

ORENCIA AND YOU

Support for your rheumatoid arthritis

For patients prescribed ORENCIA for subcutaneous injection (ClickJect Autoinjector or safety syringe)



FOR ASSISTANCE OR SUPPORT



Please call BMS Medical Information
on **1800 067 567***

*Available Monday to Friday, 9 am to 5 pm (AEST),
excluding Victorian public holidays.

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Infections: ORENCIA increases the risk of getting infections.

- You must not be treated with ORENCIA if you have a severe infection.
- 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.

Tuberculosis (TB): You should be screened for TB prior to ORENCIA treatment. It is very important that you tell your doctor if you have ever had TB, or if you have been in close contact with someone who has had TB.

Hepatitis: Anti-rheumatic therapies have been associated with hepatitis B reactivation. You should be screened for viral hepatitis in accordance with published guidelines.

Allergic Reactions: Allergic reactions may occur after the use of ORENCIA. If you experience symptoms such as chest tightness, wheezing, severe dizziness, or light-headedness, seek medical attention immediately.

Use in Pregnancy: ORENCIA should not be used in pregnant women unless clearly necessary. If you have received ORENCIA while you were pregnant, it is important that you inform the baby's health care personnel 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.

ORENCIA AND YOU

You have been given this booklet because you have been prescribed ORENCIA (abatacept) as a subcutaneous injection (ClickJect Autoinjector or safety syringe) to treat rheumatoid arthritis

This booklet explains how ORENCIA works and how to take ORENCIA

You should also consult the Instructions for Use, provided inside your pack of ORENCIA

You should consult the Consumer Medicine Information which can be obtained from your pharmacist

It is important to continue taking your methotrexate to get the maximum benefit from ORENCIA

Information in this booklet does not replace advice provided by your healthcare team. Please ask your doctor if you have any questions about your treatment or condition



Patient's name: _____

Start date of ORENCIA treatment: _____

Doctor's name: _____

Doctor's phone number: _____

Keep this card with you for 3 months after the last ORENCIA dose, since side effects may occur a long time after your last dose of ORENCIA.

ORENCIA® is a registered trademark of Bristol-Myers Squibb Company, Bristol-Myers Squibb Australia Pty Ltd, 4 Nexus Court, Mulgrave VIC 3170, Australia. Date of preparation: October 2019, 427/AU1905234-15, BMRB15820W, Ward6.



PATIENT ALERT CARD

This alert card contains some of the important safety information that you need to be aware of before you are given ORENCIA and during treatment with ORENCIA. Show this card to any doctor involved in your treatment.

Please open and read both sides of this card for more important safety information.

For more safety information, please read the ORENCIA® package leaflet. Further information is also included in the Consumer Medicine Information, which is available from your pharmacist. Please make sure you also have a list of all your other medicines with you at any visit to a health care professional.

ORENCIA SUPPORT

Resources to help you when you start ORENCIA:

- ORENCIA patient booklet and alert card
- ORENCIA GP Guide
- Subcutaneous self-injection video
- Complimentary sharps container and replacement
- ORENCIA Travel Cool Bag*

*Maximum of one bag.



Access these resources online at:

bms.com/au/gated/OrenciaGO.html

or scan the QR code

password: BMSG0



ABOUT ORENCIA

ORENCIA contains abatacept; a medicine used for the treatment of rheumatoid arthritis (RA).

You may be given ORENCIA and methotrexate to:¹

- Reduce pain and joint inflammation caused by RA
- Slow down the damage to your bones and joints
- Improve your physical function and your ability to do normal daily activities

Why has my doctor prescribed me ORENCIA?

Your doctor has decided to treat you with ORENCIA and methotrexate because your RA is still active and you are not responding well enough to other treatments.

How does ORENCIA work?

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 infections caused by bacteria and viruses. Normally, the immune system leaves healthy body tissues alone. In adults with RA, 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 process, decreasing the immune system's attack on healthy tissues.¹

FREQUENTLY ASKED QUESTIONS



Who should NOT take ORENCIA?

You should not receive ORENCIA if you are allergic to any of the substances contained in ORENCIA or have a severe infection, including tuberculosis (TB).

What should I tell my doctor before taking ORENCIA?

Before taking ORENCIA you should tell your doctor if you:¹

- Have allergies to any other medicines or any other substances, such as foods, preservatives or dyes
- Are pregnant or are planning to become pregnant
- Are breastfeeding
- Have any kind of infection, even if it's only mild. If you think you might have an infection, talk to your doctor
- Have an infection that won't go away or a history of infections that keep coming back
- Have had TB, or have recently been in close contact with someone who has TB
- Have diabetes and use a blood glucose monitor to check your blood glucose levels
- Are on a diet that restricts your sodium (salt) intake
- Are scheduled to have surgery

continued over

- Recently received a vaccination or are scheduled for a 'live' vaccination, e.g. vaccines for chicken pox, measles, mumps and rubella. **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
- Have chronic obstructive pulmonary (lung) disease (COPD). This is also known as chronic bronchitis or emphysema
- Have multiple sclerosis
- Are a carrier of the hepatitis B virus (HBV), have active HBV or if you think you might be at risk of contracting HBV

If you are not sure if any of the above applies to you or you have any questions about the information provided, please ask your doctor.

