

Imraldi™ treatment

(adalimumabi)

Practical information and instructions for the user

This booklet is for patients who have been prescribed Imraldi™ (adalimumab)



Why Imraldi™

Instructions for using Imraldi™

For your safety

Why Imraldi™

This booklet is intended for patients who have been prescribed Imraldi™ (adalimumab). If you are new to biologic medicines, or new to biosimilars, you probably have some questions. This booklet was designed to make it easy for you to find the information and answers you need.

We have also included a quick reference guide with step-by-step instructions for how to inject with pre-filled pen or pre-filled syringe.

This booklet does not replace careful reading of the package leaflet before you start the treatment.

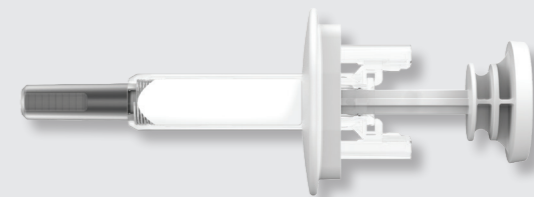
Ask a pharmacist, a doctor or a nurse if you have any questions. Refer to the package leaflet containing the instructions for use.

Please consult your doctor if you have any questions related to your medical condition.

Adverse events should be reported

If any side effects occur, talk to your doctor, nurse or pharmacist.

There is a full list of all the possible side effects in the leaflet that comes in the Imraldi™ package.



What is Imraldi™?

What is Imraldi™ used for?

How does Imraldi™ work?

What are biosimilars?

Biosimilars are approved according to the same standards of pharmaceutical quality, safety and efficacy that apply to all biological medicines approved in the EU.

What is Imraldi™ and how does it work?

The active ingredient in Imraldi™ (adalimumab) is an anti-TNF biologic – an antibody that specifically attaches to TNF and decreases inflammation associated with your disease. Tumor necrosis factor (TNF or TNF-alpha) is a protein that is part of your immune system.

In some people, the immune system may act abnormally, triggering increased levels of TNF and the inflammation associated with your condition. Anti-TNF biologics precisely target that source of inflammation.

What is Imraldi™ used for?

- Rheumatoid arthritis
- Polyarticular juvenile idiopathic arthritis
- Enthesitis-related arthritis
- Ankylosing spondylitis
- Psoriatic arthritis
- Plaque psoriasis
- Hidradenitis suppurativa
- Axial spondyloarthritis without radiographic evidence of ankylosing spondylitis
- Crohn's disease
- Ulcerative colitis
- Non-infectious uveitis

What are biosimilars?

Biosimilars are medicines that contain the same active substance as the original biological medicine (reference product), but in a different form. Biosimilars and original biological medicine are therapeutically equivalent to each other.

Biological medicines are used to treat for example arthritis, asthma, diabetes and cancer.

Biological methods are used to produce biological medicines, which makes it more complex and more expensive than using traditional chemical medicines.

When the patent of the reference product has expired, the biosimilar can be brought to the market. This, in turn, may cause price competition that lowers treatment costs. With reduced treatment costs more patients can benefit from biological medicines.

The Imraldi™ pen

Imraldi™ is available as a single dose, pre-filled, button-free pen and is administered by injection under the skin (subcutaneously). One pre-filled pen has 40 mg of Adalimumab. Imraldi™ is given by injection under the skin (subcutaneously).

Take a few minutes to learn about your autoinjector pen and how to use it.



