Package leaflet: Information for the user

Remsima 120 mg solution for injection in pre-filled pen
infliximab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- Your doctor will also give you a patient reminder card, which contains important safety information you need to be aware of before and during your treatment with Remsima.
- When starting a new card, keep this card as a reference for 4 months after your last dose of Remsima.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Remsima is and what it is used for

Remsima contains the active substance infliximab. Infliximab is a monoclonal antibody - a type of protein that attaches to a specific target in the body called TNF (tumour necrosis factor) alpha.

Remsima belongs to a group of medicines called 'TNF blockers'. It is used in adults for the following inflammatory diseases:
- Rheumatoid arthritis
- Psoriatic arthritis
- Ankylosing spondylitis (Bechterew's disease)
- Psoriasis
- Crohn's disease
- Ulcerative colitis.

Remsima works by selectively attaching to TNF alpha and blocking its action. TNF alpha is involved in inflammatory processes of the body so blocking it can reduce the inflammation in your body.

Rheumatoid arthritis
Rheumatoid arthritis is an inflammatory disease of the joints. If you have active rheumatoid arthritis you will first be given other medicines. If these medicines do not work well enough, you will be given Remsima which you will take with another medicine called methotrexate to:
- reduce the signs and symptoms of your disease,
- slow down the damage in your joints,
- improve your physical function.

Psoriatic arthritis
Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. If you have active psoriatic arthritis you will first be given other medicines. If these medicines do not work well enough, you will be given Remsima to:
- reduce the signs and symptoms of your disease,
- slow down the damage in your joints,
- improve your physical function.

Ankylosing spondylitis (Bechterew's disease)
Ankylosing spondylitis is an inflammatory disease of the spine. If you have ankylosing spondylitis you will first be given other medicines. If these medicines do not work well enough, you will be given Remsima to:
- reduce the signs and symptoms of your disease,
- improve your physical function.

Psoriasis
Psoriasis is an inflammatory disease of the skin. If you have moderate to severe plaque psoriasis, you will first be given other medicines or treatments, such as phototherapy. If these medicines or treatments do not work well enough, you will be given Remsima to reduce the signs and symptoms of your disease.

Ulcerative colitis
Ulcerative colitis is an inflammatory disease of the bowel. If you have ulcerative colitis you will first be given other medicines. If these medicines do not work well enough, you will be given Remsima to treat your disease.

Crohn's disease
Crohn's disease is an inflammatory disease of the bowel. If you have Crohn's disease you will first be given other medicines. If these medicines do not work well enough, you will be given Remsima to:
- treat active Crohn's disease,
- reduce the number of abnormal openings (fistulae) between your bowel and your skin that have not been controlled by other medicines or surgery.

2. What you need to know before you use Remsima

You must not use Remsima if
- you are allergic to infliximab or any of the other ingredients of this medicine (listed in section 6),
- 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.

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

<u>Had treatment with any medicine containing infliximab before</u>

- Tell your doctor if you have had treatment with medicines containing infliximab in the past and are now starting Remsima treatment again.
- If you have had a break in your treatment with infliximab of more than 16 weeks, there is a higher risk for allergic reactions when you start the treatment again.

Local injection site reactions

- Some patients receiving infliximab via injection under the skin have experienced local injection site reactions. Signs of a local injection site reaction can include redness, pain, itching, swelling, hardness, bruising, bleeding, cold sensation, tingling sensation, irritation, rash, ulcer, hives, blisters and scab on the skin of the injection site.
- Most of these reactions are mild to moderate and mostly resolve on their own within a day.

Infections

- Tell your doctor before you are given Remsima if you have an infection even if it is a very minor one.
- Tell your doctor before you are given Remsima if you have ever lived in or travelled to an area where infections called histoplasmosis, coccidioidomycosis, or blastomycosis are common. These infections are caused by specific types of fungi that can affect the lungs or other parts of your body.
- You may get infections more easily when you are being treated with Remsima. If you are 65 years of age or older, you have a greater risk.
- These infections may be serious and include tuberculosis, infections caused by viruses, fungi, bacteria or other organisms in the environment and sepsis that may be life-threatening.

