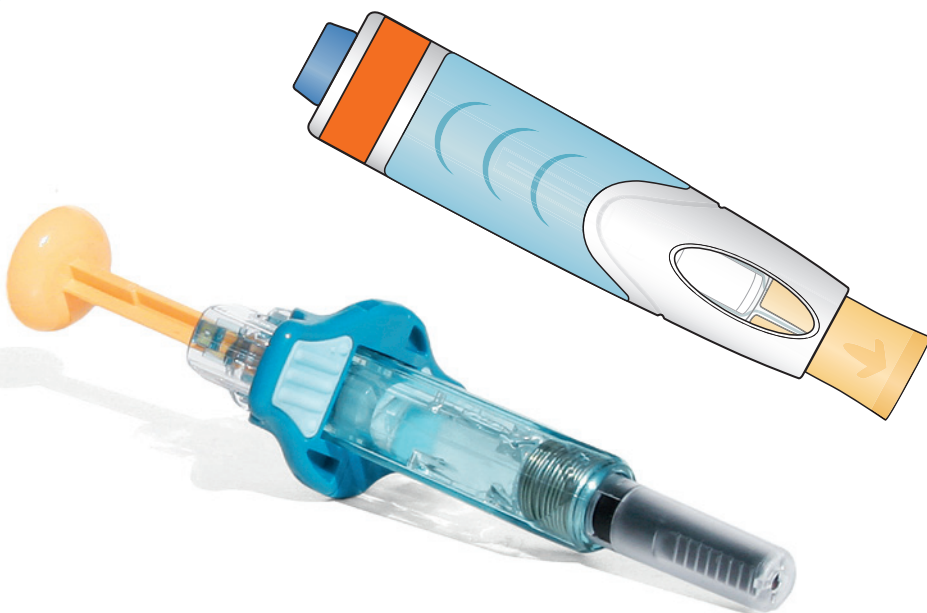


Administering ORENCIA® (abatacept): Your Step-by-Step Guide

How to prepare, use and dispose of the abatacept pre-filled syringe
or ClickJect® pre-filled pen in five steps



427IE1500061-01

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Administering ORENCIA® (abatacept): Your Step-by-Step Guide

IMPORTANT – PLEASE READ

This guide contains information on how to administer ORENCIA® using the two subcutaneous injection types available for ORENCIA®: the pre-filled syringe and the ClickJect® pen.

Their method of administration is different, so it is important that you refer to the appropriate section of this guide.

Please refer to the opposite page and select a section tab according to the type of ORENCIA® product you have been given.



Select the correct guide for your version of ORENCIA® ...

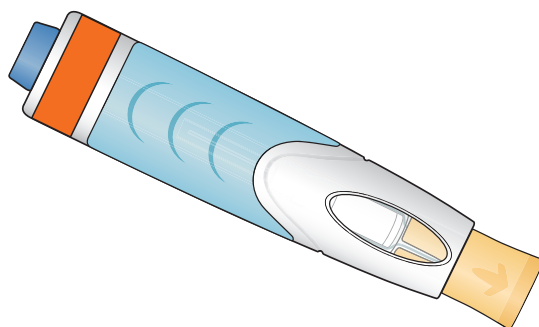
If your ORENCIA® looks like this (syringe):

TURN TO SECTION



If your ORENCIA® looks like this (ClickJect® pen):

TURN TO SECTION



Administering ORENCIA® (abatacept) using the pre-filled safety syringe





Your step-by-step guide to using the pre-filled safety syringe

Abatacept is available as a pre-filled safety syringe and a ClickJect® pre-filled pen. The following guide relates to the pre-filled safety syringe.