Can I take other medicines with ORENCIA?

You can take other medicines with ORENCIA if your doctor has prescribed them or has told you that it is OK to take them while you are receiving ORENCIA.

It is very important to continue taking your methotrexate to get the maximum benefit from ORENCIA.

ORENCIA should not be taken with some other medicines given for RA such as Actemra® (tocilizumab), Enbrel® (etanercept), Humira® (adalimumab), Olumiant® (baricitinib) or Xeljanz® (tofacitinib citrate).

It is important to tell your doctor if you are taking any other medicines, even if they are not listed in this booklet, over-the-counter, pharmacy medicines, vitamins, supplements or herbal products, before you are treated with ORENCIA.¹

If you start taking, or plan to start taking, any new medicine while you are receiving ORENCIA, you should tell your doctor, dentist or pharmacist.

What are the possible side effects of ORENCIA?

Like other medicines, ORENCIA may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. The most common side effects experienced with ORENCIA include:¹

- Lower respiratory tract infection, such as bronchitis
- Urinary tract infection
- Herpes (cold sores)
- Pneumonia
- Upper respiratory tract infection such as sore throat, runny or blocked nose
- Headache, dizziness
- Increase in blood pressure
- Cough
- Abdominal pain, diarrhoea, mouth ulcers, nausea or indigestion
- Rash, dermatitis
- Fatigue, weakness, local injection site reactions (subcutaneous injection only)
- Changes to liver function test

This is not a complete list of side effects. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

How do I know if I'm having an allergic reaction to ORENCIA?

Symptoms of an allergic reaction may be:¹

- 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
- Chills, fever, fast heart beat, dizziness
- Flushing, sweating

If you develop these symptoms during or after receiving ORENCIA, you may be having an allergic reaction. You should call your doctor immediately or go to the Emergency Department at your nearest hospital.

Is ORENCIA safe during pregnancy and breastfeeding?

ORENCIA has not been studied in pregnant women or nursing mothers, so the effects of ORENCIA are not known in pregnant women and nursing babies. You should tell your doctor if you are pregnant, breastfeeding or planning to become pregnant.¹



HOW TO SELF-INJECT ORENCIA¹

We know it takes time to get comfortable with self-injecting, even if your doctor or nurse did a great job training you. Some tips and instructions are included in this section to help you get used to self-injecting ORENCIA.

You can also watch a video on how to self-inject ORENCIA using the ClickJect Autoinjector and safety syringe. The videos can be accessed at:

 bms.com/au/gated/OrenciaGO.html
or scan the QR code
password: BMSG0



Two self-injection devices

ORENCIA may be injected under the skin using one of the following prefilled devices:



ClickJect Autoinjector

Turn to page 15 for more information on using the ClickJect Autoinjector.



Safety syringe

Turn to page 24 for more information on using the safety syringe.

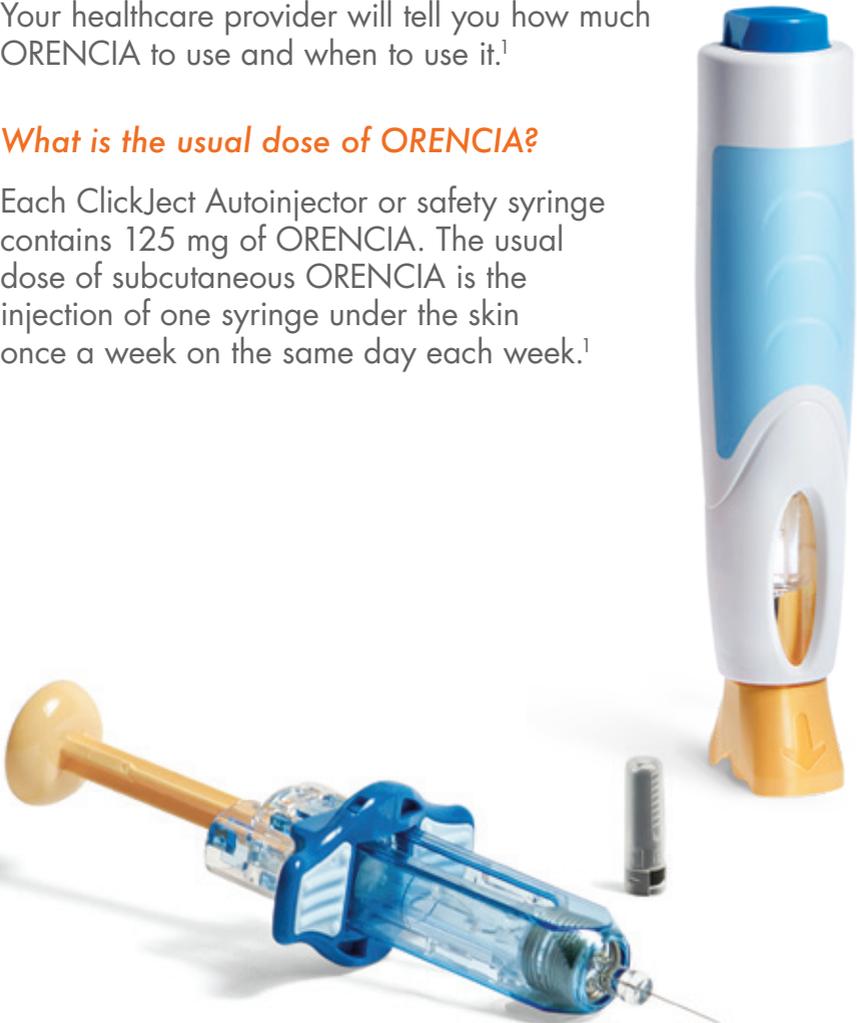
How will I take ORENCIA?

