

Package leaflet: Information for the patient
ORENCIA 125 mg solution for injection in pre-filled pen
abatacept

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What ORENCIA is and what it is used for
2. What you need to know before you use ORENCIA
3. How to use ORENCIA
4. Possible side effects
5. How to store ORENCIA
6. Contents of the pack and other information

1. What ORENCIA is and what it is used for

ORENCIA contains the active substance abatacept, a protein produced in cell cultures. ORENCIA lessens the immune system's attack on normal tissues by interfering with the immune cells (called T lymphocytes) that contribute to the development of rheumatoid arthritis. ORENCIA selectively modulates the activation of T cells involved in the immune system's inflammatory response.

ORENCIA is used to treat rheumatoid arthritis and psoriatic arthritis in adults.

Rheumatoid Arthritis

Rheumatoid arthritis is a long-term progressive systemic disease that, if untreated, can lead to serious consequences, such as joint destruction, increased disability and impairment of daily activities. In people with rheumatoid arthritis the body's own immune system attacks normal body tissues, leading to pain and swelling of the joints. This can cause joint damage. Rheumatoid arthritis (RA) affects everyone differently. In most people, joint symptoms develop gradually over several years. However, in some, RA may progress rapidly and yet other people may have RA for a limited period of time and then enter a period of remission. RA is usually a chronic (long-term), progressive disease. This means, even if you're on treatment, whether or not you're still having symptoms, RA could be continuing to damage your joints. By finding the right treatment plan for you, you may be able to slow down this disease process, which may help reduce long-term joint damage, as well as pain and fatigue and improve your overall quality of life.

ORENCIA is used to treat moderate to severe active rheumatoid arthritis when you do not respond well enough to treatment with other disease-modifying medicines or with another group of medicines called 'tumour necrosis factor (TNF) blockers'. It is used in combination with a medicine called methotrexate.

ORENCIA can also be used with methotrexate to treat highly active and progressive rheumatoid arthritis without previous methotrexate treatment.

ORENCIA is used to:

- slow down the damage to your joints
- improve your physical function

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 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.

ORENCIA is used to treat psoriatic arthritis alone or in combination with methotrexate

2. What you need to know before you use ORENCIA

Do not use ORENCIA

- **if you are allergic** to abatacept or any of the other ingredients of this medicine (listed in section 6).
- **if you have a severe or uncontrolled infection**, do not start treatment with ORENCIA. Having an infection could put you at risk of serious side effects from ORENCIA.

Warnings and precautions

Talk to your doctor, pharmacist or nurse:

- **if you experience allergic reactions** such as chest tightness, wheezing, severe dizziness or lightheadedness, swelling or skin rash **tell your doctor immediately**.
- **if you have any kind of infection**, including long-term or localised infection, if you often get infections or **if you have symptoms of infection (e.g. fever, malaise, dental problems), it is important to tell your doctor**. ORENCIA can lower your body's ability to fight infection and the treatment can make you more likely to get infections or make any infection you have worse.
- **if you have had tuberculosis (TB)** or have symptoms of tuberculosis (persistent cough, weight loss, listlessness, mild fever) **tell your doctor**. Before you use ORENCIA, your doctor will examine you for tuberculosis or do a skin test.
- **if you have viral hepatitis** tell your doctor. Before you use ORENCIA, your doctor may examine you for hepatitis.
- **if you have cancer**, your doctor will decide if you can still be given ORENCIA.
- **if you recently had a vaccination** or are planning to have one, **tell your doctor**. Some vaccines should not be given while you are receiving ORENCIA. **Check with your doctor before you are given any vaccines**. Certain vaccinations may cause infections from the vaccine. If you received ORENCIA while you were pregnant, your baby may be at a higher risk for getting such an infection for up to approximately 14 weeks after the last dose you received during pregnancy. It is important that you tell your baby's doctors and other health care professionals about your ORENCIA use during your pregnancy so they can decide when your baby should receive any vaccine.

