



**Remsima**<sup>®</sup>  
Infliximab

SUBCUTANEOUS

## Your guide to Remsima<sup>®</sup>

This booklet has been developed by Celltrion Healthcare to support patients prescribed with Remsima<sup>®</sup> subcutaneous formulation. Please note that the information provided in this booklet does not replace professional medical advice, please speak with your physician or other healthcare professional for any questions on the product.

 HEALTHCARE  
**CELLTRION**

# Remsima® subcutaneous injection

## infliximab

- Ingredient<sup>1</sup>** Remsima® contains the active ingredient infliximab.
- Indications<sup>1</sup>** Remsima® SC provides a subcutaneous infliximab treatment option for adults with Crohn's Disease (CD), Ulcerative Colitis (UC), Ankylosing Spondylitis (AS), Psoriatic Arthritis (PsA), Plaque Psoriasis (PsO) and Rheumatoid Arthritis (RA).
- Dosage<sup>1</sup>** Remsima® comes in a pre-filled dose of 120 mg, which is injected under the skin. The recommended dose is one injection (120 mg) every 2 weeks, regardless of weight.
- **If you are new to using infliximab treatment**, your doctor will start your treatment with two infliximab intravenous infusions, administered 2 weeks apart (at week 0 and 2). Four weeks later (week 6), you will be started on Remsima® subcutaneous injection.
  - **If you are switching from intravenous infliximab treatment**, you can switch to Remsima® 8 weeks after your last infusion. Your healthcare professional will give you your first dose.



## How does Remsima® (infliximab) work?<sup>1</sup>

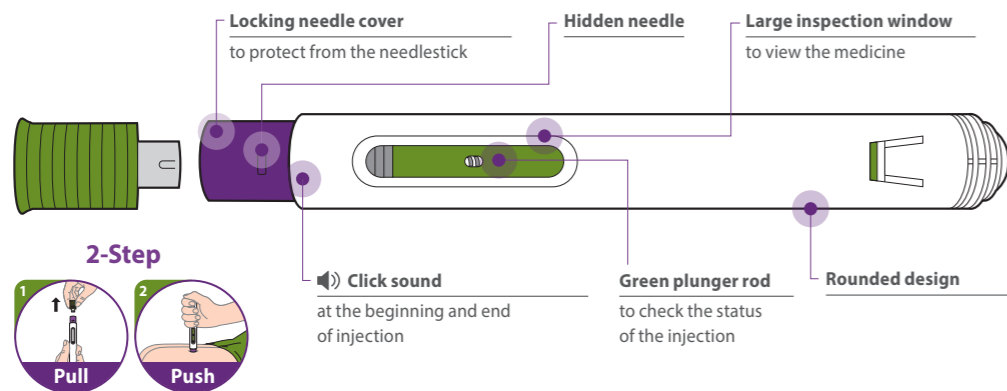
- Remsima® contains the active ingredient infliximab.
- Infliximab attaches to a special protein in the body called tumour necrosis factor alpha (TNF- $\alpha$ ), which is involved in causing inflammation.
- By blocking TNF- $\alpha$ , infliximab can reduce inflammation and disease symptoms.

Abbreviation: TNF- $\alpha$ : tumor necrosis factor alpha

## PRE-FILLED PEN

### CHARACTERISTICS

- ✓ **2-STEP** operation<sup>1</sup>
- ✓ **LATEX FREE**<sup>1,2</sup>
- ✓ **CITRATE FREE**<sup>1</sup>
- ✓ **UP TO 28 DAYS** stability outside the fridge<sup>1\*</sup>

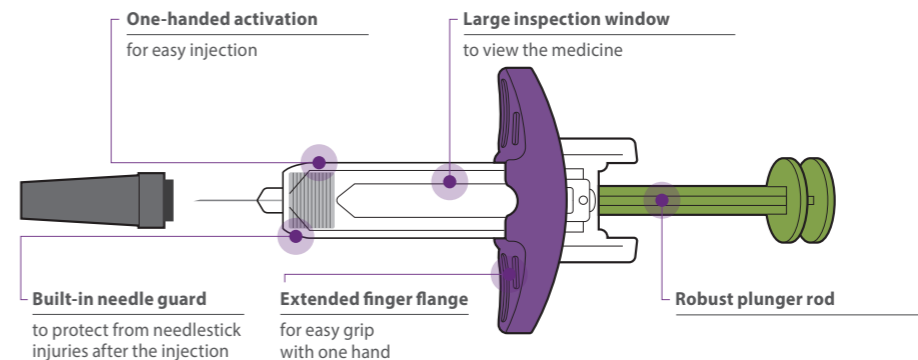


\*The Remsima® device should be stored in its carton inside the refrigerator; however, it may be stored at temperatures up to a maximum of 25°C for a single period of up to 28 days, but then must be discarded if not used. Remsima® must not be returned to refrigerated storage after being outside the fridge.