ORENCIA is available in two prefilled, self-injection devices (ClickJect Autoinjector or safety syringe), both of which are given as a weekly injection under the skin. Your healthcare provider will discuss with you which option is best for you and provide training on the right way to prepare and inject ORENCIA. Do not try to inject ORENCIA until you have been shown the right way to give yourself an injection.¹

Your healthcare provider will tell you how much ORENCIA to use and when to use it.¹

What is the usual dose of ORENCIA?

Each ClickJect Autoinjector or safety syringe contains 125 mg of ORENCIA. The usual dose of subcutaneous ORENCIA is the injection of one syringe under the skin once a week on the same day each week.¹



What should I do if I forget to take a dose?

If you forget to take a dose, contact your doctor or pharmacist.

Is it normal to feel burning or pain during injection?

When giving yourself an injection, you may feel a prick from the needle. Sometimes, the medicine can cause slight irritation near the injection site. If this happens the discomfort should be mild to moderate. If you have any side effects, including pain, swelling or discolouration near the injection site, contact your doctor, nurse or pharmacist immediately.

Learning to inject

Both injection devices are designed for easy use by you or your caregiver. It is important to use ORENCIA as directed by your doctor. Ask them to show you how to use your prescribed device correctly.

How to store your ORENCIA

Store your ORENCIA in the fridge (between 2°C to 8°C) when you get home. Do not store in the freezer. Protect from light.

Call Bristol-Myers Squibb Australia Medical Information on 1800 067 567 if you think your ORENCIA may have been exposed to conditions below 2°C or above 8°C.

Travelling with ORENCIA on board an aircraft²

Generally, you will be allowed to carry your ORENCIA prefilled ClickJect Autoinjector and safety syringe onto an aeroplane. Be sure to carry your ClickJect Autoinjector or safety syringe in your carry-on or hand luggage. Do not pack it in your checked baggage.

ORENCIA should be stored at a temperature of 2°C to 8°C until you are ready to use. Do not freeze it.

The ORENCIA Travel Cool Bag can be used to store two doses of ORENCIA. When used according to the instructions provided, the Travel Cool Bag will keep your ORENCIA between a temperature of 2°C to 8°C for a period of 6 hours at a room temperature of 20°C to 25°C. The ORENCIA Travel Cool Bag can be requested online and includes an 'ORENCIA On-The-Go Guide' with detailed instructions on how to travel with ORENCIA. Order it at:

 bms.com/au/gated/OrenciaGO.html

or scan the QR code

password: BMSGO



Please refrigerate your ORENCIA ClickJect Autoinjector or safety syringe as soon as you reach your destination.

Airport security procedures and airline policies change from time to time, so it's best to check with airport authorities and the airline for any special rules.

Before you travel, ask your doctor to provide you with a letter explaining that you are traveling with prescription medicine that uses a device with a needle; if you are carrying a sharps container in your carry-on baggage, notify the screener at the airport.

POINTS TO REMEMBER WHEN YOU SELF-INJECT

DOs

✓	Inject ORENCIA subcutaneously <u>once a week</u> , on the same day each week, as prescribed by your doctor
✓	Store your ORENCIA ClickJect Autoinjector or safety syringe in the refrigerator between 2°C to 8°C (not in the freezer)
✓	Keep your ORENCIA out of sunlight
✓	Take your ORENCIA out of the fridge 30 minutes before you inject <ul style="list-style-type: none">• Let it reach room temperature slowly
✓	Leave the needle cover on until you're ready to inject
✓	Follow the instructions for use in this book
✓	Double-check the expiry date and the colour of the liquid before injecting
✓	Use the provided sharps container to dispose of your ORENCIA ClickJect Autoinjector or safety syringe
✓	Keep a record of your injections. Contact your doctor or pharmacist if you miss an ORENCIA dose.