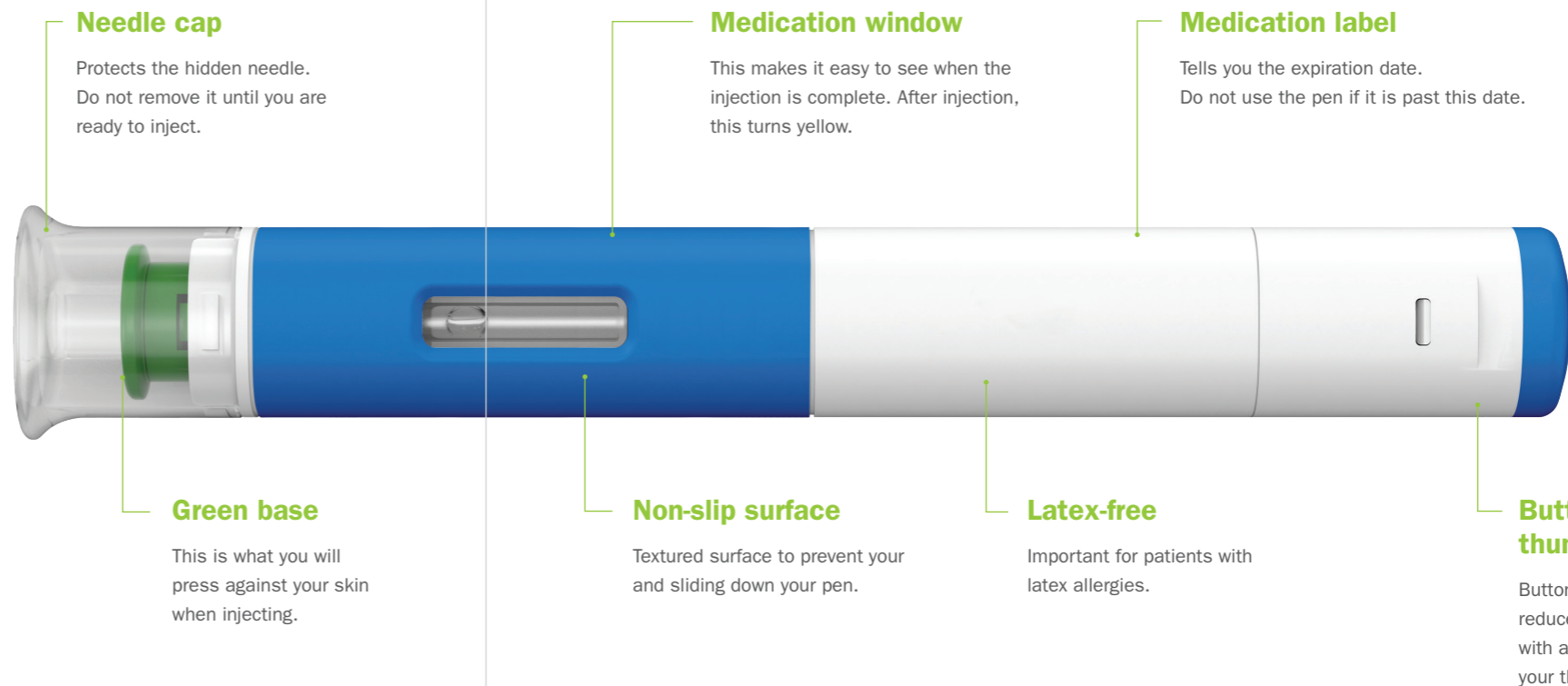
Sure grip shape

Four sided design to prevent the pen from rolling off surfaces with rounded corners for comfort and stability.



Non-slip surface

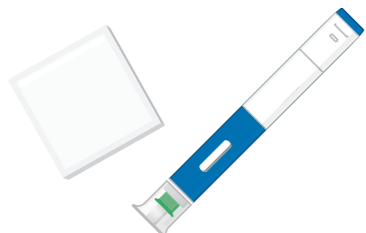
Pen surface has a textured feel to help improve grip and control.



How to use your Imraldi™ autoinjector pen

1

⚠ Do not remove the cap just yet!

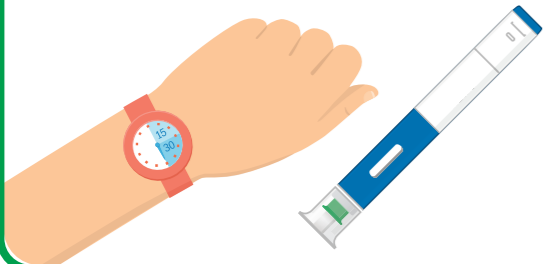


1 | WASH HANDS AND GATHER SUPPLIES

- ▶ Wash your hands and place the pen and alcohol pad for disinfection on a clean, dry surface.