## PRE-FILLED SYRINGE WITH NEEDLE GUARD

### CHARACTERISTICS

- ✓ **BUILT-IN NEEDLE GUARD** to protect from needle stick injuries after the injection<sup>1</sup>
- ✓ **LATEX FREE**<sup>1,2</sup>
- ✓ **UP TO 28 DAYS** stability outside the fridge<sup>1\*</sup>
- ✓ **MANUAL INJECTION CONTROL**<sup>1</sup>
- ✓ **CITRATE FREE**<sup>1</sup>



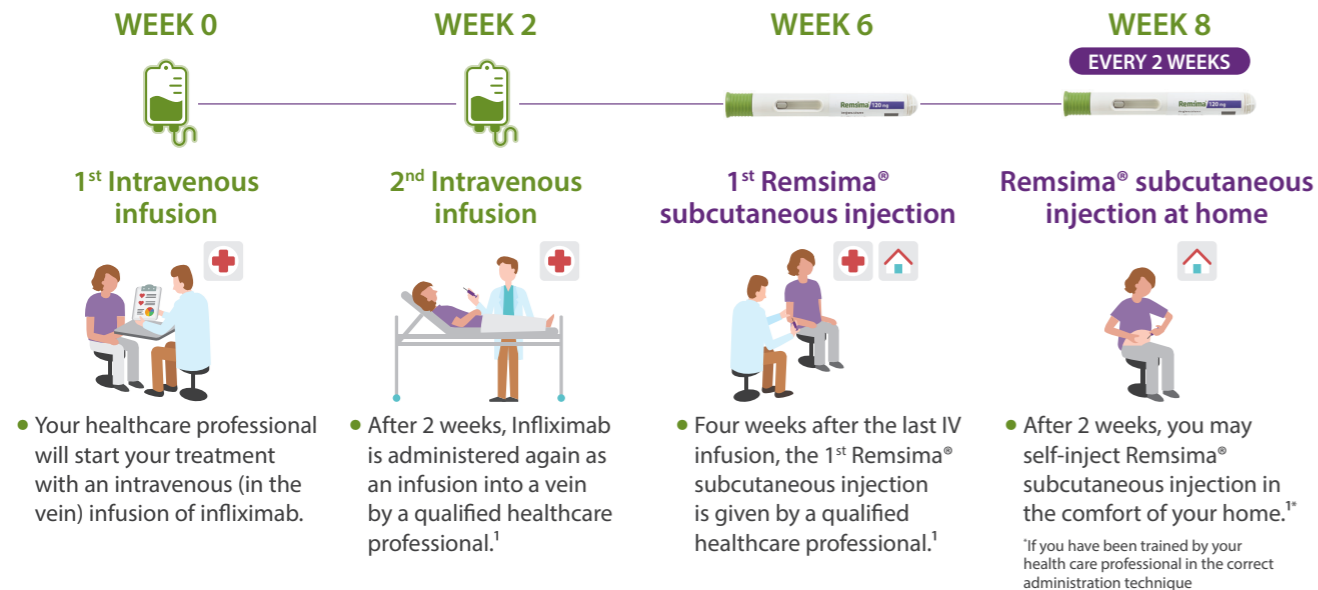
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# When can I administer Remsima®?