The recommended dose of ORENCIA is 125 mg given every week. Each pre-filled syringe contains 125 mg of abatacept in one ml. This syringe has been specially designed with features to make it as easy to use as possible. If you and your doctor have decided that you will inject abatacept yourself at home, you will receive training on the correct way to administer the injection. This booklet provides guidance to remind you of the procedure in five simple steps. You may also find it useful to watch the instructional video available at www.bms-optimal.ie

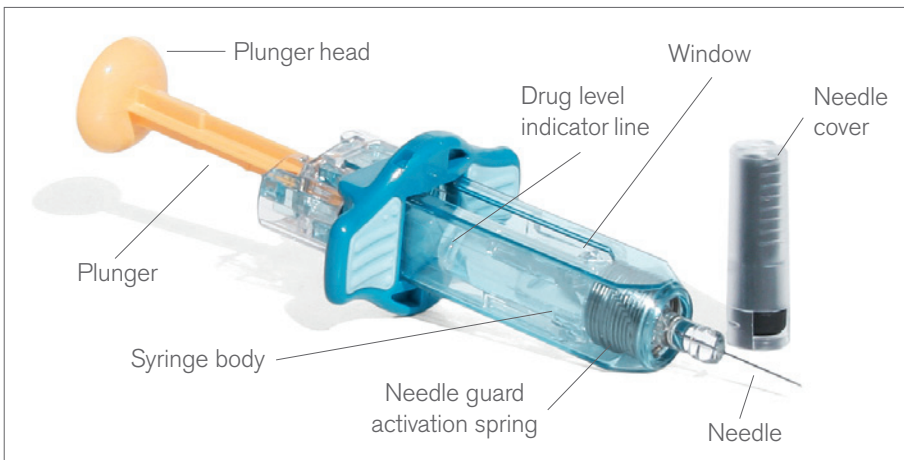
If you have any questions or concerns about your medicine or how to take it you should discuss these with your doctor or nurse.



Abatacept is used to treat moderate to severe active rheumatoid arthritis in adults 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.

The abatacept pre-filled syringe

The abatacept pre-filled syringe includes several features to make it as easy as possible to use.



Needle guard

As soon as you have used the syringe, the needle will retract until it is completely covered by the needle guard. This is designed to prevent injuries.

Window

This enables you to view the contents of the syringe. It is important to check that the liquid inside the syringe is clear and colourless to pale yellow, and free from any large particles before you use the syringe.

Needle cover

The needle cover should be left in place until immediately before the injection is given.



Your step-by-step guide to using the pre-filled safety syringe

Step 1: Getting ready to inject abatacept

The first step in administering abatacept is to get the syringe ready for use. Each syringe should be kept in a refrigerator in its original packaging until it is time for it to be used. Store abatacept out of the sight and reach of children.

Take the syringe out of the refrigerator and carefully remove it from its packaging by gripping it at the point indicated by the arrows on the tray. Inspect the syringe for any damage and check the use-by date. If the syringe is damaged or has passed its use-by date, discard it. Do not remove the needle cover at this stage.

Place the syringe on a clean, flat surface and allow it to warm up to room temperature for 30 minutes. Do not attempt to speed up the warming process in any way. Ensure that the syringe is out of the sight and reach of children at all times.

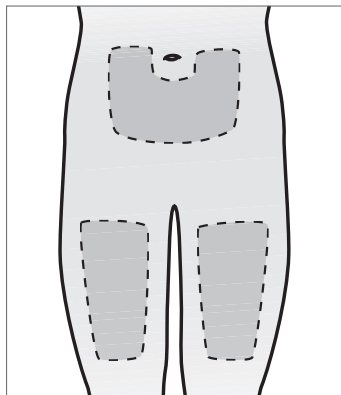
Once the syringe has reached room temperature, inspect the liquid. To do this, hold the syringe by the syringe body with the covered needle pointing downwards and look at the liquid through the viewing window. The liquid should be clear and colourless to pale yellow. Do not use the syringe if the liquid is cloudy, discoloured or if you can see large particles in it. It's normal to see an air bubble in the liquid and there is no reason to remove it.

Gather together the things you will need for the injection – an alcohol swab and a cotton wool ball, as well as your disposable sharps container to dispose of your syringe afterwards. Now wash your hands thoroughly with soap and warm water.