Tell your doctor straight away if you get signs of infection during treatment with Remsima. Signs include fever, cough, flu-like signs, feeling unwell, red or hot skin, wounds or dental problems. Your doctor may recommend temporarily stopping Remsima.

Tuberculosis (TB)

- 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 or has TB.
- Your doctor will test you to see if you have TB. Cases of TB have been reported in patients treated with infliximab, even in patients who have already been treated with medicines for TB. Your doctor will record these tests on your patient reminder card.
- If your doctor feels that you are at risk for TB, you may be treated with medicines for TB before you are given Remsima.

Tell your doctor straight away if you get signs of TB during treatment with Remsima. Signs include persistent cough, weight loss, feeling tired, fever, night sweats.

Hepatitis B virus

- Tell your doctor before you are using Remsima if you are a carrier of hepatitis B or have ever had it.
- Tell your doctor if you think you might be at risk of contracting hepatitis B.
- Your doctor should test you for hepatitis B virus.
- Treatment with TNF blockers such as Remsima may result in reactivation of hepatitis B virus in patients who carry this virus, which can be life-threatening in some cases.
- If you experience reactivation of hepatitis B, your doctor may need to stop your treatment and may give you medicines such as effective antiviral therapy with supportive treatment.

Heart problems

- Tell your doctor if you have any heart problems, such as mild heart failure.
- Your doctor will want to closely monitor your heart.

Tell your doctor straight away if you get new or worsening signs of heart failure during treatment with Remsima. Signs include shortness of breath or swelling of your feet.

Cancer and lymphoma

- Tell your doctor before you are given Remsima if you have or have ever had lymphoma (a type of blood cancer) or any other cancer.
- Patients with severe rheumatoid arthritis, who have had the disease for a long time, may be at higher risk of developing lymphoma.
- Patients taking Remsima may have an increased risk of developing lymphoma or another cancer.
- Some patients who have received TNF-blockers, including infliximab have developed a rare type of cancer called hepatosplenic T-cell lymphoma. Of these patients, most were teenage boys or young men and most had either Crohn's disease or ulcerative colitis. This type of cancer has usually resulted in death. Almost all patients had also received medicines containing azathioprine or mercaptopurine in addition to TNF-blockers.
- Some patients treated with infliximab have developed certain kinds of skin cancer. If there are any changes in your skin or growths on the skin during or after therapy, tell your doctor.
- Some women being treated for rheumatoid arthritis with infliximab have developed cervical cancer. For women taking Remsima including those over 60 years of age, your doctor may recommend regular screening for cervical cancer.

Lung disease or heavy smoking

- Tell your doctor before you are given Remsima if you have a lung disease called chronic obstructive pulmonary disease (COPD) or if you are a heavy smoker.
- Patients with COPD and patients who are heavy smokers may have a higher risk of developing cancer with Remsima treatment.

Nervous system disease

- Tell your doctor before you are given Remsima if you have or have ever had a problem that affects your nervous system. This includes multiple sclerosis, Guillain-Barré syndrome, if you have fits or have been diagnosed with 'optic neuritis'.

Tell your doctor straight away if you get symptoms of a nerve disease during treatment with Remsima. Signs include changes in your vision, weakness in your arms or legs, numbness or tingling in any part of your body.

Abnormal skin openings

- Tell your doctor if you have any abnormal skin openings (fistulae) before you are given Remsima.

Vaccinations

- Talk to your doctor if you recently have had or are due to have a vaccine.
- You should receive recommended vaccinations before starting Remsima treatment. You may receive some vaccines during treatment with Remsima but you should not receive live vaccines (vaccines that contain a living but weakened infectious agent) while using Remsima because they may cause infections.
- If you received Remsima while you were pregnant, your baby may also be at higher risk for getting an infection with live vaccines for up to six months after birth. It is important that you tell your baby's doctors and other health care professionals about your Remsima use so they can decide when your baby should receive any vaccine, including live vaccines such as BCG (used to prevent tuberculosis). For more information see section on Pregnancy and breast-feeding.