2

⚠ Do not remove the cap just yet!



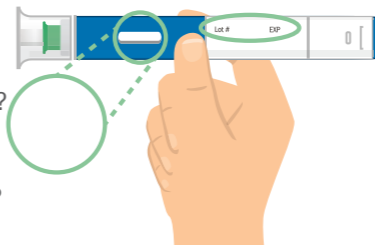
2 | BRING MEDICATION TO ROOM TEMPERATURE

- ▶ Wait 15-30 minutes for your pre-filled pen to reach room temperature, which helps reduce your pain during injection.
- ▶ Do not warm up the medication in any other way (for example in microwave or in hot water).

3

⚠ Do not remove the cap just yet!

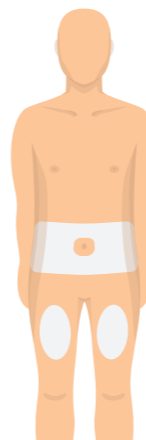
- ✓ No Particles?
- ✓ Clear?
- ✓ Colourless?
- ✓ Not Expired?



3 | INSPECT MEDICINE & EXPIRATION DATE

- ▶ Wash your hands again thoroughly.
- ▶ If your medication is not clear, not free of particles, or is expired, do not use it.
- ▶ You may see 1 or more bubbles, and that is okay. There is no reason to remove it.

4

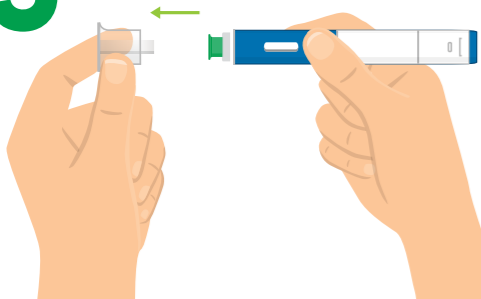


4 | CHOOSE INJECTION SITE AND CLEAN SKIN

- ▶ Choose an injection site on your body. Your abdomen (except the area around the navel) or thighs are best.
- ▶ Avoid skin that is sore, bruised, scarred, scaly, or has red patches.
- ▶ Clean the injection site with an alcohol pad and let it dry.
- ▶ Do not touch the area again before the injection.

How to use your Imraldi™ autoinjector pen

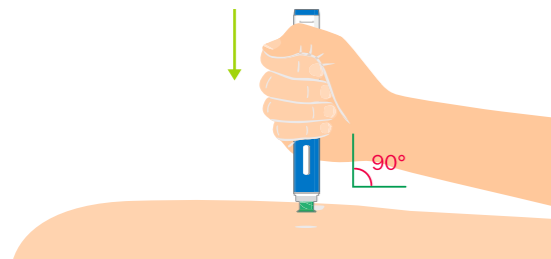
5



5 | CAREFULLY PULL THE TRANSLUCENT CAP OFF THE PEN

- ▶ It is normal to see a few drops of liquid come out of the needle.
- ▶ If you do take off the cap before you are ready to inject, **do not put the needle cap back on.**

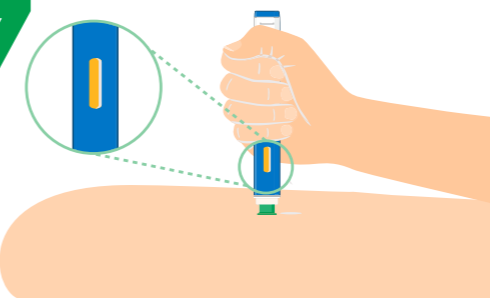
6



6 | INJECTING

- ▶ Place the green base on the skin, press down firmly and hold.
- ▶ When you push down, the injection starts. You may hear a 1st click.

7



7 | CONTINUE TO HOLD THE PEN FIRMLY IN PLACE

- ▶ Hold the pen firmly in place against the skin until the yellow indicator fills the medication window.
- ▶ Several seconds later you hear a 2nd click.