Step 2: Choosing and preparing the injection area

The second step is to choose and prepare the place on your body where you will administer the injection. Choose a different site for each new injection. If you take any other medicines by injection, avoid injecting abatacept into the same site that you have used for your other medicines.

Use the Administration Record at the end of this section to keep a record of each injection site.



Avoid injecting into areas where the skin is tender, bruised, red, scaly or hard and any areas with scars or stretch marks

Choose an area of your body for the injection. You can use the front of your thigh and/or your abdomen, except for the 5 centimetre area around the navel.

Choose a different injection site for each new injection. You may use the same area of your body (front of thigh or abdomen) for weekly injections as long as each injection site is approximately 2.5 centimetre away from where you last injected.

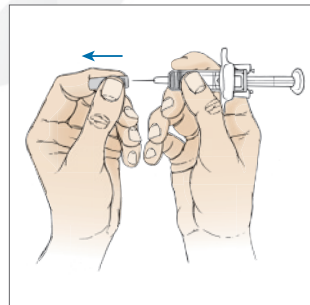
Make sure that you have the syringe ready to use immediately after you have prepared the injection site

Prepare the injection site by wiping it with an alcohol swab in a circular motion. Let the skin dry naturally and avoid touching it, fanning it or blowing on it before you have given the injection.

Step 3: Administering the injection

To remove the needle cover, hold the body of the syringe with one hand and pull the cover straight off with your other hand. Be careful not to touch the plunger while you are removing the needle cover and don't remove the cover until you are ready to give the injection.

Hold the body of the syringe in one hand between your thumb and your index finger. Next, use your other hand to gently pinch the area of skin that you cleaned and hold it firmly.





Your step-by-step guide to using the pre-filled safety syringe

Use a swift and smooth motion to insert the needle into the pinched skin at a 45 degree angle. Now inject all of the medicine in the syringe by using your thumb to push the plunger until the plunger head is completely between the needle guard sides.

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

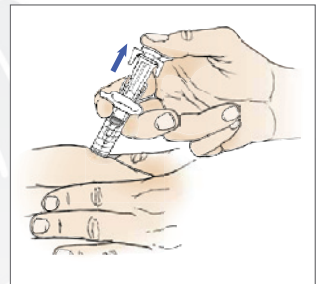
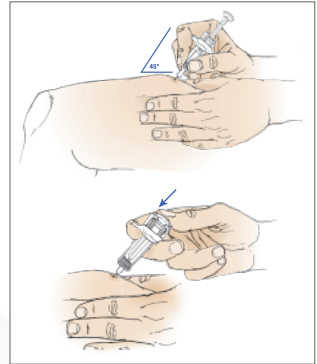
To ensure that the needle guard moves into place, remove your thumb slowly from the plunger after the injection

Press a cotton wool ball over the injection site and hold it for ten seconds. Don't rub the injection site.

Step 4: Disposing of the syringe

Place the used syringe directly in your sharps container. Always store your sharps container out of the sight and reach of children.

Your Rheumatology team will discuss with you the process for sharps container disposal and replacement.



Step 5: Keeping records

It can be helpful to keep a record of where you administered each injection and any problems that you encountered. Discuss any problems with your doctor or nurse.

Use the Administration Record at the end of this section to keep a record of each injection site.

