REMSIMA®

Active ingredient: *Infliximab*

Infliximab 120mg solution for injection in pre-filled syringe/ pre-filled syringe with automatic needle-guard

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using REMSIMA?

REMSIMA contains the active ingredient infliximab. REMSIMA is used to reduce the signs and symptoms of rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and ulcerative colitis. REMSIMA is also used to treat moderate to severe psoriasis and Crohn's disease.

For more information, see Section 1. Why am I using REMSIMA? in the full CMI.

2. What should I know before I use REMSIMA?

Do not use if you have ever had an allergic reaction to mouse proteins or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use REMSIMA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with REMSIMA and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use REMSIMA?

REMSIMA 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 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.

More instructions can be found in Section 4. How do I use REMSIMA? in the full CMI.

5. What should I know while using REMSIMA?

Things you should do	• Remind any doctor, nurse, dentist or pharmacist you visit that you are using REMSIMA before you undergo any surgical procedures or receive any vaccinations. • Tell your doctor, nurse or pharmacist if the medicine starts to upset you or your symptoms become worse. • Tell your doctor if symptoms of tuberculosis, hepatitis B or any other infection appears. • Tell your doctor if you are receiving therapeutic infectious agents for the treatment of cancer. • Continue to take adequate contraceptive measures to avoid pregnancy.
Things you should be careful of	• Tell your doctor if you think you have an infection. • Tell your doctor immediately if you develop a skin rash or hives. • If you suffer from congestive heart failure, tell your doctor immediately if your condition worsens.
Driving or using machines	• REMSIMA is unlikely to make you drowsy. If you are tired, do not drive a car or work with machinery.

For more information, see Section 5. What should I know while using REMSIMA? in the full CMI.

6. Are there any side effects?

REMSIMA may cause side effects, including but not limited to: propensity to viral infections, fever, headache, dizziness, flushing, bronchitis, pneumonia, difficulty to breathe, sinusitis, nausea, diarrhoea, abdominal pain, rash, urticaria, increased sweating, dry skin, fatigue, chest pain and injection site related reactions.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

REMSIMA®

Active ingredient: *Infliximab*

Infliximab 120mg sloution for injection in pre-filled syringe

Consumer Medicine Information (CMI)

This leaflet provides important information about using REMSIMA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using REMSIMA.**

Where to find information in this leaflet:

1. Why am I using REMSIMA?

REMSIMA contains the active ingredient infliximab.

REMSIMA is an approved biosimilar medicine. Comparability in safety, efficacy and quality between REMSIMA and the reference product has been established.

Infliximab is a monoclonal antibody that is produced from human and mouse proteins by recombinant technology. Monoclonal antibodies are proteins that recognise and bind to certain special proteins in the body.

Infliximab acts by binding to a special protein in the body called tumour necrosis factor alpha (TNFα).

In people with diseases such as, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and psoriasis, the body produces too much TNFα, which can cause the body's immune system to attack normal healthy parts of the body.

REMSIMA can block the damage caused by too much TNFα.

Rheumatoid arthritis

Rheumatoid arthritis is an inflammatory disease of the joints. REMSIMA is used to reduce the signs and symptoms of rheumatoid arthritis and to prevent damage to the joints. You will also be given a disease-modifying medicine called methotrexate.

Ankylosing Spondylitis

Ankylosing spondylitis is an inflammatory disease of the spine. REMSIMA can reduce the signs and symptoms of ankylosing spondylitis, thereby improving physical function.

Psoriatic arthritis

Psoriatic arthritis is an inflammatory disease of the joints in which psoriasis usually occurs in association with arthritis. Often the fingers and toes are affected, although it may occur in other parts of the body. REMSIMA is used to reduce the signs and symptoms of psoriatic arthritis and improve the physical function in adults who have not responded well enough to previous treatments with other disease-modifying anti-rheumatic drugs (DMARDS).
REMSIMA may be given alone or in combination with methotrexate.