Therapeutic infectious agents

- Talk to your doctor if you have recently received or are scheduled to receive treatment with a therapeutic infectious agent (such as BCG instillation used for the treatment of cancer).

Operations or dental procedures

- Tell your doctor if you are going to have any operations or dental procedures.
- Tell your surgeon or dentist that you are having treatment with Remsima by showing them your patient reminder card.

Liver problems

- Some patients receiving infliximab have developed serious liver problems.
- Tell your doctor straight away if you get symptoms of liver problems during treatment with Remsima. Signs include yellowing of the skin and eyes, dark-brown coloured urine, pain or swelling in the upper right side of the stomach area, joint pain, skin rashes, or fever.

Low blood counts

- In some patients receiving infliximab, the body may not make enough of the blood cells that help fight infections or help stop bleeding.
- Tell your doctor straight away if you get symptoms of low blood counts during treatment with Remsima. Signs include persistent fever, bleeding or bruising more easily, small red or purple spots caused by bleeding under the skin, or looking pale.

Immune system disorder

- Some patients receiving infliximab have developed symptoms of an immune system disorder called lupus.
- Tell your doctor straight away if you develop symptoms of lupus during treatment with Remsima. Signs include joint pain or a rash on cheeks or arms that is sensitive to the sun.

Children and adolescents
Do not give this medicine to children and adolescents under 18 years of age because there are no data that show that this medicine is safe and works in this age group.

Other medicines and Remsima
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 were using Remsima during pregnancy, tell your baby's doctor and other health care professionals caring for your baby about your Remsima use before the baby receives any vaccines.

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

Pregnancy, breast-feeding and fertility
- 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 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.
- Do not breast-feed when you are being treated with Remsima or for 6 months after your last treatment with Remsima.
- 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, giving BCG vaccine (used to prevent tuberculosis) to your baby within 6 months after birth may result in infection with serious complications, including death. Live vaccines such as BCG should not be given to your baby within 6 months after birth. For more information see section on vaccination.
- Severely decreased numbers of white blood cells have been reported in infants born to women treated with infliximab during pregnancy. If your baby has continual fevers or infections, contact your baby's doctor immediately.

Driving and using machines
Remsima is not likely to affect your ability to drive or use tools or machines. If you feel tired, dizzy, or unwell after having Remsima, do not drive or use any tools or machines.

Remsima contains sodium and sorbitol
This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free' and 45 mg sorbitol in each 120 mg dose.

3. How to use Remsima

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 (given to you into a vein, usually in your arm, over a period of 2 hours). They are administered 2 weeks apart via intravenous infusion. 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 (Bechterew's disease) and psoriasis
Your doctor will start your treatment with two Remsima intravenous infusion doses of 5 mg for every kg of body weight (given to you into a vein, usually in your arm, over a period of 2 hours). They are administered 2 weeks apart via intravenous infusion. 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.

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 (given to you into a vein, usually in your arm, over a period of 2 hours). They are

administered 2 weeks apart via intravenous infusion. 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.

How Remsima is given
- 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. You will find detailed **"Instructions for Use"** at the end of this leaflet.

If you use more Remsima than you should
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.

If you forget to use Remsima

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 thereafter bi-weekly.

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 thereafter bi-weekly.

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

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible 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.

Tell your doctor straight away if you notice any of the following:
- **Signs of an allergic reaction** such as swelling of your face, lips, mouth or throat which may cause difficulty in swallowing or breathing, skin rash, hives, swelling of the hands, feet or ankles. Some of these reactions may be serious or life-threatening. An allergic reaction could happen within 2 hours of your injection or later. More signs of allergic side effects that may happen up to 12 days after your injection include pain in the muscles, fever, joint or jaw pain, sore throat or headache.
- **Signs of a local injection site reaction** such as redness, pain, itching, swelling, hardness, bruising, bleeding, cold sensation, tingling sensation, irritation, rash, ulcer, hives, blisters and scab.