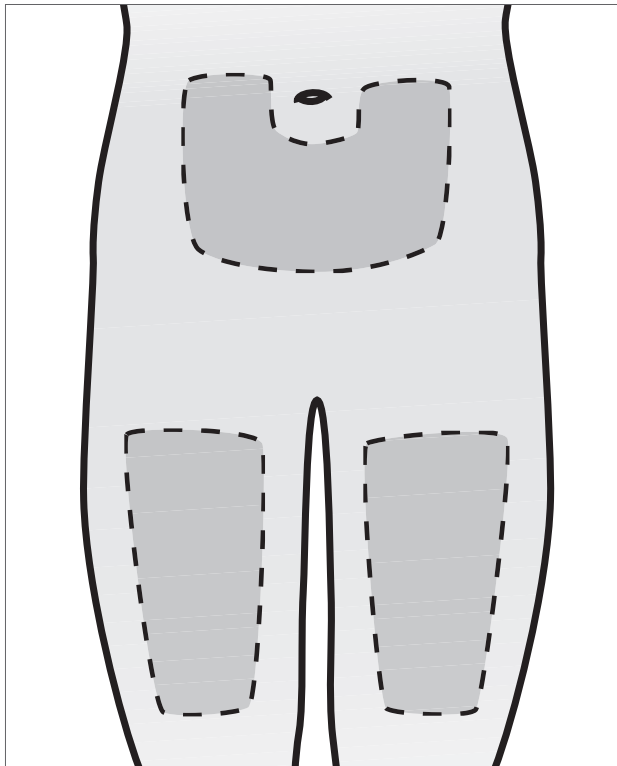




Your step-by-step guide to using the pre-filled safety syringe

Administration Record

It is important to record the date and site of your injection. After administering your injection write the date and location against one of the numbers on the opposite page (e.g. 1. Sunday 25th October '15 - lower left thigh; Sunday 1st November '15 - right abdomen).



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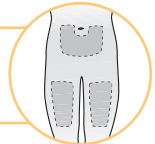
Your step-by-step guide to using the pre-filled safety syringe

Five simple steps for administering abatacept

1. Prepare and check the syringe, gather your supplies and wash your hands



2. Choose and prepare an injection site



3. Administer the injection



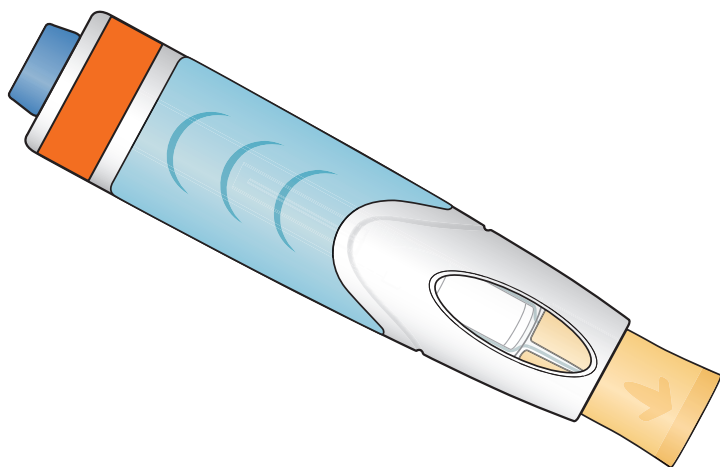
4. Dispose of the used syringe



5. Keep a record



Administering ORENCIA® (abatacept) using the ClickJect® pre-filled pen





Your step-by-step guide to using the ClickJect® pre-filled pen

Abatacept is available as a pre-filled safety syringe and a ClickJect® pre-filled pen. The following guide relates to the ClickJect® pre-filled pen.

The recommended dose of ORENCIA® is 125 mg given every week. Each pre-filled pen contains 125 mg of abatacept in 1 ml. The pen has been designed with specific features to make it convenient to use. If you and your doctor have decided that you will inject ORENCIA® yourself at home, you will receive training on the correct way to administer the injection. This guide provides instructions on the five-step injection process. You may also find it useful to watch the instructional video available at www.bms-optimal.ie