Psoriasis

Psoriasis is an inflammatory disease of the skin. REMSIMA is used to treat patients with moderate to severe psoriasis who have not responded well enough to treatments such as phototherapy or conventional systemic treatments, or when these treatments are not appropriate.

Crohn's disease

Crohn's disease is a chronic inflammatory disease of the bowel. It may also affect any part of the gut. REMSIMA is used to treat moderate to severe Crohn's disease in adult patients who have not responded well enough to other treatments.

REMSIMA can also reduce the number of abnormal openings from the bowel through the skin (called draining enterocutaneous fistula), a common complication of Crohn's disease.

Ulcerative Colitis

Ulcerative colitis is an inflammatory disease of the bowel. REMSIMA is used to treat the signs and symptoms of ulcerative colitis in adult patients who have not responded well enough to other treatments.

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

Your doctor, however, may prescribe REMSIMA for another purpose.

Ask your doctor if you have any questions about why REMSIMA has been prescribed for you.

2. What should I know before I use REMSIMA?

Warnings

Do not use REMSIMA if:

- you have an allergy to mouse proteins or any of the ingredients listed at the end of this leaflet.

  Some of the symptoms of an allergic reaction to REMSIMA may include skin rash, hives, fatigue, wheezing, difficulty in breathing, and/or low blood pressure.
- you have severe infections such as tuberculosis and infected abscesses, a repeating infection or have had repeating infections.
- you are already taking another medicine for arthritis,

which contains the substance called anakinra.

If you have never been given REMSIMA and have congestive heart failure, you should not use it.

Check with your doctor if you:

- currently have an infection, or if you are prone to infections, or if you have a history of infections

  REMSIMA may affect the normal immune response. You might get infections more easily. Some cases of serious infections, including tuberculosis (TB) and sepsis have been reported in patients treated with REMSIMA.
- have ever had or been in close contact with TB, even if you were treated for it.
- have ever had or had been in close contact with hepatitis B

  Reactivation of hepatitis B have been reported in people treated with TNFα blockers. However, these reports are very rare.
- have lived in or travelled to an area where fungal infections called histoplasmosis, coccidioidomycosis, or blastomycosis are common. Ask your doctor if you don't know if these infections are common in the area in which you have lived in or travelled to.

  These infections are caused by fungus that can affect the lungs or other parts of your body.
- have had cancer

  A type of blood cancer called lymphoma has been reported in patients receiving TNF-blockers. The reports are rare but are more frequent than expected for people in general. Cancers, other than lymphoma, have also been reported.
- have a long history of Crohn's disease rheumatoid arthritis, ankylosing spondylitis or psoriatic arthritis, especially if you have a highly active disease and/or have been taking medicine that reduces the activity of the body's natural defences.

  You may be more likely to develop infections and lymphomas than people in general, even without receiving TNF-blockers such as REMSIMA.
- have or have had a disease that affects the nervous system such as multiple sclerosis and seizures, or if you experience any numbness, weakness, tingling, or sight disturbances.
- suffer from congestive heart failure.

  Steps must be taken to monitor any changes to your condition during treatment with REMSIMA.
- have ongoing blood disorders or a history of blood disorders.
- are scheduled to receive any vaccines Patients receiving REMSIMA should not receive some types of vaccines. If possible, you should have all of your vaccines brought up to date before starting treatment with REMSIMA.

Your doctor will discuss with you the benefits of using REMSIMA against the potential risks.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you:

- **are pregnant or intend to become pregnant.**

Treatment with REMSIMA is not recommended while you are pregnant. REMSIMA crosses the placenta and has been detected in the bloodstream of infants for up to 12 months following birth.

You must use adequate contraception for at least 6 months after receiving the last REMSIMA injection to avoid falling pregnant.

- **are breast-feeding**

REMSIMA has been detected in breast milk. Your doctor will discuss with you if the benefit of REMSIMA treatment for you outweighs the potential risk to your infant while breast feeding.

3. What if I am taking other medicines?

Tell your doctor if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may affect the way other medicines work.