DON'Ts

✘	Don't self-inject ORENCIA if you are not feeling well <ul style="list-style-type: none">• If you have any symptoms such as high temperature, headache, body aches, runny nose, sore throat or upset stomach, call your doctor
✘	Don't self-inject if the expiry date of your ORENCIA ClickJect Autoinjector or safety syringe has passed
✘	Don't self-inject if the liquid inside the ClickJect Autoinjector or safety syringe is cloudy, is any colour other than clear to pale yellow, or has visible particles
✘	Don't twist the needle cover off the ClickJect Autoinjector; pull it straight off instead
✘	Don't try to put the cap back on the ClickJect Autoinjector or safety syringe after injecting – put them straight into a sharps container
✘	Don't dispose of the ClickJect Autoinjector or safety syringe in your normal household bin

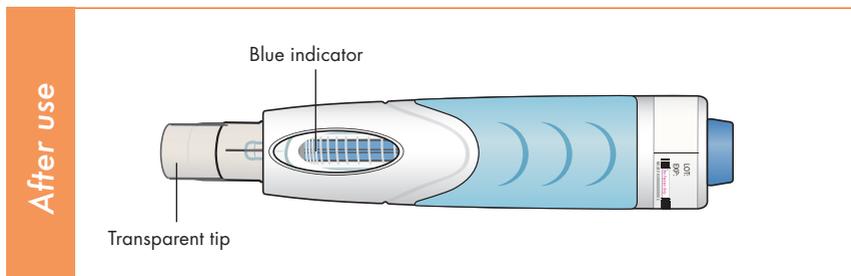
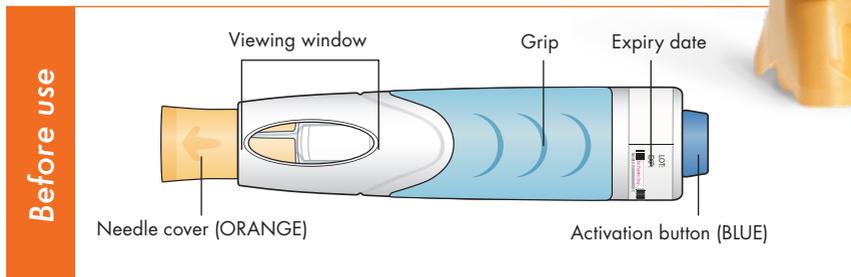
GETTING TO KNOW YOUR CLICKJET AUTOINJECTOR

Before use: the ClickJect Autoinjector is supplied with an orange cap covering the needle.

After use: a transparent tip will lock over the needle once you've completed your injection and removed the ClickJect Autoinjector from your skin.



DO NOT remove the needle cover until you are ready to inject.



STEP 1:



Assemble your injection supplies

Take the ClickJect Autoinjector out of the fridge **30 minutes before** your injection and allow ORENCIA to slowly warm up to room temperature. You may also like to use a timer to help you keep track of the time. Keep ORENCIA out of sunlight and do not speed up the warming process.

WAIT 30 MINUTES



Wash your hands thoroughly. Find a comfortable space with a clean, flat surface and set up the following items:

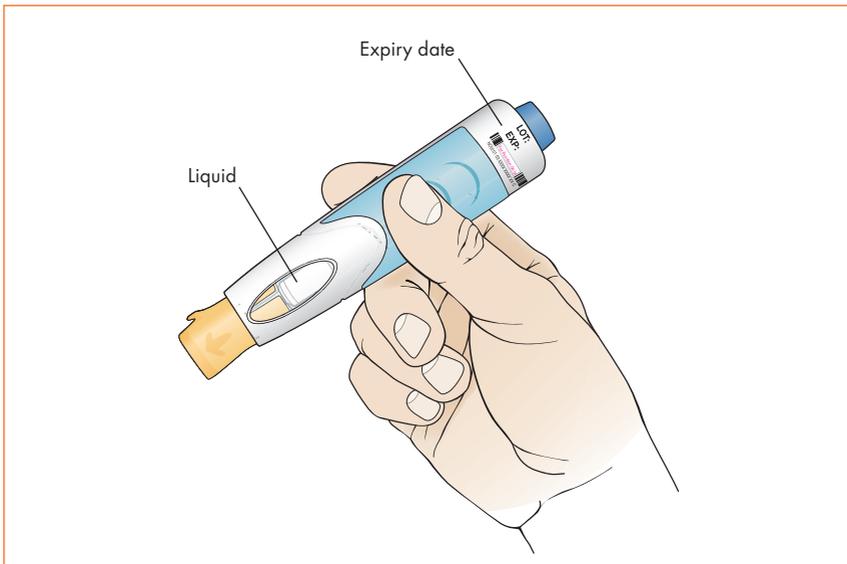
- 1 x ORENCIA ClickJect Autoinjector
- 1 x alcohol swab*
- 1 x cotton ball or gauze*
- 1 x adhesive bandage*
- 1 x sharps disposal container

* Alcohol swabs can be purchased from your local pharmacy, whilst adhesive bandages and cotton balls or gauze can be purchased from any supermarket.