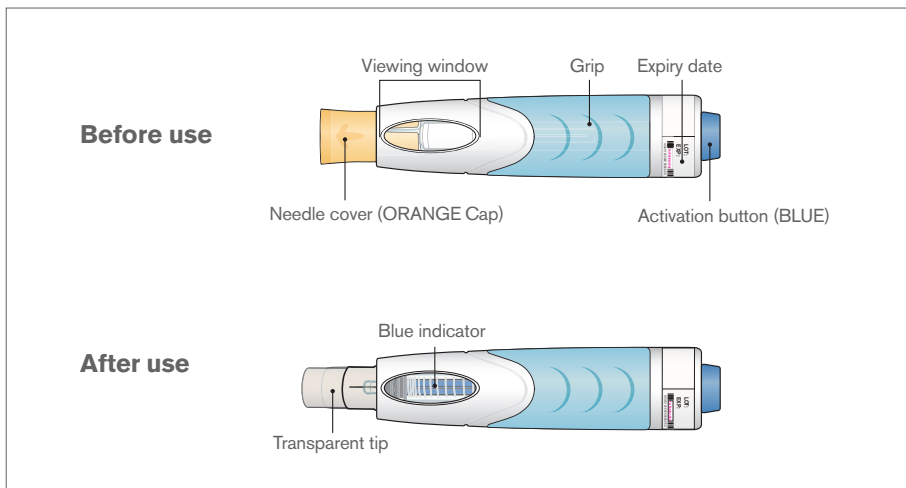
If you have any questions or concerns about your medicine or how to take it you should discuss these with your doctor or nurse.

Abatacept is used to treat moderate to severe active rheumatoid arthritis in adults 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.

The ClickJect® pre-filled pen

The ClickJect® pre-filled pen includes several features to make it convenient

- The pen automatically delivers the medication. 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**



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 wool ball or gauze
- ClickJect® pre-filled pen
- Sharps disposal container



Your step-by-step guide to using the ClickJect® pre-filled pen

Step 1: Prepare your ClickJect® pre-filled pen

Let your ClickJect® pre-filled pen warm up.

Remove one pen from the refrigerator and let it rest at room temperature for **30 minutes**.

DO NOT remove the needle cover from the pen while allowing it to reach room temperature.

DO NOT attempt to speed up the warming process in any way.

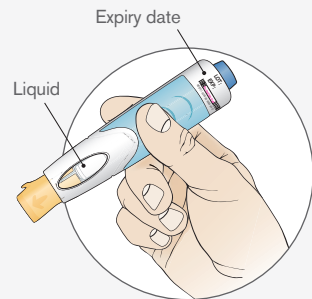
- Each pen should be kept in its original packaging in a refrigerator at 2°C to 8°C until it is time for it to be used
- Once you have removed a pen for use, ensure that remaining pens are returned immediately to the refrigerator
- Store ORENCIA® out of the sight and reach of children



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 particles



Step 2: Prepare for injection

Choose your injection site on 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.

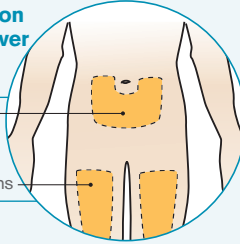
DO NOT inject into an area where the skin is tender, bruised, red, scaly, or hard. Avoid any areas with scars or stretch marks.

- You can inject into the front of your thigh and/or your abdomen, except for the 5 centimetre area around the navel

Injection areas: Self-Injection and Caregiver

Abdomen,
avoid 5 cm
around navel

Front of thighs



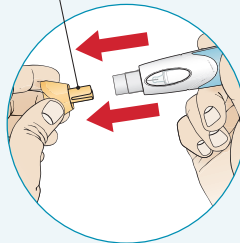
Gently clean injection site with an alcohol swab and let your skin dry.

- Let the skin dry naturally and avoid touching it, fanning it or blowing on it before you have given the injection. Make sure that you have the pre-filled pen ready to use immediately after you have cleaned the injection site

Pull orange needle cover STRAIGHT off
DO NOT twist the needle cover.

