REMSIMA® 120MG SOLUTION FOR INJECTION IN PRE-FILLED PEN (PFP)

Infliximab (120mg)

What is in this leaflet

What Remsima is used for

Remsima is used in adults for the following inflammatory diseases:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Psoriatic arthritis
- Psoriasis
- Crohn's disease
- Fistulizing Crohn's disease
- Ulcerative colitis.

How Remsima works

Remsima contains the active substance infliximab. Infliximab is a monoclonal antibody which belongs to a group of medicines called 'TNF blockers'.

Remsima works by selectively attaching to tumour necrosis factor (TNF) alpha and blocking its action, thereby reducing the inflammation in your body.

Before you use Remsima

– *When you must not use it*

You must not be given Remsima if

- you are allergic to infliximab or any of the other ingredients of this medicine,
- you are allergic to proteins that come from mice,
- you have tuberculosis (TB) or another serious infection such as pneumonia or sepsis (serious bacterial infection of the blood),
- you have heart failure that is moderate or severe.

Do not use Remsima if any of the above applies to you. If you are not sure, talk to your doctor before you are given Remsima.

Children and adolescents

Do not give this medicine to children and adolescents under 18 years of age.

– *Before you start to use it*

Pregnancy and breast-feeding

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Remsima should only be used during pregnancy or while breast-feeding if your doctor feels it is necessary for you.
- You should avoid getting pregnant when you are being treated with Remsima and for 6 months after you stop being treated with it. Discuss the use of contraception during this time with your doctor.
- If you received Remsima 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 healthcare professionals about your Remsima use before your baby is given any vaccine. If you received Remsima while pregnant, live vaccines such as the the BCG vaccine should not be given to your baby within 12 months after birth, unless your baby's doctor recommends otherwise.
- If you are breast-feeding, live vaccines should not be given to your baby while you are breast-feeding unless your baby's doctor recommends otherwise.
- If your baby has continual fevers or infections, contact your baby's doctor immediately.

– *Taking other medicines*

Patients who have inflammatory diseases already take medicines to treat their problem. These medicines may cause side effects. Your doctor will advise you what other medicines you must keep using while you are having Remsima.

Tell your doctor if you are using, have recently used or might use any other medicines, including any other medicines to treat Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis or psoriasis or medicines obtained without a prescription, such as vitamins and herbal medicines.

In particular, tell your doctor if you are using any of the following medicines:

- Medicines that affect your immune system.
- Kineret (which contains anakinra). Remsima and Kineret should not be used together.
- Orencia (which contains abatacept). Remsima and Orencia should not be used together.

While using Remsima you should not receive live vaccines.

If you are not sure if any of the above applies to you, talk to your doctor, pharmacist or nurse before using Remsima.

How to use Remsima

- Remsima 120 mg solution for injection is administered by injection under the skin (subcutaneous use) only. It is important to check the product labels to ensure that the correct formulation is being given as prescribed.
- The initial two intravenous infusions will be given to you by your doctor or nurse.
- After the first two intravenous infusions, the first dose of Remsima will be administered under the supervision of your doctor.

- After proper training, if you feel you are well-trained and confident to inject Remsima yourself, your doctor may allow you to inject subsequent doses of Remsima yourself at home.
- Talk to your doctor if you have any questions about giving yourself an injection.

Instruction for Use:

Remsima SC Pre-filled Pen:

About the Remsima pen

Parts of the pen (see Figure A):

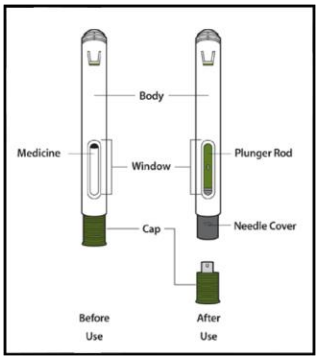

Figure A

• **Do not** remove the cap until you are ready to inject. Once you remove the cap, **do not** recap the pen.