8



8 | CONFIRM COMPLETION AND DISPOSE AS DIRECTED

- ▶ You received your dose if...
 - ▶ The entire medication window is yellow
 - ▶ No medicine leaked out (a small drop is okay)
- ▶ Throw away the used pen in a special container as instructed by your doctor, nurse or pharmacist. If you are not sure you received the dose, contact your doctor, nurse, or pharmacist.

How to use your Imraldi™ pre-filled syringe

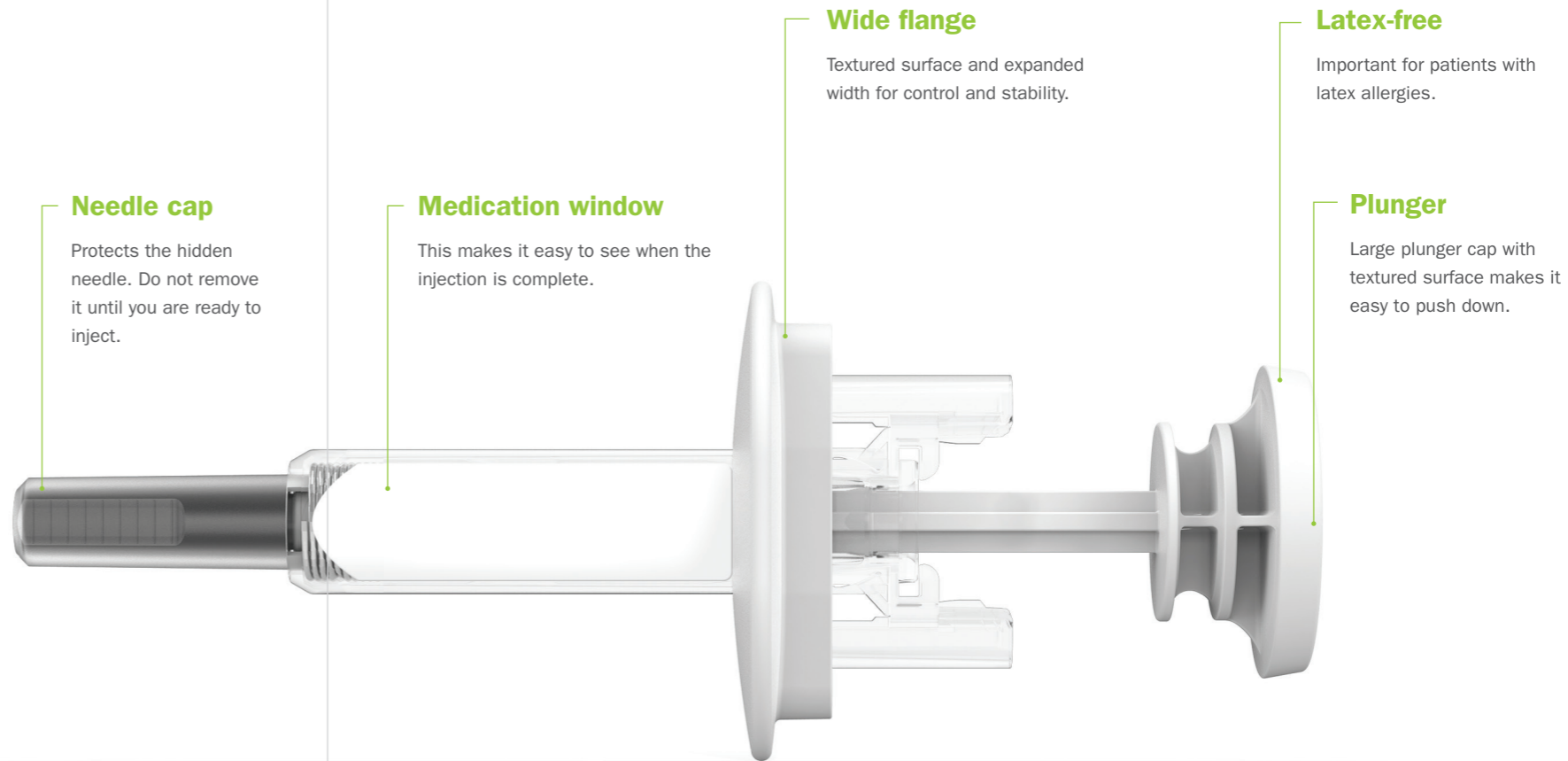
The Imraldi™ pre-filled syringe

Imraldi™ is available as a single dose, pre-filled syringe with an automatic retracting needle for safety. Take a few minutes to learn about your syringe and how to use it.



Automatic Retracting Needle

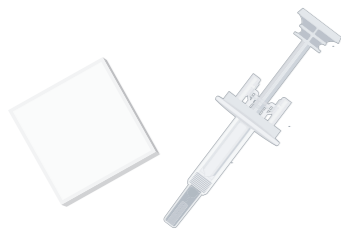
After injection, needle automatically retracts into syringe body for increased safety.



How to use your Imraldi™ pre-filled syringe

1

⚠ Do not remove the cap just yet!



1 | WASH HANDS AND GATHER SUPPLIES

- ▶ Wash your hands and place the syringe and alcohol pad for disinfection on a clean, dry surface.

2

⚠ Do not remove the cap just yet!



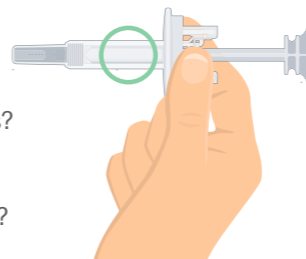
2 | BRING MEDICATION TO ROOM TEMPERATURE