Your doctor may also do tests to examine your blood values.

Children and adolescents

ORENCIA solution for injection in pre-filled pen has not been studied in children and adolescents under the age of 18 years. Therefore, ORENCIA solution for injection in pre-filled pen is not recommended for use in this patient population.

ORENCIA powder for concentrate for solution for infusion is available for paediatric patients 6 years of age and older.

ORENCIA solution for injection pre-filled syringe is available for paediatric patients 2 years of age and older.

Other medicines and ORENCIA

Tell your doctor if you are taking, have recently taken or might take any other medicines.

ORENCIA should not be used with biological medicines for rheumatoid arthritis, including TNF-blockers like adalimumab, etanercept, and infliximab; there is not enough evidence to recommend its being given with anakinra and rituximab.

ORENCIA can be used with other medicines commonly used to treat rheumatoid arthritis, such as steroids or painkillers, including non-steroidal anti-inflammatories such as ibuprofen or diclofenac. Ask your doctor or pharmacist for advice before taking any other medicine while using ORENCIA.

Pregnancy and breast-feeding

The effects of ORENCIA in pregnancy are not known, so do not use ORENCIA if you are pregnant unless your doctor specifically recommends it.

- if you are a woman who could become pregnant, you must use reliable contraception (birth control) while using ORENCIA and up to 14 weeks after the last dose. Your doctor will advise you on suitable methods.
- if you become pregnant while using ORENCIA, tell your doctor.
- If you received ORENCIA during your pregnancy, your baby may have a higher risk for getting an infection. It is important that you tell your baby's doctors and other health care professionals about your ORENCIA use during your pregnancy before the baby receives any vaccine (for more information see section on vaccination).

It is not known whether ORENCIA passes into human milk. **You must stop breast-feeding** if you are being treated with ORENCIA and for up to 14 weeks after the last dose.

Driving and using machines

The use of ORENCIA is not expected to affect the ability to drive or use machines. However, if you are feeling tired or unwell after receiving ORENCIA, you should not drive or operate any machinery.

ORENCIA contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to use ORENCIA

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

ORENCIA solution for injection is injected under the skin (subcutaneous use).

Recommended dose

The recommended dose of ORENCIA for adults with rheumatoid arthritis or psoriatic arthritis is 125 mg abatacept given every week regardless of weight.

Your doctor may start your ORENCIA treatment with or without a one-time dose of powder for concentrate for solution for infusion (given to you into a vein, usually in your arm, over a period of 30 minutes). If a single intravenous dose is given to start the treatment, the first subcutaneous injection of ORENCIA should be given within a day of the intravenous infusion, followed by the weekly 125 mg subcutaneous injections.

ORENCIA can be used by adults over 65 with no change in dose.

If you are already on intravenous ORENCIA treatment and wish to transition to ORENCIA subcutaneous, you should receive a subcutaneous injection instead of your next intravenous infusion, followed by weekly subcutaneous injections of ORENCIA.

Your doctor will advise you on the duration of treatment and what other medicines, including other disease-modifying medicines, if any, you may continue to take while on ORENCIA.

At the start, your doctor or nurse may inject ORENCIA. However, you and your doctor may decide that you can inject ORENCIA yourself. In this case, you will get training on how to inject ORENCIA yourself.

Talk to your doctor if you have any questions about giving yourself an injection. You will find detailed instructions for the preparation and administration of ORENCIA at the end of this leaflet (see "**Important instructions for use**").

If you use more ORENCIA than you should

If this happens, contact immediately your doctor who will monitor you for any signs or symptoms of side effects, and treat these symptoms if necessary.

If you forget to use ORENCIA

Keep track of your next dose. It is very important to use ORENCIA exactly as prescribed by your doctor. If you miss your dose within three days of when you are supposed to take it, take your dose as soon as you remember and then follow your original dosing schedule on your chosen day. If you miss your dose by more than three days, ask your doctor when to take your next dose.

