcare provider before your baby receives any vaccines.

It is not known if Orencia passes into breast milk. Talk to your healthcare provider about the best way to feed your baby.

Orencia pregnancy and breastfeeding warnings (more detail)

# **How will I receive Orencia?**

Orencia is usually injected as an infusion into the vein initially, and, depending on your condition, it can be self-administered at home as an injection under the skin. A healthcare provider will give your first dose and may teach you how to properly use the medication by yourself.

# For the treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, and psoriatic arthritis

The first dose of Orencia may be given by a healthcare provider through a vein in your arm (intravenous infusion).

- The infusion takes about 30 minutes.
- The next dose will be 2 weeks later, then 4 weeks after the first dose, and then every 4 weeks thereafter.
- Intravenous administration of Orencia is not approved for pediatric patients with psoriatic arthritis. Orencia is injected under the skin when given to a child between 2 and 6 years old.

You may also receive Orencia as an injection under your skin (subcutaneous).

- For home use, Orencia comes in a prefilled syringe or a prefilled ClickJect autoinjector.
- If you want to self-administer Orencia your healthcare provider will train you or your caregiver on the right way to prepare and inject Orencia. Do not try to inject it until you have been shown the right way to do so.
- Your healthcare provider will advise you of the dose.

# For the preventative treatment of aGVHD

Orencia is given by a healthcare provider through a vein in your arm over 60 minutes on the day before transplantation (Day 1).

- You will then receive ORENCIA on Days 5, 14, and 28 after transplantation.
- Your healthcare provider may give you antiviral medicines before, during, and after your transplantation to help prevent Epstein-Barr Virus (EBV) and Cytomegalovirus (CMV) infections.
- Detailed Orencia dosage information

# What happens if I miss a dose?

Call your doctor for instructions if you miss your Orencia dose.

# What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

# What should I avoid while using Orencia?

Do not receive a "live" vaccine while using Orencia, and for at least 3 months after your treatment ends. The vaccine may not work as well during this time, and may not fully protect you from disease. Live vaccines include measles, mumps, rubella (MMR), rotavirus, typhoid, yellow fever, varicella (chickenpox), zoster (shingles), and nasal flu (influenza) vaccine.

Avoid being near people who are sick or have infections. Tell your doctor at once if you develop signs of infection.

# What are the side effects of Orencia?

Get emergency medical help if you have signs of an allergic reaction to Orencia such as hives; difficulty breathing; or swelling of your face, lips, tongue, or throat.

Some side effects may occur during the injection. Tell your caregiver right away if you feel dizzy, light-headed, itchy, or have a severe headache or trouble breathing within 1 hour after receiving the injection.

Orencia may cause serious side effects, including:

- infections which may be serious or fatal. Call your healthcare provider right away if you have any symptoms of an infection, such as:
  - o fever
  - flu-like symptoms
  - feeling very tired
  - o warm, red, or painful skin
  - a cough
  - pain, or burning when you urinate.
- hepatitis B infection in people who carry the virus in their blood. Your healthcare provider may do a blood test before you start treatment
- breathing problems in people with Chronic Obstructive Pulmonary Disease (COPD). You may get certain respiratory
  problems more often if you receive ORENCIA and have COPD. Symptoms of respiratory problems include COPD
  that becomes worse, difficulty breathing, or a cough
- cancer (malignancies). Certain kinds of cancer have been reported in people using Orencia, including skin cancers. It is not known if Orencia increases your chance of getting cancer
- Cytomegalovirus (CMV) and Epstein-Barr Virus (EBV) infections in people receiving preventative treatment of aGVHD during unrelated HSCT. Your healthcare provider will monitor you for 6 months after transplantation and may treat you with medicines to help prevent CMV and EBV infection if needed.

The most common side effects of Orencia include:

headache

- · sore throat
- upper respiratory tract infection
- nausea.

In children and adolescents, other side effects may include:

- diarrhea
- fever
- cough
- · abdominal pain.