Do not use REMSIMA if you are already taking another medicine for arthritis, which contains the substance anakinra.

Tell your doctor if you are already taking another medicine for arthritis which contains the substance abatacept.

Tell your doctor if you are receiving other treatments:

- for rheumatoid arthritis
- for ankylosing spondylitis
- for psoriatic arthritis
- for psoriasis, such as phototherapy or other treatments
- for Crohn's disease or ulcerative colitis
- to prevent rejection in organ transplantation**.**

Tell your doctor you are taking REMSIMA before receiving any vaccinations.

Some vaccinations should not be given while you are being treated with REMSIMA.

Your doctor or pharmacist will be able to tell you what to do when being given REMSIMA with other medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect REMSIMA.

4. How do I use REMSIMA?

How REMSIMA is given

REMSIMA 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.

For patients with rheumatoid arthritis, your doctor or nurse will start the treatment with or without two intravenous infusions. For patients with Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis or psoriasis, two REMSIMA infusion doses will be given to start your REMSIMA treatment.

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.

A period of observation follows treatment.

Rheumatoid arthritis

Your doctor may start your treatment with or without 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). If REMSIMA intravenous infusion doses are given to start the treatment, they are administered 2 weeks apart via intravenous infusion. 4 weeks after the last intravenous infusion, you will be given REMSIMA® via injection under the skin (subcutaneous injection).

If REMSIMA treatment is initiated without two REMSIMA intravenous infusion doses, the following describes how often you will usually have this medicine after your first dose:

- 2nd dose: 1 week after your 1st dose
- 3rd dose: 2 weeks after your 1st dose
- 4th dose: 3 weeks after your 1st dose
- 5th dose: 4 weeks after your 1st dose
- Further doses: 6 weeks after your 1st dose and every 2 weeks thereafter

Ankylosing Spondylitis, Psoriasis arthritis 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.

If you miss a dose

If you miss an Injection of REMSIMA subcutaneous formulation, you should take the missed dose immediately in case this happens within 7 days from the missed dose, and then remain on your original dosing schedule. If the dose is delayed by 8 days or more, please skip the missed dose, wait until your next scheduled dose, and then remain on your original dosing schedule.

If you are given too much

If you think you or anybody else has been given too much REMSIMA, you should immediately:

- tell your doctor, or
- phone the Poisons Information Centre (**by calling 13 11 26**), or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using REMSIMA?

Things you should do

Tell your doctor or nurse straight away if:

- the medicine starts to upset you or your symptoms become worse.
- you are being treated with REMSIMA before you undergo any surgical procedures.
- you have symptoms of TB (persistent cough, weight loss, listlessness, fever), or any other infection appear. Do this immediately.
- you have symptoms of hepatitis B (upset stomach, loss of appetite, vomiting, tiredness, dark yellow or brown urine, and yellow eyes or skin) appear. Do this immediately.
- you are taking REMSIMA before receiving any vaccinations.

  Some vaccinations should not be given while you are being treated with REMSIMA.
- If you are receiving therapeutic infectious agents for the treatment of cancer.

  Patients receiving REMSIMA should not receive some medicines, such as live attenuated bacteria used for the treatment of cancer.

You should continue to take adequate contraceptive measures to avoid pregnancy.

Your doctor will also advise you not to breastfeed.

If you have a baby while you are using REMSIMA, tell your doctor about your REMSIMA use before your baby receives any vaccinations. A 12-month waiting period is recommended before administering live vaccines to your baby.

Things you should be careful of

Tell your doctor if you think you have an infection.

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.

Tell your doctor immediately if you develop a skin rash or hives.

Your doctor may discontinue REMSIMA until the symptoms go away and then begin giving the medicine again. Symptoms will resolve with appropriate treatment.

If you suffer from congestive heart failure, tell your doctor immediately if your condition worsens.

Driving or using machines

REMSIMA is unlikely to make you drowsy. If you are tired, do not drive a car or work with machinery.