- **Signs of a heart problem** such as chest discomfort or pain, arm pain, stomach pain, shortness of breath, anxiety, lightheadedness, dizziness, fainting, sweating, nausea (feeling sick), vomiting, fluttering or pounding in your chest, a fast or a slow heartbeat, and swelling of your feet.
- **Signs of infection (including TB)** such as fever, feeling tired, cough which may be persistent, shortness of breath, flu-like symptoms, weight loss, night sweats, diarrhoea, wounds, collection of pus in the gut or around the anus (abscess), dental problems or burning sensation when urinating.
- **Possible signs of cancer** including but not limited to swelling of lymph nodes, weight loss, fever, unusual skin nodules, changes in moles or skin colouring, or unusual vaginal bleeding.
- **Signs of a lung problem** such as coughing, breathing difficulties or tightness in the chest.
- **Signs of a nervous system problem (including eye problems)** such as signs of a stroke (sudden numbness or weakness of your face, arm or leg, especially on one side of your body; sudden confusion, trouble speaking or understanding; trouble seeing in one or both eyes, trouble walking, dizziness, loss of balance or coordination or a severe headache), fits, tingling/numbness in any part of your body, or weakness in arms or legs, changes in eyesight such as double vision or other eye problems.
- **Signs of a liver problem** (including hepatitis B infection when you have had hepatitis B in the past) such as yellowing of the skin or eyes, dark-brown coloured urine, pain or swelling in the upper right side of the stomach area, joint pain, skin rashes, or fever.
- **Signs of an immune system disorder called lupus** such as joint pain or a rash on cheeks or arms that is sensitive to the sun (lupus) or cough, shortness of breath, fever or skin rash (sarcoidosis).
- **Signs of low blood counts** such as persistent fever, bleeding or bruising more easily, small red or purple spots caused by bleeding under the skin, or looking pale.
- **Signs of serious skin problems** such as reddish-target-like spots or circular patches often with central blisters on the trunk, large areas of peeling and shedding (exfoliating) skin, ulcers of mouth, throat, nose, genitals and eyes or small pus-filled bumps that can spread over the body. These skin reactions can be accompanied by fever.

Tell your doctor straight away if you notice any of the above.

The following side effects have been observed with Remsima:

Very common: may affect more than 1 in 10 people
- 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.

Common: may affect up to 1 in 10 people
- Changes in how your liver works, increase in liver enzymes (shown in blood tests)
- Lung or chest infections such as bronchitis or pneumonia
- Difficult or painful breathing, chest pain
- Bleeding in the stomach or intestines, diarrhoea, indigestion, heartburn, constipation
- Nettle-type rash (hives), itchy rash or dry skin
- Balance problems or feeling dizzy
- Fever, increased sweating
- Circulation problems such as low or high blood pressure
- Bruising, hot flush or nosebleed, warm, red skin (flushing)
- Feeling tired or weak
- Bacterial infections such as blood poisoning, abscess or infection of the skin (cellulitis)
- Infection of the skin due to a fungus

- Blood problems such as anaemia or low white blood cell count
- Swollen lymph nodes
- Depression, problems sleeping
- Eye problems, including red eyes and infections
- Fast heart beat (tachycardia) or palpitations
- Pain in the joints, muscles or back
- Urinary tract infection
- Psoriasis, skin problems such as eczema and hair loss
- Reactions at the injection site such as pain, swelling, redness or itching
- Chills, a build-up of fluid under the skin causing swelling
- Feeling numb or having a tingling feeling.