Examine your ClickJect Autoinjector

- Check the viewing window of your ClickJect Autoinjector to ensure the liquid inside is clear and colourless to pale yellow
- It's normal to see an air bubble; you do not need to remove it



DO NOT use the ClickJect Autoinjector if:

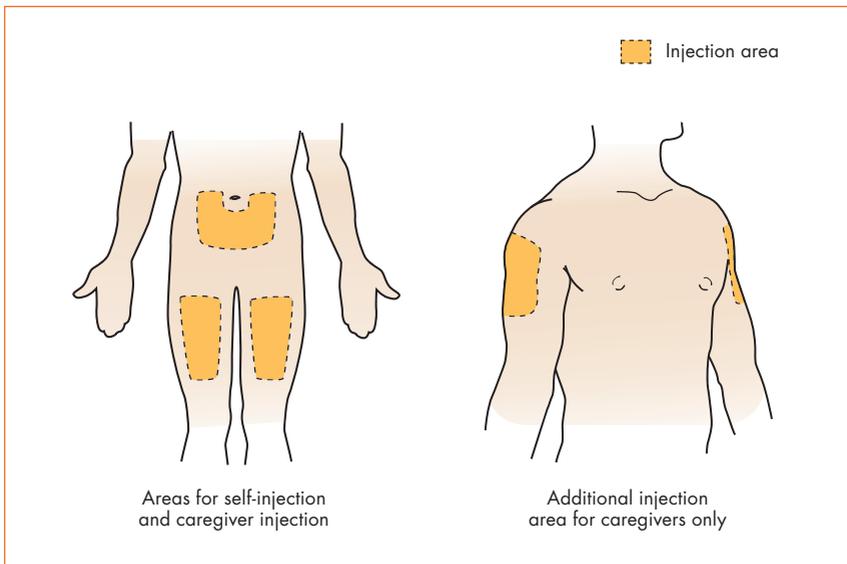
- The liquid in the viewing window is cloudy, discoloured or has visible particles
- Any part of the device is cracked or broken
- The expiry date has passed

STEP 2



Choose and prepare an injection site

- Choose an injection site in either the abdomen (avoid 5 cm around your navel) or front of the thigh. Use a new site each time you inject. Each new injection site should be approximately 2.5 cm (1 inch) from where you last injected. The outer areas of your upper arms may be used if the injection is being given by a caregiver. Do not attempt to use the upper arm area by yourself

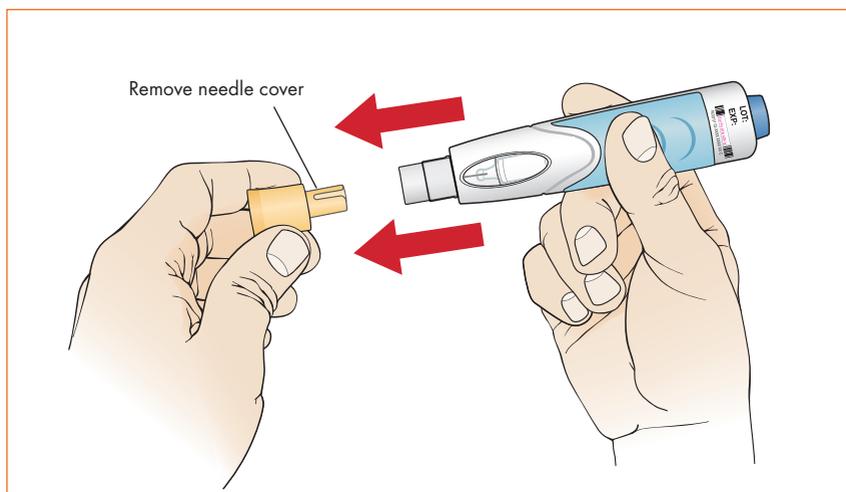


- Select a site that isn't tender, bruised, scaly, red or hard. Avoid areas with scars or stretch marks
- Gently clean the injection site with an alcohol swab and let your skin air dry. Do not touch the injection site again before giving the injection

STEP 3

Inject ORENCIA with the ClickJect Autoinjector

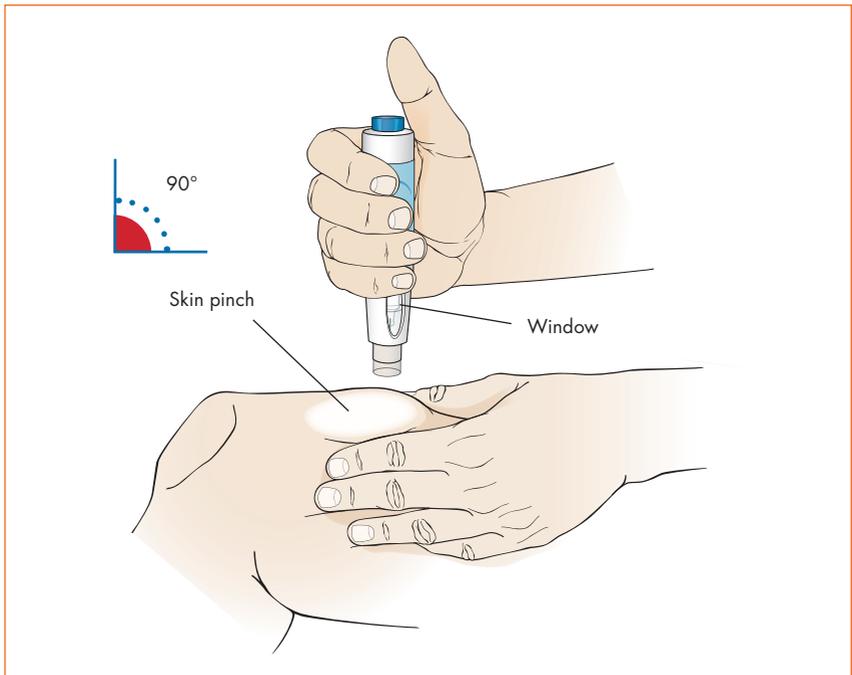
- Pull the orange needle cover straight off. It's normal to see a drop of fluid leaving the needle
- Discard the needle cover in your household waste after the injection