If you stop using ORENCIA

The decision to stop using ORENCIA should be discussed with your doctor.

If you have any further questions on the use of this medicine, **ask your doctor, pharmacist or nurse.**

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The most common side effects with ORENCIA are infections of the upper airway (including infections of the nose and throat), headache and nausea, as listed below. ORENCIA can cause serious side effects, which may need treatment.

Possible serious side effects include serious infections, malignancies (cancer) and allergic reactions, as listed below.

Tell your doctor immediately if you notice any of the following:

- severe rash, hives or other signs of allergic reaction
- swollen face, hands or feet
- trouble breathing or swallowing
- fever, persistent cough, weight loss, listlessness

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

- feeling generally unwell, dental problems, burning sensation during urination, painful skin rash, painful skin blisters, coughing

The symptoms described above can be signs of the side effects listed below, all of which have been observed with ORENCIA in adult clinical trials:

List of side effects:

Very common (may affect more than 1 in 10 people):

- infections of the upper airway (including infections of the nose, throat and sinuses).

Common (may affect up to 1 in 10 people):

- infections of lungs, urinary infections, painful skin blisters (herpes), flu
- headache, dizziness

- high blood pressure
- cough
- abdominal pain, diarrhoea, nausea, upset stomach, mouth sores, vomiting
- rash
- fatigue, weakness, injection site reactions
- abnormal liver function tests.

Uncommon (may affect up to 1 in 100 people):

- tooth infection, nail fungal infection, infection in the muscles, blood stream infection, collection of pus under the skin, kidney infection, ear infection
- low white blood cells count
- skin cancer, skin warts
- low blood platelet count
- allergic reactions
- depression, anxiety, sleep disturbance
- migraine
- numbness
- dry eye, reduced vision
- eye inflammation
- palpitation, rapid heart rate, low heart rate
- low blood pressure, hot flush, blood vessels inflammation, flushing
- difficulty in breathing, wheezing, shortness of breath, acute worsening of a lung disease called chronic obstructive pulmonary disease (COPD)
- throat tightness
- rhinitis
- increased tendency to bruise, dry skin, psoriasis, skin redness, excessive sweating, acne
- hair loss, itching, hives
- painful joints
- pain in the extremities
- absence of menstruation, excessive menses
- flu-like illness, increased weight

Rare (may affect up to 1 in 1,000 people):

- tuberculosis
- inflammation of uterus, fallopian tubes and/or ovaries
- gastrointestinal infection
- cancer of white blood cells, lung cancer

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store ORENCIA

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C). Do not freeze.

Store in the original package in order to protect from light.

Do not use this medicine if the liquid is cloudy or discoloured, or has large particles. The liquid should be clear to pale yellow.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What ORENCIA contains

- The active substance is abatacept.
- Each pre-filled pen contains 125 mg of abatacept in one mL.

- The other ingredients are sucrose, poloxamer 188, sodium dihydrogen phosphate monohydrate, disodium phosphate anhydrous, and water for injections (see section 2 "ORENCIA contains sodium").

What ORENCIA looks like and contents of the pack

ORENCIA solution for injection (injection) is a clear, colourless to pale yellow solution provided in a pre-filled pen called ClickJect.

ORENCIA is available in the following presentations:

- pack of 4 pre-filled pens and multipack containing 12 pre-filled pens (3 packs of 4).

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Bristol-Myers Squibb Pharma EEIG
Plaza 254
Blanchardstown Corporate Park 2
Dublin 15, D15 T867
Ireland

Manufacturer

Swords Laboratories Unlimited Company t/a Bristol-Myers Squibb Cruiserath Biologics
Cruiserath Road, Mulhuddart
Dublin 15
Ireland

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Important instructions for use. Read carefully.