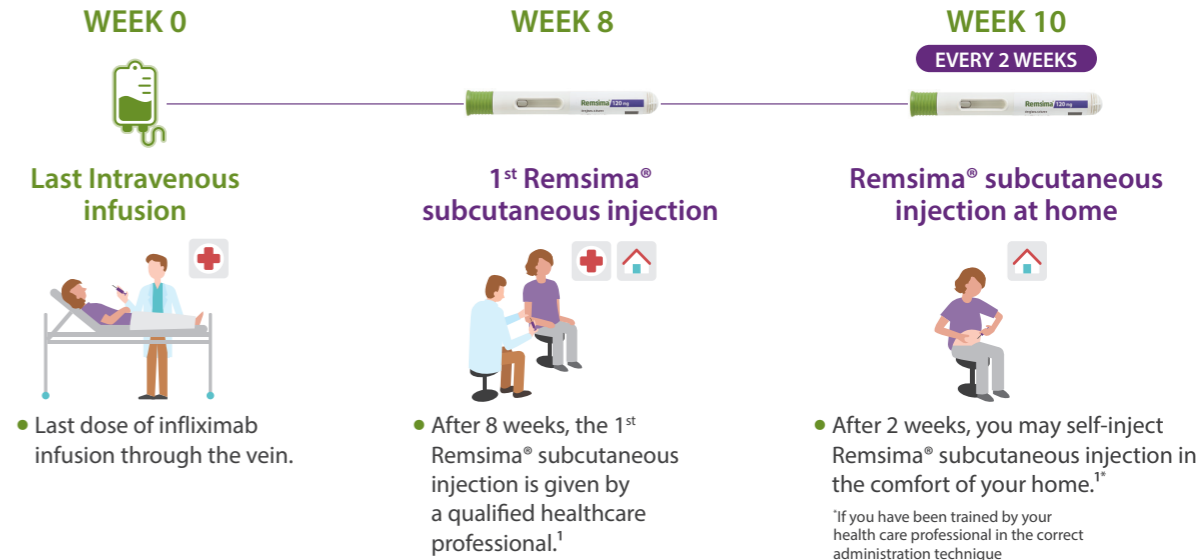
Always use Remsima® exactly as prescribed by your doctor. If you are unsure about the administration schedule, please check with your doctor. Remsima® contains the active ingredient infliximab.



## ① If you are starting infliximab treatment

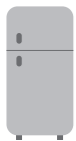


## ② If you are switching from infliximab IV infusion maintenance therapy



# Tips for using Remsima®

## How to store Remsima®<sup>1</sup>



Keep Remsima®  
in the refrigerator (2°C-8°C).



Keep Remsima® in **its carton** to  
protect it from light.



You can store Remsima® in its carton **outside the refrigerator up to 25°C for 28 days**. Do not return to the refrigerator again. In this case, discard the medicine if not used within 28 days or within the date printed on the carton whichever is earlier.

## Important information<sup>1</sup>

- ✓ Do not use Remsima® if you are allergic to infliximab or any other ingredients of this medicine.
- ✓ Do not use Remsima® past its expiry date.
- ✓ Check if the device is cracked or damaged before use.
- ✓ Tell your doctor immediately if you experience signs of an allergic reaction, heart problems, signs of infection or possible signs of cancer. Refer to consumer medicine information for more details.

# Frequently Asked Questions

## Q) What if I use more Remsima® than you should?<sup>1</sup>

- A) • If you use more than the prescribed dose, speak to your doctor, pharmacist or nurse immediately.
- Always keep the outer carton of the medicine, even if it is empty.

## Q) Who should not use Remsima®?<sup>1</sup>

- A) • If you are allergic to infliximab or any other ingredients of the medicine (listed in package leaflet).
- If you are allergic to mouse proteins.
  - If you have severe infections such as tuberculosis or infected abscesses, a repeating infection or have had repeating infections.
  - If you have moderate or severe heart failure and are not already using Remsima®.
  - If you are already taking another medicine for arthritis, which contains the substance called anakinra.
  - If you are not sure, talk to your doctor before injection, especially if you are pregnant or planning to become pregnant, have had any cancers, nervous system or blood disorders or are planning to have a vaccine.

# Frequently Asked Questions

## Q) What are the side effects of Remsima® subcutaneous injection?<sup>1</sup>

**A)** Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects are mild to moderate. However some patients may experience serious side effects and may require treatment. Side effects may also occur after your treatment with Remsima® has stopped.

**Do not be alarmed by the following list of possible side effects. You may not experience any of them.**

**During the injection of Remsima® the following reactions may occur:**

- fever or chills
- itchiness or hives
- chest pain
- low blood pressure
- high blood pressure
- shortness of breath.

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

- pain or tenderness in chest, muscles, joints or jaw
- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing

- fever
- muscle pains
- joint pains
- tiredness
- abnormal chest sounds
- rash
- itching
- symptoms that may indicate heart failure, e.g. shortness of breath, especially with exercise or lying down, or swelling of your feet
- injection site reactions such as: redness, pain, itching, swelling, hardening of the skin, bruising, coldness, pins and needles, irritation, rash, ulcer, bleeding under the skin or scarring.

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

- headache
- dizziness and lightheadedness
- fatigue
- fever
- rash
- hives
- itching
- sore throat
- coughing
- hoarseness
- shortness of breath
- chest pain
- back pain
- muscle pain
- abdominal pain

- indigestion
- diarrhoea
- weight loss, muscle wasting
- problems with urination
- changes in the way your heart beats, for example, if you notice it beating faster
- flushing
- dry skin or increased sweating
- fluid retention
- new onset of psoriasis, mainly on the soles of the feet and on palms
- worsening of rheumatoid arthritis.