- **DO NOT** twist the orange needle cover off.
- **DO NOT** use the ClickJect Autoinjector if you drop it after removing the cover.
- **DO NOT** replace the needle cover on your ClickJect Autoinjector

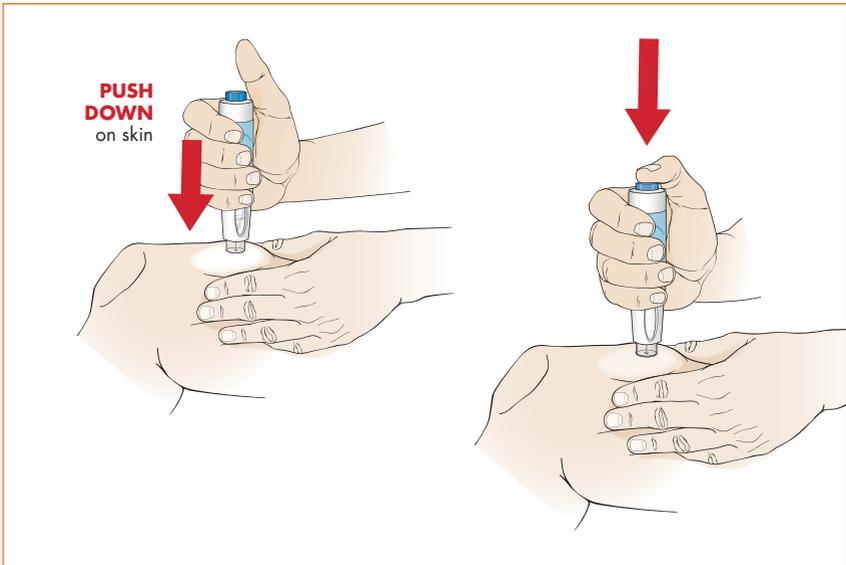


- Position the ClickJect Autoinjector so you can see the viewing window and it's at a 90° angle to the injection site
- Gently pinch the cleansed area of skin with your other hand

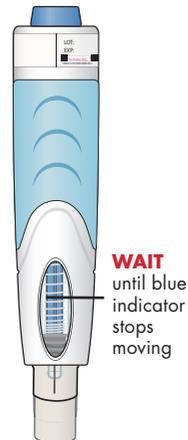


Complete all steps for full dose delivery

- Push down on your skin to unlock the ClickJect Autoinjector
- Press the activation button and hold the ClickJect Autoinjector in place for 15 seconds – **you will hear a click** as the injection begins



- Watch the viewing window and wait until the blue indicator stops moving
- Remove the ClickJect Autoinjector 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 your skin pinch



After the injection



- Check the bottom of the viewing window to make sure there's no liquid left inside. If you haven't received the full dose, consult your doctor, nurse, or pharmacist
- Put the used ClickJect Autoinjector into your sharps container. Do not put the needle cover back on your ClickJect Autoinjector
- There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site and use an adhesive bandage if necessary
- Do not rub the injection site
- Record the date, time and specific part of your body where you injected yourself



FREQUENTLY ASKED QUESTIONS



Why do I need to allow the ClickJect Autoinjector to warm up at room temperature for 30 minutes prior to injecting?

This step is mainly for your comfort. If ORENCIA is cold, the injection may take longer than 15 seconds. Never try to speed up the warming process in any way (e.g. do not use a microwave or place the ClickJect Autoinjector in warm water).

What if I accidentally remove the orange needle cover before I'm ready to inject?

If you remove the cover before you are ready to use the ClickJect Autoinjector, be careful. Do not try to replace it. Use the ClickJect Autoinjector as soon as possible according to the instructions in this booklet. While you prepare for the injection, carefully place the ClickJect Autoinjector on its side on a clean, flat surface. Be sure to keep the ClickJect Autoinjector away from children and pets.

What if the injection does not trigger?