Prepare for the injection

1. Gather the supplies for the injection.

a. Prepare a clean, flat surface, such as a table or countertop, in a well-lit area.

b. Remove the pen from the carton stored in your refrigerator.

c. Ensure you have the following supplies:

- Pen
- Alcohol swab
- Cotton ball or gauze*
- Adhesive bandage*
- Sharps disposal container*

*Items not included in the carton.

2. Inspect the pen. Do not use the pen if:

Do not use the pen if:

- It is cracked or damaged.
- The expiration date has passed.

3. Inspect the medicine (see Figure B).

The liquid should be clear and colourless to pale brown. **Do not** use the pen if the liquid is cloudy, discoloured or contains particles in it.

Note: You may see air bubbles in the liquid. This is normal.

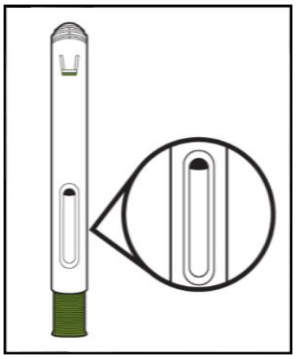

Figure B

4. Wait 30 minutes.

a. Leave the pen at room temperature for 30 minutes to allow it to naturally warm up.

Do not warm the pen using heat sources such as hot water or a microwave.

5. Choose an injection site (see Figure C).

a. Select an injection site. You may inject into:

- The front of the thighs.
- The abdomen except for the 5 cm around the belly button (navel).
- The outer area of the upper arms (caregiver ONLY).

Do not inject into skin that is within 5 cm of your belly button (navel), or is tender, damaged, bruised, or scarred. *Note: Rotate the injection site each time you give an injection. Each new injection site should be at least 3 cm away from the previous injection site.*

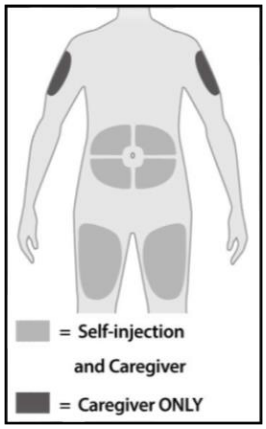

Figure C

6. Wash your hands.

a. Wash your hands with soap and water and dry them thoroughly.

7. Clean the injection site.

a. Clean the injection site with an alcohol swab.

b. Let the skin dry before injecting.

Do not blow on or touch the injection site again before giving the injection.

Give the injection

8. Remove the cap (see Figure D).

a. Pull the cap straight off and set it aside.

Do not touch the needle. Doing so may result in a needle stick injury.

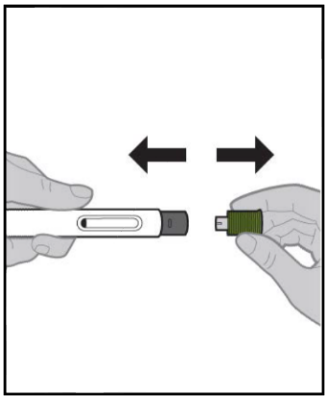

Figure D

9. Place the pen on the injection site (see Figure E).

a. Hold the pen so that you can see the window.

b. Without pinching or stretching the skin, place the pen over the injection site at a 90-degree angle.

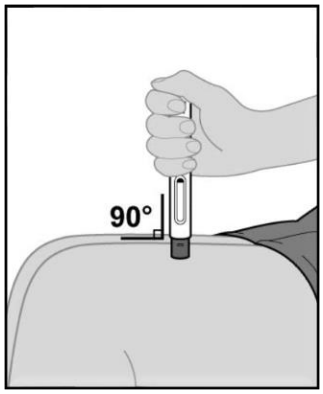

Figure E

10. Start the injection (see Figure F).

a. Press the pen **firmly** against the skin.

Note: When the injection starts you will hear the 1st loud "click" and the olive green plunger rod will begin to fill the window.

b. Keep holding the pen firmly against the skin and listen for the 2nd loud "click."