- **DO NOT** remove the cover until you are ready to give the injection
- **DO NOT** replace the needle cover on the pen. You can discard the cover in your household waste after the injection
- **DO NOT** use the pen if it is dropped after the cover is removed. It is normal to see a drop of fluid leaving the needle

Remove
needle cover



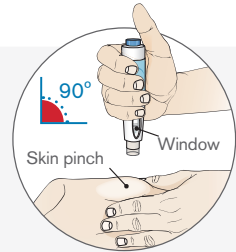


Your step-by-step guide to using the ClickJect® pre-filled pen

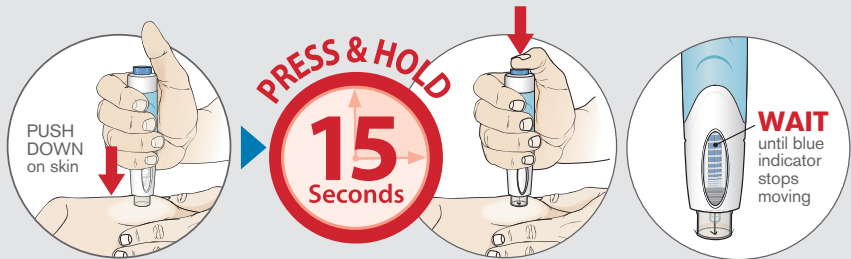
Step 3: Administering the injection

Position the ClickJect® pre-filled pen

so you can see the **viewing window** and so that 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 15s** AND **watch window**.

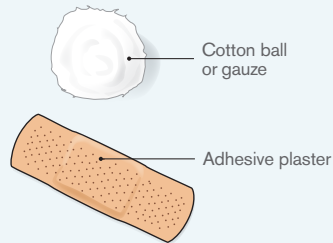
- You will hear a click as the injection begins
- For full-dose delivery, hold the pre-filled pen in place for 15 seconds **AND** wait until blue indicator stops moving in window

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.

Step 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 the used ClickJect® pre-filled pen into a sharps container right away after use.

- **DO NOT** replace the needle cover on the used pen
- 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
- A sharps container is included in the ClickJect® pre-filled pen patient starter kit
- Always store your sharps container out of the sight and reach of children

Your Rheumatology team will discuss with you the process for sharps container disposal and replacement.



Your step-by-step guide to using the ClickJect® pre-filled pen

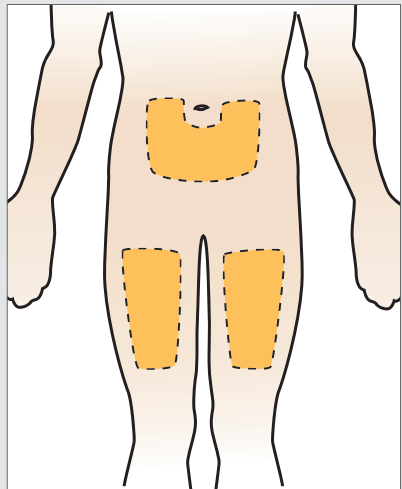
Step 5: Keeping records

It can be helpful to keep a record of where you administered each injection and any problems that you encountered. Discuss any problems with your doctor or nurse.

Use the Administration Record on the next page to keep a record of each injection.

Administration Record

It is important to record the date and site of your injection. After administering your injection write the date and location against one of the numbers on the opposite page (For example:
1. Sunday 12th July '15 – lower left thigh;
2. Sunday 19th July '15 – right abdomen).



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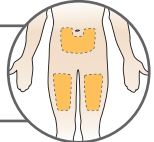
Your step-by-step guide to using the ClickJect® pre-filled pen

Five steps for administering ORENCIA®

1. Prepare and check ClickJect® pre-filled pen, gather your supplies and wash your hands



2. Choose and prepare injection site



3. Administer injection



4. Dispose of used pen and care for injection site



5. Keep a record



How to prepare, use and dispose of the ClickJect® pre-filled pen in five steps





Notes

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 via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

If you have any questions or concerns regarding your treatment, please contact your doctor or nurse for assistance.

This information is prepared by BMS and intended only for patients who have been prescribed abatacept

This guide does not substitute the Patient Information Leaflet. Please refer to the Patient Information Leaflet before using the pre-filled safety syringe or ClickJect® pre-filled pen.

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