# Frequently Asked Questions

**Remsima® may affect the normal immune response. There is a possibility that you may be more prone to infections. You will be watched closely for signs of infection.**

There have been rare cases where people taking infliximab have developed liver problems or cancers, including skin cancer. People with a lung disease called Chronic Obstructive Pulmonary Disease and who have a history of heavy smoking may have an increased risk for getting cancer while being treated with Remsima®.

## Q) What if I miss a dose of Remsima®?<sup>2</sup>

**A) If you miss a dose and the current date is 7 days or less since the date of the original scheduled dose**

- Take the missed dose immediately.
- Take your next dose on the originally scheduled date and thereafter every 2 weeks.
- Do not take a double dose on the same day to make up for a missed dose.

**If you miss a dose and the current date is 8 days or more after the date of the original scheduled dose**

- Do not take the missed dose.
- Take your next dose on the next originally planned date and thereafter every 2 weeks.

# Frequently Asked Questions

## Q) How should I discard the Remsima® injection device?<sup>1</sup>

- A)**
- Discard in an approved disposal container immediately after use.
  - If you do not have one, you may use a household container that is:
    - made of heavy-duty plastic with a tight-fitting, puncture-resistant lid.
  - Refer to the *Instructions for self injection brochure* for complete list of possible containers.
  - Do not throw away any medicines via wastewater or household waste.
  - Ask your pharmacist how to throw away medicines you no longer use.

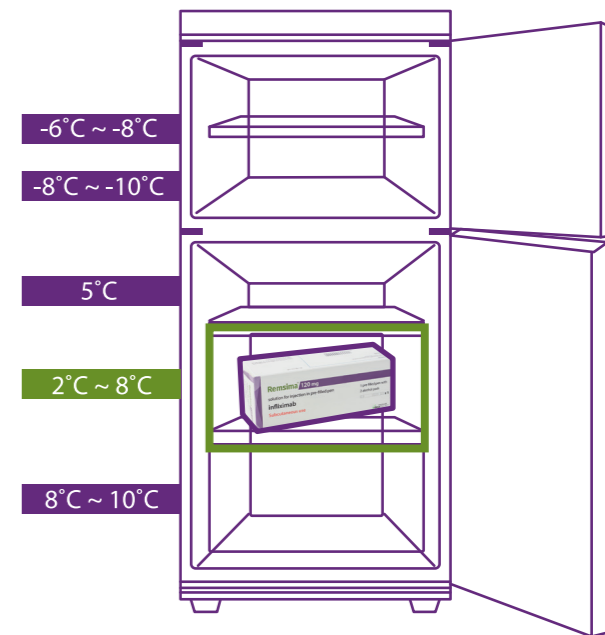
## Q) How long can Remsima® stay out of fridge?<sup>1</sup>

- A)**
- You can store your medicine in the original package outside of the refrigerator up to maximum of 25°C for up to 28 days.
  - Write the new expiry date on the carton including day/month/year.
  - Discard the medicine if not used by the new expiry date or the expiry date printed on the carton, whichever is earlier.
  - Do not return to refrigerated storage again.

# Frequently Asked Questions

## Q) How should I store Remsima®?<sup>1</sup>

- A)**
- Keep the medicine out of sight and reach of children.
  - Do not use the medicine after the expiry date written on the label and the carton after "EXP".  
The expiry date refers to the last day of that month.
  - After taking out a device from the carton, keep the remaining medicine in the fridge if there is any.
  - Store in a refrigerator (2°C-8°C). Do not freeze. Keep the medicinal product in its outer carton to protect from light.
  - It is highly recommended to store the medicine in the middle part of the refrigerator.



# Frequently Asked Questions

## Q) Where can I get more information about Remsima®?

Guide video on how to self-inject Remsima® using a pre-filled pen



Guide video on how to self-inject Remsima® pre-filled syringe (with needle guard)



Remsimate website for more patient information



Or visit [www.remsimate.com.au](http://www.remsimate.com.au) for more patient information using AUSTR number 326188

# Notes

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- Reference: 1.** Remsima® Consumer Medicine Information. Available at: <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2021-CMI-01618-1&d=202106111016933>. Accessed on 12-Jun-2021.
- 2.** Remsima® Approved Australian Product Information available at <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2020-PI-02540-1> Accessed 21 June 2023

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