The most common side effects of Orencia in the prevention of aGVHD include:

- · low red blood cell count
- nosebleeds
- · high blood pressure
- decreased CD4 lymphocytes
- CMV infection
- · increased levels of magnesium in the blood
- fever
- · kidney problems
- pneumonia.

These are not all the possible side effects of Orencia. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Orencia side effects (more detail)

# Related/similar drugs

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Naproxen is a nonsteroidal antiinflammatory drug used to treat pain or inflammation caused by ...

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# What other drugs will affect Orencia?

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Orencia may affect the way other medicines work, and other medicines may affect the way it works causing serious side effects.

You may have a higher chance of getting a serious infection if you take ORENCIA with other biologic medicines that may affect your immune system. Especially tell your healthcare provider if you take other biologic medicines that may affect your immune system, such as:

- adalimumab
- anakinra
- certolizumab
- etanercept
- golimumab
- infliximab
- rituximab
- · tocilizumab.

Orencia can cause false results with certain blood glucose tests, showing high blood sugar readings. If you have diabetes, talk to your doctor about the best way to test your blood sugar.

Orencia for intravenous infusion contains maltose, a type of sugar, that can give false high blood sugar readings with certain types of blood glucose monitors on the day of the infusion. Your healthcare provider may tell you to use a different way to monitor your blood sugar levels. Orencia for subcutaneous injection does not contain maltose.

This list is not complete. Other drugs may interact with abatacept, including prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible drug interactions are listed here.

① Orencia drug interactions (more detail)

# Does Orencia interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

Orencia	
+	
Enter a drug name	Add

# **Storage**

Store in the refrigerator at 36°F to 46°F (2°C to 8°C) in its original package (protected from light). Do not freeze.

The prefilled syringe or autoinjector can be left out of the refrigerator for up to 6 hours (without light protection) if the temperature remains between 46°F to 77°F (8°C to 25°C).

# Ingredients

Active: abatacept.

Intravenous, inactive: maltose, monobasic sodium phosphate, sodium chloride for administration.

**Subcutaneous, inactive**: sucrose, poloxamer 188, monobasic sodium phosphate monohydrate, dibasic sodium phosphate anhydrous, water for injection.

# **Manufacturer**

Bristol-Myers Squibb Company.

# **Orencia Biosimilars**

Biosimilar and interchangeable products are biological products that are highly similar to and have no clinically meaningful differences from the reference product.

# Reference products

These are biological products that have already been approved by the FDA, against which biosimilar products are compared. There is 1 for Orencia.

#### Orencia (abatacept) - Bristol-Myers Squibb Company

Formulation type	Strength
Autoinjector	125 mg/mL
Pre-Filled Syringe	125 mg/mL
Pre-Filled Syringe	50 mg/0.4 mL
Pre-Filled Syringe	87.5 mg/0.7 mL
Single-Dose Vial	250 mg

# Popular FAQ

How long can Orencia be out of the fridge?

How long does Orencia stay in your system?

Does Orencia cause weight gain?	~
How long does it take for Orencia to start working?	~
How does Orencia work?	~
Is Orencia a biologic?	~

# **More FAQ**

• What are the new drugs for rheumatoid arthritis (RA)?

#### References

1. Product Label

# More about Orencia (abatacept)

- · Check interactions
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- Patient tips
- During pregnancy
- FDA approval history
- Drug class: antirheumatics
- Breastfeeding
- En español

# **Patient resources**

• Orencia (Abatacept Infusion) patient information

# **Professional resources**

- Orencia prescribing information
- Abatacept (AHFS Monograph)

# Related treatment guides

- Rheumatoid Arthritis
- Psoriatic Arthritis
- Graft Versus Host Disease Prophylaxis
- Polyarticular Juvenile Idiopathic Arthritis

# **Further information**

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

#### **DRUG STATUS**

#### **Availability**

Rx Prescription only

# **Pregnancy & Lactation**

ঝ্ Risk data available

**CSA Schedule\*** 

N/A Not a controlled drug

**Approval History** 

10+ years FDA approved 2005

# **User Reviews & Ratings**

6.0 / 10

71 Reviews

### **Images**

Orencia 125 mg/mL ClickJect autoinjector



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