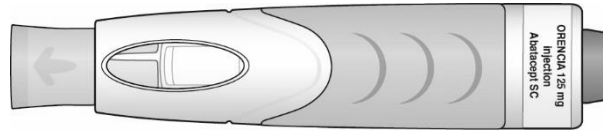
HOW TO USE

ORENCIA (abatacept)

ClickJect Pre-filled Pen

125 mg, solution for injection

subcutaneous use



Read these instructions before you use the ClickJect Pre-filled Pen.

Before you use the ClickJect Pen for the first time, make sure your healthcare provider shows you the right way to use it.

Keep the pen refrigerated until ready to use. **DO NOT FREEZE.**

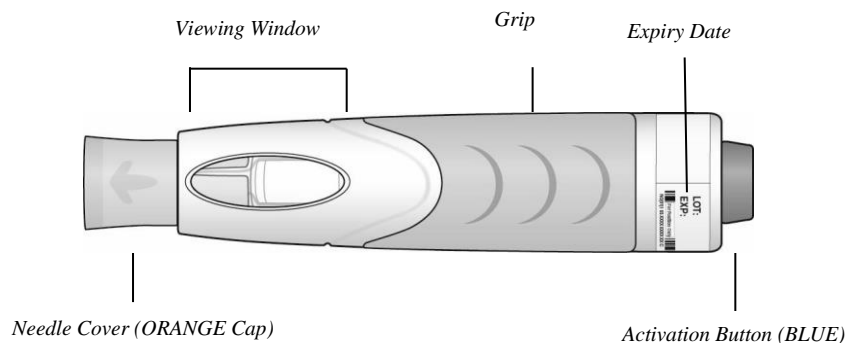
If you have questions about this product, please read the Package Leaflet.

BEFORE YOU BEGIN

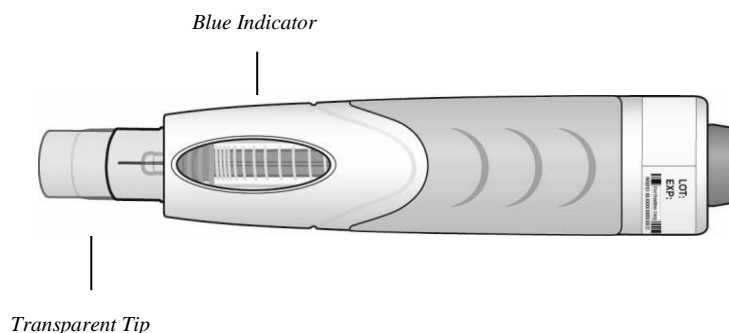
Get to know the ClickJect Pre-filled Pen

- The Pen automatically delivers the medicine. The transparent tip locks over the needle once the injection is complete and the Pen is removed from the skin.
- **DO NOT remove the orange needle cover until you are ready to inject.**

Before Use



After Use



Gather supplies for your injection on a clean, flat surface

(only the ClickJect Pre-filled Pen is included in the package):

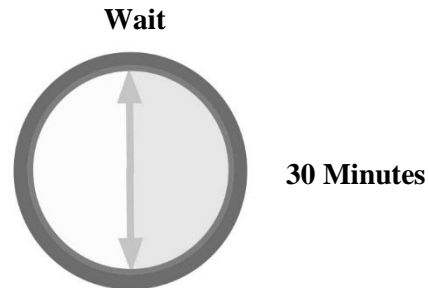
- Alcohol swab
- Adhesive plaster
- Cotton ball or gauze
- ClickJect Pre-filled Pen
- Sharps disposal container

Proceed to Step 1

1. PREPARE YOUR CLICKJECT PEN

Let your ClickJect Pen warm up.