Uncommon: may affect up to 1 in 100 people
- Shortage of blood supply, swelling of a vein
- Collection of blood outside the blood vessels (haematoma) or bruising
- Skin problems such as blistering, warts, abnormal skin colouration or pigmentation, or swollen lips, or thickening of the skin, or red, scaly, and flaky skin
- Severe allergic reactions (e.g. anaphylaxis), an immune system disorder called lupus, allergic reactions to foreign proteins
- Wounds taking longer to heal
- Swelling of the liver (hepatitis) or gall bladder, liver damage
- Feeling forgetful, irritable, confused, nervous
- Eye problems including blurred or reduced vision, puffy eyes or sties
- New or worsening heart failure, slow heart rate
- Fainting
- Convulsions, nerve problems
- A hole in the bowel or blockage of the intestine, stomach pain or cramps
- Swelling of your pancreas (pancreatitis)
- Fungal infections such as yeast infection, or fungal infection of the nails
- Lung problems (such as oedema)
- Fluid around the lungs (pleural effusion)
- Narrowed airway in the lungs, causing difficulty breathing
- Inflamed lining of the lung, causing sharp chest pains that feel worse with breathing (pleurisy)
- Tuberculosis
- Kidney infections
- Low platelet count, too many white blood cells
- Infections of the vagina
- Blood test result showing ‘antibodies’ against your own body.

Rare: may affect up to 1 in 1,000 people
- A type of blood cancer (lymphoma)
- Your blood not supplying enough oxygen to your body, circulation problems such as narrowing of a blood vessel
- Inflammation of the lining of the brain (meningitis)
- Infections due to a weakened immune system
- Hepatitis B infection when you have had hepatitis B in the past
- Inflamed liver caused by a problem with the immune system (autoimmune hepatitis)
- Liver problem that causes yellowing of the skin or eyes (jaundice)
- Abnormal tissue swelling or growth
- Severe allergic reaction that may cause loss of consciousness and could be life-threatening (anaphylactic shock)
- Swelling of small blood vessels (vasculitis)
- Immune disorders that could affect the lungs, skin and lymph nodes (such as sarcoidosis)
- Collections of immune cells resulting from an inflammatory response (granulomatous lesions)

- Lack of interest or emotion
- Serious skin problems such as toxic epidermal necrolysis, Stevens-Johnson syndrome and acute generalised exanthematous pustulosis
- Other skin problems such as erythema multiforme, blisters and peeling skin, or boils (furunculosis)
- Serious nervous system disorders such as transverse myelitis, multiple sclerosis-like disease, optic neuritis and Guillain-Barré syndrome
- Inflammation in the eye that may cause changes in the vision, including blindness
- Fluid in the lining of the heart (pericardial effusion)
- Serious lung problems (such as interstitial lung disease)
- Melanoma (a type of skin cancer)
- Cervical cancer
- Low blood counts, including a severely decreased number of white blood cells
- Small red or purple spots caused by bleeding under the skin
- Abnormal values of a blood protein called 'complement factor' which is part of the immune system
- Lichenoid reactions (itchy reddish-purple skin rash and/or threadlike white-grey lines on mucous membranes).

Not known: frequency cannot be estimated from the available data
- Cancer
- A rare blood cancer affecting mostly young men (hepatosplenic T-cell lymphoma)
- Liver failure
- Merkel cell carcinoma (a type of skin cancer)
- Kaposi's sarcoma, a rare cancer related to infection with human herpes virus 8. Kaposi's sarcoma most commonly appears as purple lesions on the skin.
- Worsening of a condition called dermatomyositis (seen as a skin rash accompanying muscle weakness)
- Heart attack
- Stroke
- Temporary loss of sight during or within 2 hours of infusion
- Infection due to a live vaccine because of a weakened immune system.

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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Remsima

- 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.
- Store in a refrigerator (2°C - 8°C). Do not freeze. Keep the medicinal product in its outer carton to protect from light.
- This medicine can also be stored in the original carton outside of refrigerated storage up to a maximum of 25°C for a single period of up to 28 days, but not beyond the original expiry date. In this situation, do not return to refrigerated storage again. Write the new expiry date on the carton including day/month/year. Discard this medicine if not used by the new expiry date or the expiry date printed on the carton, whichever is earlier.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Remsima contains
- 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.

What Remsima looks like and contents of the pack
Remsima is a clear to opalescent, colourless to pale brown solution which is supplied as a single use pre-filled pen.

Each pack contains 1 pre-filled pen with 2 alcohol pads, 2 pre-filled pens with 2 alcohol pads, 4 pre-filled pens with 4 alcohol pads or 6 pre-filled pens with 6 alcohol pads.