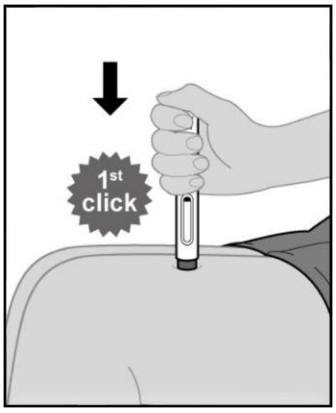

Figure F

11. Finish the injection (see Figure G).

a. After you hear the 2nd loud "click," **continue to hold the pen firmly against the skin and count slowly to at least five** to ensure you inject the full dose.

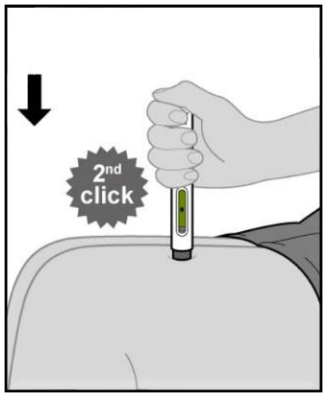

Figure G

12. Remove the pen from the injection site.

a. Look at the pen and confirm that the olive green plunger rod is filling the window completely.

b. Lift the pen from the injection site (see Figure H).

c. Gently press a cotton ball or gauze over the injection site and apply an adhesive bandage, if necessary.

Do not rub the injection site.

Note: After you remove the pen from the injection site, the needle will be automatically covered (see Figure I).

Note: If the olive green plunger rod does not fill the window completely, you did not receive your full dose. ***Do not*** *reuse the pen in this case. Call your healthcare provider immediately.*

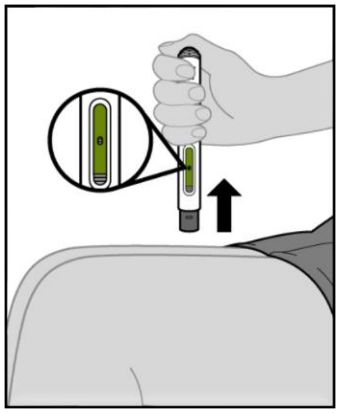

Figure H

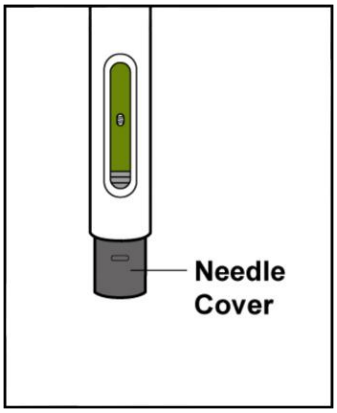

Figure I

After the injection

13. Dispose of the pen (see Figure J).

a. Put the used pen in an approved sharps disposal container immediately after use.

b. If you **do not** have an approved sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic;
- able to close with a tight-fitting,

puncture-resistant lid, without sharps being able to come out;

- upright and stable during use;
- leak-resistant; and
- properly labelled to warn of hazardous waste inside the container.

c. When your sharps disposal container is almost full, it should be disposed of in accordance with local requirements.

Do not recap the pen.

Note: Keep the pen and sharps disposal container out of the sight and reach of children.

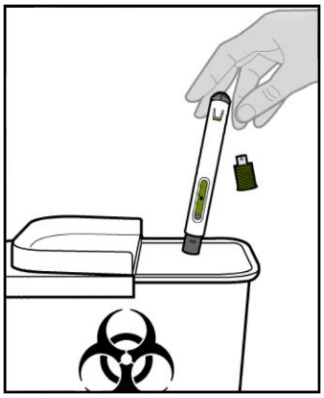

Figure J

– <u>*How much to use*</u>

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

Rheumatoid arthritis

Your doctor will start your treatment with two Remsima intravenous infusion doses of 3 mg for every kg of body weight, administered 2 weeks apart. After 4 weeks from the last intravenous infusion, you will be given Remsima via injection under the skin (subcutaneous injection).

The usual recommended dose of Remsima subcutaneous injection is 120 mg once every 2 weeks regardless of weight.