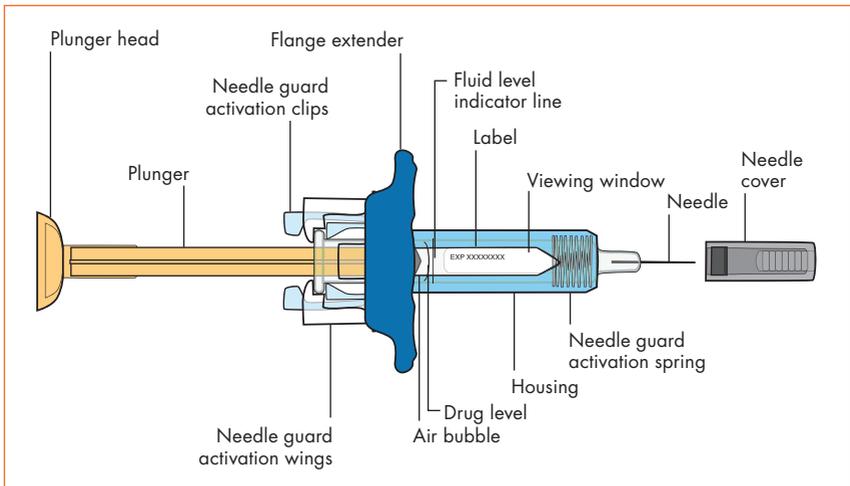
Before the injection can be triggered, the device must be unlocked. To unlock, firmly push the ClickJect Autoinjector down on the skin without touching the button. Once the stop-point is felt, the device is unlocked and can be triggered by pushing the button.

GETTING TO KNOW YOUR SAFETY SYRINGE



Your prefilled safety syringe with needle guard* has extended, rubberised finger grips that make it easier to hold the syringe and inject.

* BD Ultrasafe Passive™ needle guard (BD = Becton, Dickinson and Company).



- **DO NOT** remove the needle cover until you are ready to inject.
- **DO NOT** pull back on the plunger at any time

STEP 1:



Assemble your injection supplies

Take the safety syringe out of the fridge **30 minutes before** your injection and allow ORENCIA to slowly warm up to room temperature. You may also like to use a timer to help you keep track of the time. Keep ORENCIA out of sunlight and do not speed up the warming process.

WAIT 30 MINUTES



Wash your hands thoroughly. Find a comfortable space with a clean, flat surface and set up the following items:

- 1 x ORENCIA safety syringe
- 1 x alcohol swab*
- 1 x cotton ball or gauze*
- 1 x adhesive bandage*
- 1 x sharps disposal container

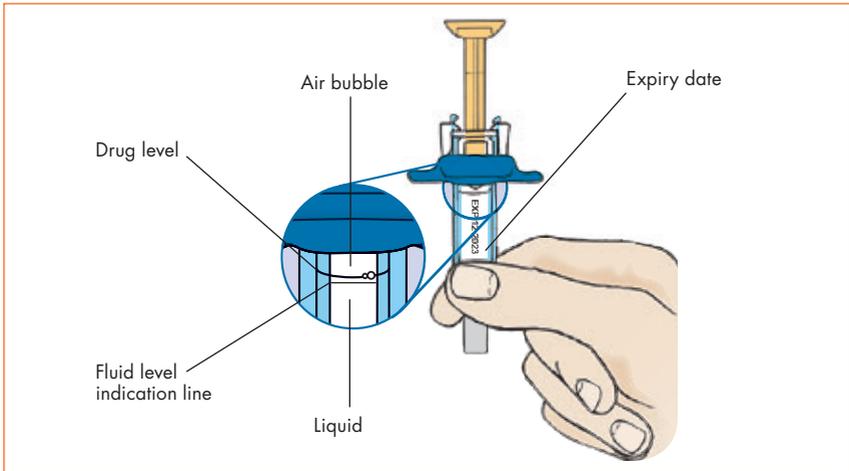
* Alcohol swabs can be purchased from your local pharmacy, whilst adhesive bandages and cotton balls or gauze can be purchased from any supermarket.



Examine your safety syringe



- Hold the safety syringe by the body with the covered needle pointing down



- Check the expiry date on the ORENCIA safety syringe
- Check the liquid inside the safety syringe. Make sure it is clear to pale yellow
- Check the drug level is above the dark blue line. It is normal to see an air bubble; you do not need to remove it

DO NOT use the safety syringe if:

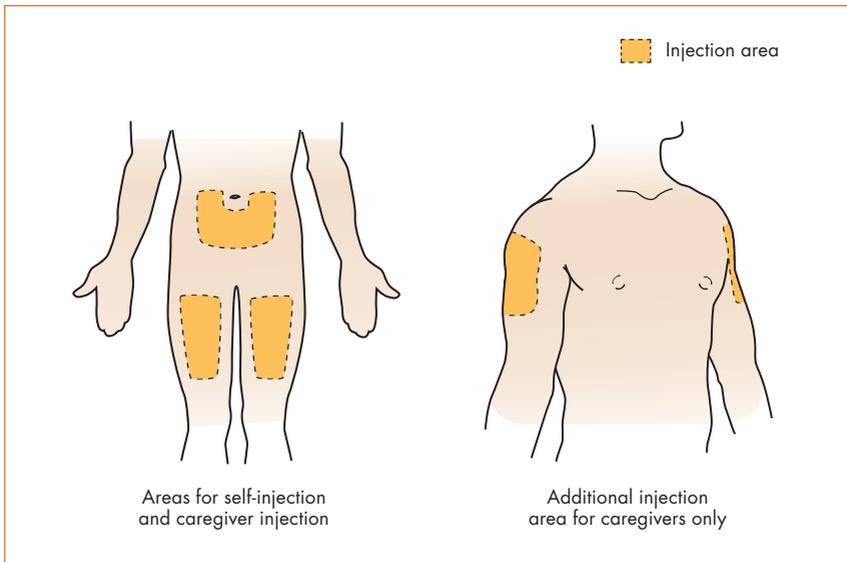
- The liquid in the viewing window is cloudy, discoloured or has visible particles
- The expiry date has passed
- It is dropped after the cap is removed
- If there are visible signs of needle damage or bending