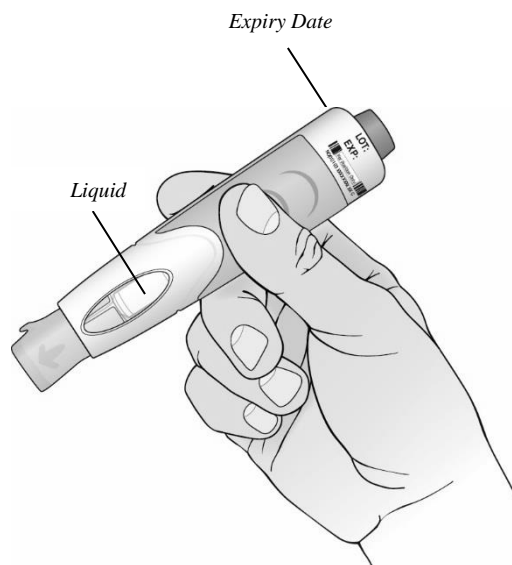
Remove one Pen from the refrigerator and let it rest at room temperature (about 25°C) for **30 minutes**. **DO NOT** remove the needle cover from the Pen while allowing it to reach room temperature.



Wash your hands well with soap and water to prepare for injection.

Examine the ClickJect Pre-filled Pen:

- **Check the expiry date** printed on the label. **DO NOT** use if past the expiry date.
- **Check the Pen for damage.** **DO NOT** use if it is cracked or broken.
- **Check the liquid** through the viewing window. It should be clear to pale yellow. You may see a small air bubble. You do not need to remove it. **DO NOT inject** if the liquid is cloudy, discoloured or has visible particles.



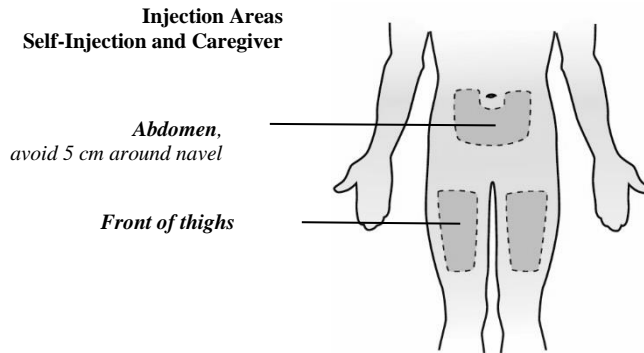
Proceed to Step 2

2. PREPARE FOR INJECTION

Choose your injection site in either the **abdomen** or front of the **thigh**.

Each week you can use the same area of your body, but use a different injection site in that area.

DO NOT inject into an area where the skin is tender, bruised, red, scaly, or hard. Avoid any areas with scars or stretch marks.

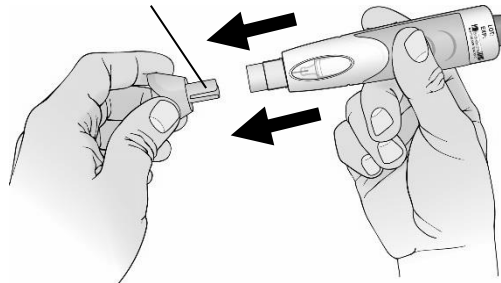


Gently clean injection site with an alcohol swab and let your skin dry.

Pull orange needle cover STRAIGHT off.

- **DO NOT** twist the needle cover.
- **DO NOT** replace the cap on the Pen.
You can discard the cap in your household waste after the injection.
- **DO NOT** use the Pen if it is dropped after the cap is removed.
It's normal to see a drop of fluid leaving the needle.