- ▶ Wait 15-30 minutes for your pre-filled syringe to reach room temperature, which helps reduce your pain during injection.
- ▶ Do not warm up the medication in any other way (for example in microwave or in hot water).

3

⚠ Do not remove the cap just yet!

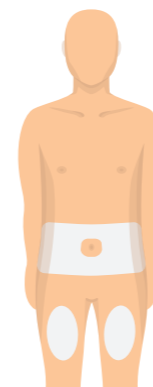
- ✓ No Particles?
- ✓ Clear?
- ✓ Colourless?
- ✓ Not Expired?



3 | INSPECT MEDICINE AND EXPIRATION DATE

- ▶ Wash your hands again thoroughly.
- ▶ If your medication is not clear, not free of particles, or is expired, do not use it.
- ▶ You may see 1 or more bubbles, and that is okay. There is no reason to remove it.

4

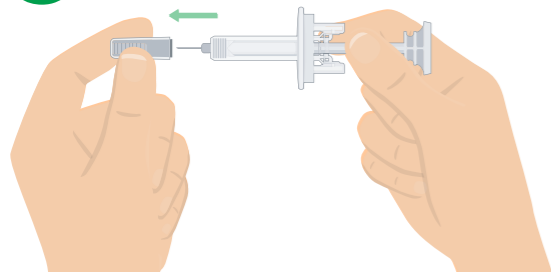


4 | CHOOSE INJECTION SITE AND CLEAN SKIN

- ▶ Choose an injection site on your body. Your abdomen (except the area around the navel) or thighs are best.
- ▶ Avoid skin that is sore, bruised, scarred, scaly, or has red patches.
- ▶ Clean the injection site with an alcohol pad, and let it dry.

How to use your Imraldi™ pre-filled syringe

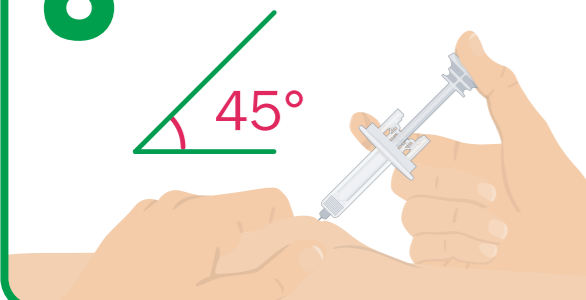
5



5 | CAREFULLY PULL OFF THE NEEDLE CAP

- ▶ It is normal to see a few drops of liquid come out of the needle.
- ▶ If you do take off the cap before you are ready to inject, **do not put the needle cap back on.**