6. Are there any side effects?

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given REMSIMA.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Generally, patients with rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis, or psoriasis already take several medicines to treat their disease.

These medicines may themselves cause side effects.

If you get additional side effects or any new symptoms, please tell your doctor.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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.

Less Serious Side effects

Side effects	What to do
Skin related symptoms: • rash • hives • itching • flushing • dry skin or increased sweating • new onset of psoriasis, mainly on the soles of the feet and on palms • 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 and scan on the skin of the injection site. **Gastrointestinal symptoms:** • nausea or vomiting • abdominal pain • indigestion • diarrhoea • fluid retention **Pain and alertness** • fatigue • headache • dizziness and light-headedness • chest pain • back pain • muscle pain **Cough and cold like symptoms:** • fever • sore throat • coughing • hoarseness • shortness of breath • respiratory infections (such as bronchitis, sinus infections, cold) **Other:** • weight loss (or gain), muscle wasting • problems with urination • changes in the way your heart beats, for example, if you notice it beating faster • worsening of rheumatoid arthritis.	**Tell your doctor or nurse as soon as possible if you notice any of these side effects**

Serious side effects

Serious side effects	What to do
Aches and pains: • pain or tenderness in chest, muscles, joints or jaw • muscle pains • joint pains **Skin related symptoms:** • rash • itching **Swelling or numbness:** • swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing • numbness or paralysis in the face, leg, or arm, most likely on just one side of the body • blurred or darkened vision **Heart and chest related symptoms:** • abnormal chest sounds • symptoms that may indicate heart failure, e.g. shortness of breath, especially with exercise or lying down, or swelling of your feet. **Other:** • fever • tiredness **Liver related symptoms:** There have been very rare cases where people taking REMSIMA have developed liver problems. Signs that you could be having a problem • jaundice (skin and eyes turning yellow) • dark-brown coloured urine • right-sided abdominal pain • fever • severe fatigue (tiredness).	**Tell your doctor or nurse immediately or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or nurse if you notice anything else that may be making you feel unwell.

Most of the side effects are mild to moderate in severity. Other side effects not listed above may also occur in some patients. Some side effects may appear up to six months after the last injection.

Cancers

In clinical studies, more cancers were seen in patients who received TNF-blockers, including REMSIMA, than patients who did not receive these treatments.

In children and adults being treated with TNF-blockers, the chances of getting lymphoma or other cancers may increase. It should be noted, however, that patients with longstanding and active rheumatoid arthritis or Crohn's disease may already have a higher risk for developing cancers even without TNF-blockers, making it difficult to estimate the risk of developing cancers in these patients. Nevertheless, the role of TNF-blockers in the development of cancers cannot be excluded.

A rare type of cancer called Hepatosplenic T-cell Lymphoma (HSTCL) has been reported rarely in adolescents and young adults with Crohn's disease or ulcerative colitis who have received REMSIMA. All of these patients were also receiving drugs known as azathioprine or 6-mercaptopurine. No cases of HSTCL have been reported in patients receiving REMSIMA only. HSTCL often results in death. The role of TNF-blockers in the development of cancers in children and adolescents remain unclear.

Talk to your doctor if you are concerned about this.

Skin cancers (melanoma, Merkel cell carcinoma, basal cell carcinoma, mycosis fungoides and squamous cell carcinoma) have been reported rarely in patients treated with TNF-blockers, including REMSIMA.

Tell your doctor if you notice any new skin lesions during or after therapy or if existing lesions change appearance.

Cervical cancer may occur more frequently in women treated with REMSIMA. Periodic screening of women treated with REMSIMA should continue.

Patients 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.

After REMSIMA has been stopped

Tell your doctor immediately if:

- **you notice any of the following side effects, even if they occur several weeks after stopping treatment with REMSIMA.**
  - skin rash or hives
  - frequent infections
- **symptoms of TB (persistent cough, weight loss, listlessness, fever), or any other infection appear.**
- **symptoms of hepatitis B (upset stomach, loss of appetite, vomiting, tiredness, dark yellow or brown urine, and yellow eyes or skin) appear.**

These symptoms may appear several months after your last REMSIMA treatment.