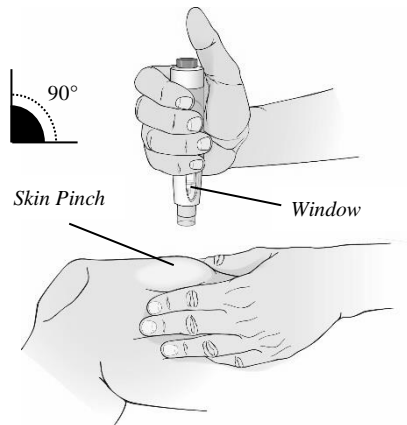
Pull Needle Cover Straight Off



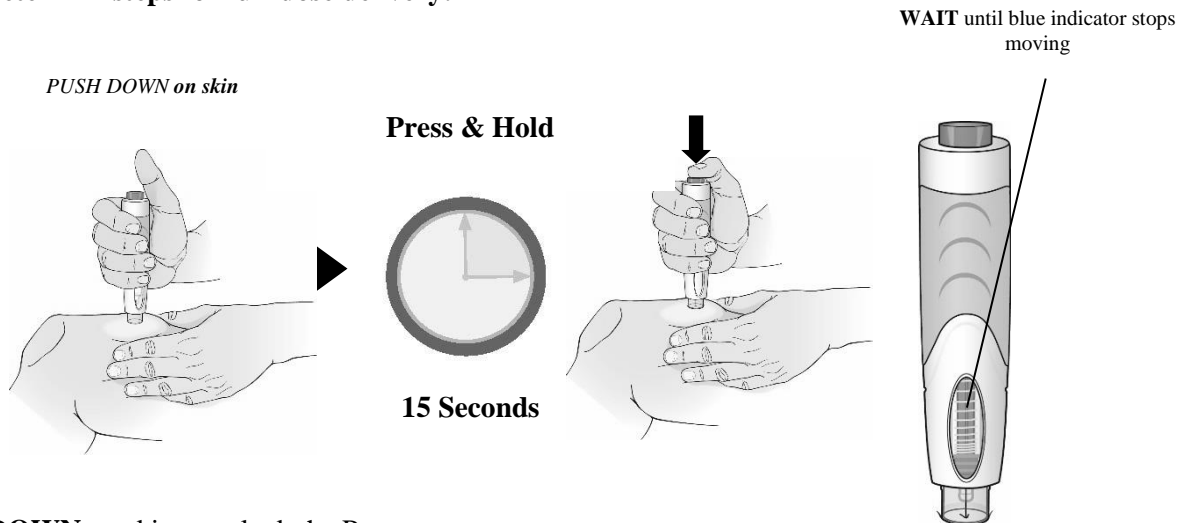
Proceed to Step 3

3. INJECT YOUR DOSE

Position the ClickJect Pen so you can see the **viewing window** and it's at a 90° angle to the injection site. With your other hand, gently **pinch the cleaned skin**.



Complete ALL steps for full-dose delivery:



Push DOWN on skin to unlock the Pen.

Press button, HOLD for 15 seconds AND watch window.

- You will hear a click as the injection begins.
- For full-dose delivery, hold the Pre-filled Pen in place for 15 seconds AND wait until blue indicator stops moving in window.

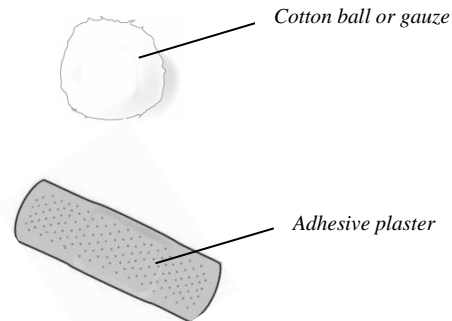
Remove the ClickJect Pre-filled Pen from the injection site by lifting it straight up. Once you remove it from your skin, the transparent tip will lock over the needle. Release skin pinch.

Proceed to Step 4

4. AFTER THE INJECTION

Care of injection site:

- There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site.
- **DO NOT** rub the injection site.
- If needed, you may cover the injection site with a small adhesive plaster.



Dispose of used ClickJect Pre-filled Pen into sharps disposal container right away after use. Should you have any questions, ask your pharmacist.

- **DO NOT** replace the cap on the used Pen.

See Package Leaflet for additional disposal information.

If your injection is administered by a caregiver, this person must also handle the Pen carefully to prevent accidental needle stick injury and possibly spreading infection.

Keep Pen and the disposal container out of the reach of children.

Record the date, time and site where you injected.