Not all pack sizes may be marketed.

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

7. Instructions for use

Read carefully these instructions before using the Remsima pen. Consult your healthcare provider if you have questions about using the Remsima pen.

Important information

- 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.

- **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.

About the Remsima pen

Parts of the pen (see *Figure A*):

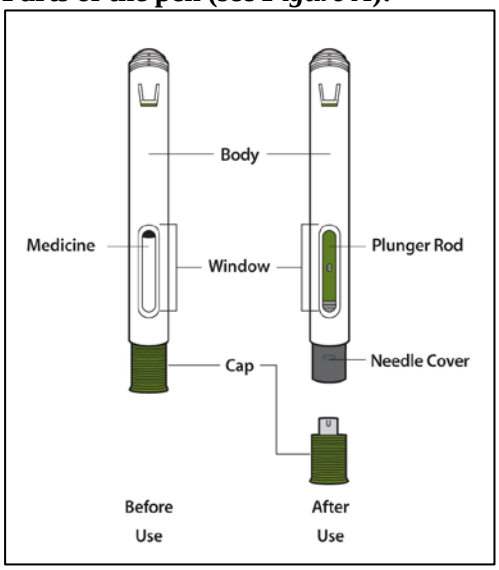

Figure A

- **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:

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

3. Inspect the medicine (see *Figure B*).

Do not use the pen if the liquid is different to clear colourless or pale brown or contains particles in it.

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

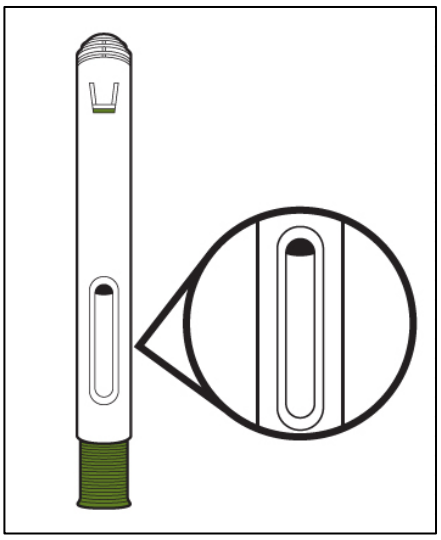

Figure B

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.

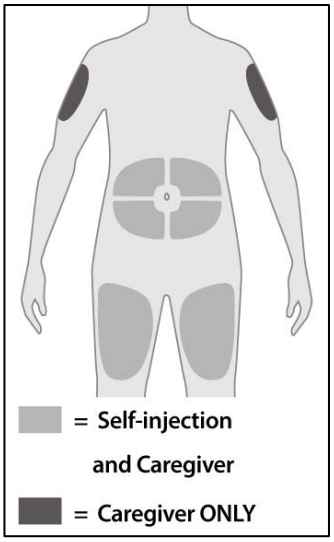

Figure C

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 olive green cap straight off and set it aside.

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

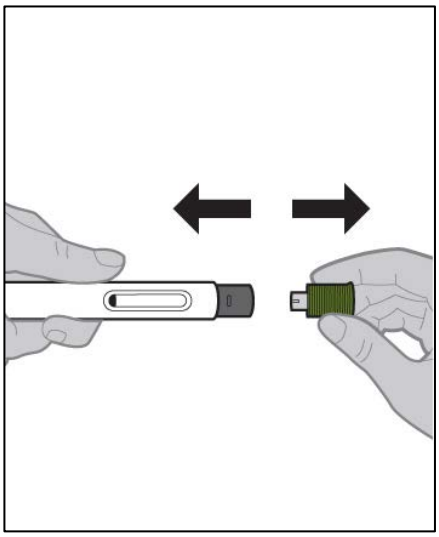

Figure D

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.