Psoriatic arthritis, ankylosing spondylitis and psoriasis

Your doctor will start your treatment with two Remsima intravenous infusion doses of 5 mg for every kg of body weight, administered 2 weeks apart. After 4 weeks from the last intravenous infusion, you will be given Remsima via injection subcutaneously.

The usual recommended dose of Remsima subcutaneous injection is 120 mg once every 2 weeks regardless of weight.

Crohn's disease and ulcerative colitis

Your doctor will start your treatment with two Remsima intravenous infusion doses of 5 mg for every kg of body weight, administered 2 weeks apart. After 4 weeks from the last intravenous infusion, you will be given Remsima via injection subcutaneously.

The usual recommended dose of Remsima subcutaneous injection is 120 mg once every 2 weeks regardless of weight.

− *When to use it*

Use the pen ONLY if your healthcare provider has trained you on the right way to prepare for and to give an injection.

− *How long to use it*

Ask your healthcare provider how long you will need to use this product.

− *If you forget to use it*

Missed dose for up to 7 days

If you miss a dose of Remsima for up to 7 days, after the original scheduled dose, you should take the missed dose immediately. Take your next dose on the next originally planned date and then follow the original dosing schedule.

Missed dose for 8 days or more

If you miss a dose of Remsima for 8 days or more, after the original scheduled dose, you should not take the missed dose. Take your next dose on the next originally planned date and then follow the original dosing schedule.

If you are not sure when to inject Remsima, call your doctor.

− *If you use too much (overdose)*

If you have used more Remsima than you should (either by injecting too much on a single occasion or by using it too frequently), talk to a doctor, pharmacist or nurse immediately. Always have the outer carton of the medicine with you, even if it is empty.

While you are using it

− *Things you must do*

- Read carefully these instructions before using the Remsima pen. Consult your healthcare provider if you have questions about using the Remsima pen.
- Use the pen ONLY if your healthcare provider has trained you on the right way to prepare for and to give an injection.
- Ask your healthcare provider how often you will need to give an injection.
- Rotate the injection site each time you give an injection. Each new injection site should be at least 3 cm away from the previous injection site.

− *Things you must not do*

- Do not use the pen if it has been dropped or is visibly damaged. A damaged pen may not function properly.
- Do not reuse the pen.
- Do not shake the pen at any time.

− *Things to be careful of*

Talk to your doctor before or during treatment with Remsima if you have:

- Had treatment with any medicine containing infliximab before
- Local injection site reactions
- Infections
- Tuberculosis (TB)
- Hepatitis B virus
- Heart problems
- Cancer and lymphoma
- Lung disease or heavy smoking
- Nervous system disease
- Abnormal skin openings (fistulae)
- Vaccinations
- Therapeutic infectious agents
- Operations or dental procedures
- Liver problems
- Low blood counts
- Immune system disorder

Side effects

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.

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

- Stomach pain, feeling sick
- Viral infections such as herpes or flu
- Upper respiratory infections such as sinusitis
- Headache
- Side effect due to an injection
- Pain.

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Remsima

− *Storage*

Store in a refrigerator (2°C - 8°C).

Do not freeze. Keep the medicinal product in its outer carton in order to protect from light.
The medicinal product may be stored at temperatures up to a maximum of 25°C for a period of up to 28 days. The medicinal product must be discarded if not used within the 28-day period.

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.

− *Disposal*
After use, place the pre-filled pen into a puncture resistant container and discard as required by local regulations.

Do not recycle the injecting device.

Always keep the medicinal product out of the sight and reach of children.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Product Description
− *What it looks like*
Remsima is a clear to opalescent, colourless to pale brown solution which is supplied as a single use pre-filled pen.

Pre-filled Pen: Each pack contains 1 pre-filled pen with 2 alcohol pads or 2 pre-filled pen with 2 alcohol pads.

− *Ingredients*

- The active substance is infliximab. Each 1 ml single dose pre-filled pen contains 120 mg of infliximab.
- The other ingredients are acetic acid, sodium acetate trihydrate, sorbitol, polysorbate 80 and water for injections.

− *MAL number*
MALXXXXXXXX

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