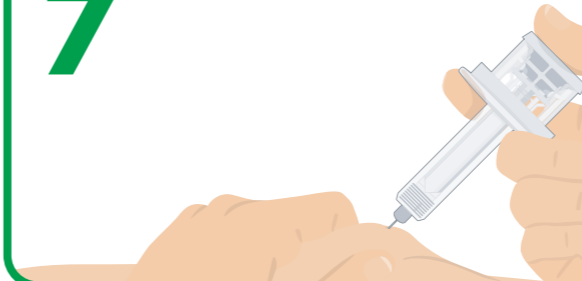
6



6 | INJECTING

- ▶ Gently pinch your skin with one hand.
- ▶ Insert the needle all the way at about a 45-degree angle.

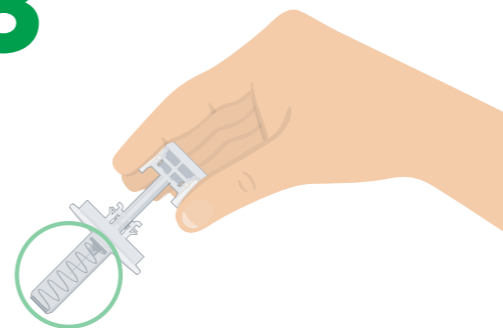
7



7 | PUSH PLUNGER ALL THE WAY DOWN

- ▶ Hold the syringe steady and press the plunger in a controlled manner all the way down.
- ▶ Then lift your thumb to let the needle retract into the body of the syringe.

8



8 | REMOVE SYRINGE AND DISPOSE AS DIRECTED

- ▶ You received your dose if...
 - ▷ Needle retracted
 - ▷ Plunger was pushed all the way down
 - ▷ No medicine leaked out (a small drop is okay)
- ▶ Confirm that the needle has retracted and immediately throw away the used syringe in a special container as instructed by your doctor, nurse or pharmacist.
- ▶ If you are not sure you received the dose, contact your doctor, nurse, or pharmacist. In that case, save the syringe.

For your safety

DO NOT USE IF:

- ▶ You are allergic to adalimumab or any of the other ingredients of this medicine
- ▶ You have a severe infection, including tuberculosis
- ▶ You have moderate or severe heart failure

Possible side effects:

As any medication, alsadalimumab can cause side effects. Most side effects are mild or moderate but some individuals may develop severe side effects. The side effects might arise also after treatment discontinuation.

Very common side effects:

- ▶ injection site reactions (including pain, swelling, redness or itching)
- ▶ respiratory infections (including cold, runny nose, sinusitis, pneumonia)
- ▶ headache
- ▶ abdominal pain
- ▶ nausea and vomiting
- ▶ rash
- ▶ pain in the muscles

Some side effects of adalimumab may not show any symptoms and can only be shown in blood samples. These include:

- ▶ low blood levels of white blood cells
- ▶ low blood levels of red blood cells
- ▶ elevated blood lipids
- ▶ elevated liver enzymes

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

- ▶ signs of infection such as fever, feeling sick or wounding
- ▶ feeling weak or tired
- ▶ coughing that does not get better within few weeks
- ▶ tingling, numbness or double vision
- ▶ a bump or open sore that does not heal
- ▶ signs and symptoms suggestive of blood disorders such as persistent fever, bruising, bleeding, paleness
- ▶ shortness of breath with exertion or upon lying down or swelling the feet

Allergic reactions

Severe allergic reactions are rare. However, any of the following symptoms might be a sign of an allergic reaction caused by adalimumab. If you experience any of these symptoms, seek medical help immediately:

- ▶ trouble breathing or swallowing
- ▶ swollen face, throat, hands or feet
- ▶ severe rash, itch or hives (red or pale stings that are often itchy)

Talk to your doctor

Cancer: Tell your doctor if you have or have ever had lymphoma (a type of blood cancer) or any other cancer before you are given adalimumab.