STEP 2:



Choose and prepare an injection site

- Choose an injection site in either the abdomen (avoid 5 cm around your navel) or front of the thigh. Use a new site each time you inject. Each new injection site should be approximately 2.5 cm (1 inch) from where you last injected. The outer areas of your upper arms may be used if the injection is being given by a caregiver. Do not attempt to use the upper arm area by yourself

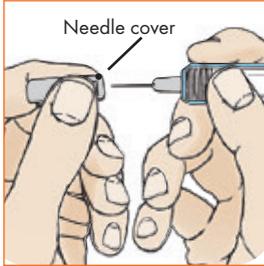


- Select a site that isn't tender, bruised, scaly, red or hard. Avoid areas with scars or stretch marks
- Gently clean the injection site with an alcohol swab and let your skin air dry. Do not touch the injection site again before giving the injection

STEP 3:



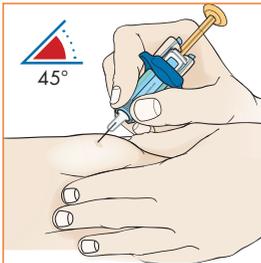
Inject ORENCIA with the safety syringe



- Remove needle cover by holding the housing and pulling the cover straight off
- Discard the cap
- It's normal to see a drop of fluid leaving the needle



DO NOT RECAP the prefilled syringe; this may damage the needle.



- Gently pinch the cleansed area of skin and hold it firmly
- Hold the body of your syringe in one hand between the thumb and index finger
- Use a quick, dart-like motion to insert the needle into the pinched skin at a 45° angle



- Use your thumb to push down on the plunger head until it is pushed in as far as it will go. To ensure that the needle guard moves into place, remove your thumb slowly from the plunger after the injection



- Once the needle is completely covered by the needle guard, remove the syringe and let go of the surrounding skin

After the injection

- Put the used syringe into your sharps container
- Do not put the needle cover back on your safety syringe
- There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site and use the adhesive bandage if necessary
- Do not rub the injection site
- Record the date, time and specific part of your body where you injected yourself.

ORENCIA SUPPORT

For patients prescribed subcutaneous injections



For assistance or support:
Please call BMS Medical
Information on **1800 067 567**

Self-injection video

It can take time to get comfortable with self-injecting, even if your doctor or nurse has shown you. You can watch a training video that will take you through each step of self-injecting using the ClickJect Autoinjector or safety syringe.

Sharps container

You can order a complimentary sharps container and replacement online, so you can safely dispose of your used ClickJect Autoinjectors or safety syringes.

*ORENCIA Travel Cool Bag**

You can order a travel bag that allows you to travel with two ORENCIA ClickJect Autoinjectors or safety syringes, which includes an 'ORENCIA On-the-Go-Guide' with detailed instructions on how to travel with ORENCIA.

*Maximum of one bag.

The videos, sharps container and travel bag can be accessed at:

bms.com/au/gated/OrenciaGO.html

or scan the QR code

password: BMSGO







GET SUPPORT

You are not alone in experiencing the symptoms, physical challenges and worries associated with having RA. All across Australia, people living with RA have combined their efforts and created organisations to share their experiences and help each other. Some of these organisations are listed below.

Arthritis Australia

Arthritis Australia provides support and information to people with arthritis as well as their family and friends, including helpful resources on managing arthritis, such as:

- Healthy eating
- Managing common household tasks
- Dealing with pain or fatigue
- Physical activity and exercise

Free call 1800 011 041 to contact the Arthritis Foundation in your state, or visit www.arthritisaustralia.com.au

The Bone and Joint Decade 2010–2020

The Bone and Joint Decade (BJD) is an umbrella organisation for professional societies, governments, patient advocacy groups, industry and researchers who work together to make bone and joint health the business of every Australian. You can visit their website for details about upcoming events, initiatives and resources at www.bjd.org.au



If you require assistance or more information please call:

 **BMS Medical Information on 1800 067 567***

*Available Monday to Friday, 9 am to 5 pm (AEST), excluding Victorian public holidays.

References 1. ORENCIA® Approved Consumer Medicine Information, July 2018. 2. ORENCIA® Package insert (instructions for use). Actemra®, Enbrel®, Humira®, Olumiant® and Xeljanz® are registered trademarks of their respective owners. ORENCIA® and ClickJect® are registered trademarks of Bristol-Myers Squibb Australia Pty Ltd ABN 33 004 333 322. Level 2, 4 Nexus Court, Mulgrave VIC 3170. Tel (03) 8523 4200. Fax (03) 8523 4455. Date of preparation: August 2021. 427-AU-2100107. BMRH22363W. Ward6.

 Bristol Myers Squibb™