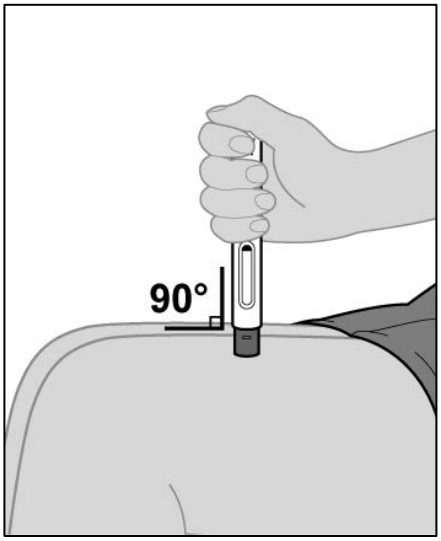

Figure E

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."

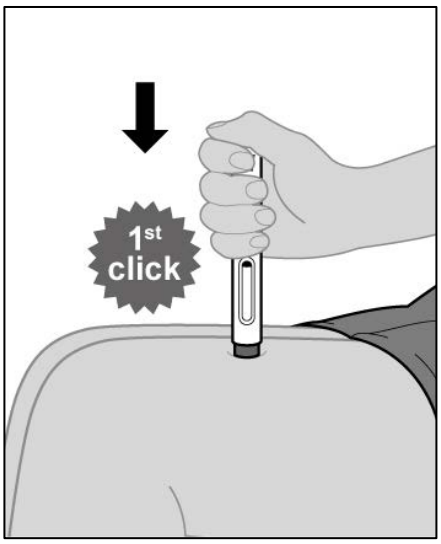

Figure F

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.

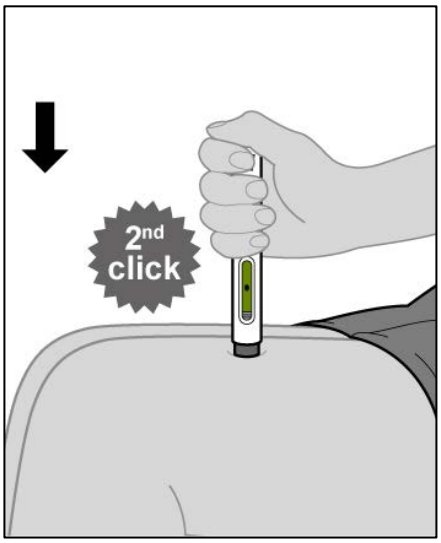

Figure G

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.

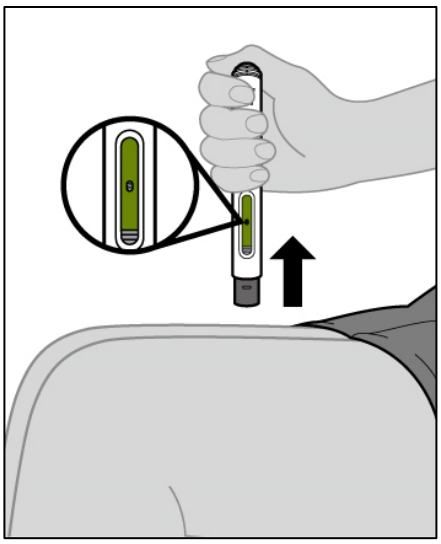

Figure H

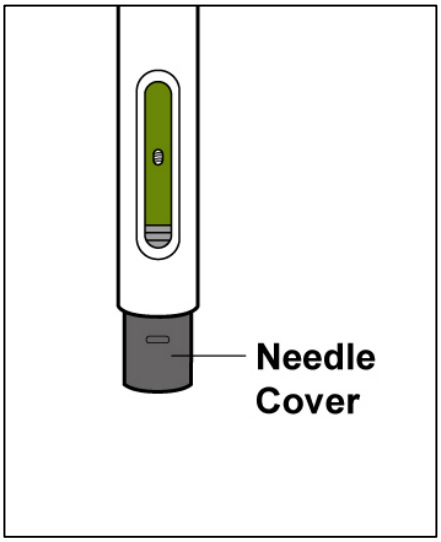

Figure I

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.

Figure J

Do not recap the pen.

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