Mild heart failure: Tell your doctor if you have a history of heart failure.

You are taking certain other medicine: Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Imraldi™ can be taken together with methotrexate or certain disease-modifying anti rheumatic agents (sulfasalazine, hydroxychloroquine, leflunomide), corticosteroids or pain medications, including non-steroidal anti-inflammatory drugs (NSAIDs).

Pregnancy and breastfeeding: If you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Breastfeeding is possible during the treatment.

Surgery: Imraldi™ is often temporarily discontinued before and after a surgery. Contact your clinic for more information.

Vaccination: Please consult your doctor before you receive any vaccines.

Imraldi is available in two different dosage volumes

Imraldi is available in both 0,4 ml and 0,8 ml injection doses. Check which dosage volume your doctor has prescribed for you on the outer packaging of the medicine.

How to store Imraldi™ (adalimumab)

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 of the carton after EXP. Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the pre-filled pen or syringe in the outer carton in order to protect from light.

When needed, a single Imraldi™ pre-filled pen or syringe may be stored at room temperature (up to 25°C). The shelf life of the medicine at room temperature depends on the dose volume:

- ▶ 0,4 ml (containing 40 mg of adalimumab) can be stored in room temperature up to 31 days
- ▶ 0,8 ml (containing 40 mg of adalimumab) can be stored in room temperature up to 28 days

Once removed from the refrigerator for room temperature storage, the pen or syringe must be used within 28 days or discarded, even if it is returned to the refrigerator. You should record the date when the pen or syringe is first removed from refrigerator, and the date after which it should be discarded.

If you use more Imraldi™ than you should:

If you accidentally inject Imraldi™ more frequently than you should, call your doctor or pharmacist and explain that you have taken more. Always take the outer carton of the medicine with you, even if it is empty.

If you forget to use Imraldi™: If you forget to give yourself an injection, you should inject the next dose of Imraldi™ as soon as you remember. Then take your next dose as you would have on your originally scheduled day, had you not forgotten a dose.

If you stop using Imraldi™: The decision to stop using Imraldi™ should be discussed with your doctor. Your symptoms may return upon stopping treatment.

www.biosimilaari-nyt.fi

Finnish website for Imraldi™ users

The website is for people who use Biogen's biologic medicines.

On the website you can find for example guides and injection instruction videos.

Logging in

Address

www.biosimilaari-nyt.fi

Password

Log in with the VNR-code on the package.

You can find the VNR-code

on the backside of the package or on the side with a blue text in a box.

For more information see www.biosimilaarit-nyt.fi



References

1. National Institutes of Health. MedlinePlus. U.S. National Library of Medicine: Autoimmune Diseases. <https://medlineplus.gov/autoimmunediseases.html>. Accessed 14.11.2022.
2. GaBI Online. Small molecule versus biological drugs. Posted 29/06/2012. Available at: <https://www.gabionline.net/biosimilars/research/Small-molecule-versus-biological-drugs>. Accessed 14.11.2022.
3. European Medicines Agency: Biosimilars in the EU: Information guide for healthcare professionals. http://www.ema.europa.eu/docs/en_GB/document_library/Leaflet/2017/05/WC500226648.pdf. Accessed 14.11.2022.
4. Imraldi™ summary of product characteristics and package leaflet.
5. Terveyskylä.fi. Mitä ovat biosimilaarit? <https://www.terveyskyla.fi/laaketalo/ajankohtaista/mit%C3%A4-ovat-biosimilaarit>. Accessed 5.12.2022.
6. Lääketeollisuus ry. Biosimilaarit. <https://www.laaketeollisuus.fi/tietoa-laakkeista/biosimilaarit.html>. Accessed 5.12.2022.
7. Fimea Biosimilaarit. https://www.fimea.fi/laaketurvallisuus_ja_tieto/biosimilaarit. Accessed 13.12.2022.

Reporting side effects: If you experience side effects, please talk to your doctor pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. This will allow quick identification of new safety information