You should continue to take adequate contraceptive measures to avoid pregnancy for at least 6 months after the last injection of REMSIMA.

Tell your doctor if you wish to breastfeed your infant after your last REMSIMA treatment.

Your doctor will discuss the risks and benefits with you.

Tell your doctor if you notice any other effects.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the

Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What REMSIMA contains

Active ingredient (main ingredient)	• Infliximab [rmc] 120mg
Other ingredients (inactive ingredients)	• Acetic acid • Sodium acetate trihydrate • Sorbitol • Polysorbate 80 • Water for injections

Do not use this medicine if you are allergic to any of these ingredients.

What REMSIMA looks like

REMSIMA is a clear to opalescent, colourless to pale brown solution.

REMSIMA ® is available in the following presentations:

Single use pre-filled syringe. (AUST R 326143)

Each pack contains;

- 1 pre-filled syringe with 2 alcohol pads.
- 2 pre-filled syringe with 2 alcohol pads
- 4 pre-filled syringe with 4 alcohol pads
- 6 pre-filled syringe with 6 alcohol pads

Not all presentations may be marketed.

Single use pre-filled syringe with automatic needle guard. (AUST R 326187)

Each pack contains;

- 1 pre-filled syringe with automatic needle guard with 2 alcohol pads.
- 2 pre-filled syringe with automatic needle guard with 2 alcohol pads.
- 4 pre-filled syringe with automatic needle guard with 4 alcohol pads.
- 6 pre-filled syringe with automatic needle guard with 6 alcohol pads.

Not all presentations may be marketed.

Storage

REMSIMA should be stored at 2°C to 8°C (Refrigerate. Do not freeze.) Do not use beyond the expiry date.

REMSIMA may be stored at temperatures up to a maximum of 25°C for a period of up to 28 days. REMSIMA must be discarded if not used within the 28-day period. Upon removal from refrigerated storage, REMSIMA must not be returned to refrigerated storage.

REMSIMA is for single use only.

Who distributes REMSIMA

REMSIMA is supplied in Australia by:

Celltrion Healthcare Australia Pty Ltd.

Suite 13-03 31 Market Street,

Sydney NSW 2000, Australia

Phone: 1800 325 228

This leaflet was prepared in March 2025.

Instructions for use

Read carefully these instructions before using the REMSIMA syringe.

Consult your healthcare provider if you have questions about using the REMSIMA® syringe.

Important information

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

About the REMSIMA® syringe

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

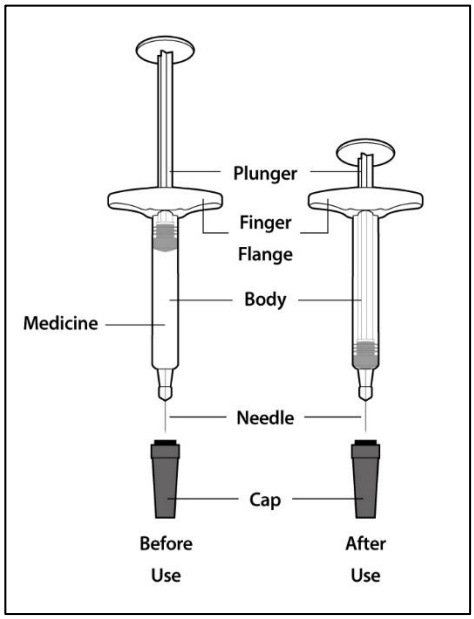

Figure A

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

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 syringe from the carton stored in your refrigerator by holding the middle of the syringe body.
c. Ensure you have the following supplies:
   - Syringe
   - Alcohol swab
   - Cotton ball or gauze*
   - Adhesive bandage*
   - Sharps disposal container*

**Items not included in the carton*

2. Inspect the syringe.

Do not use the syringe if:

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

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

Do not use the syringe 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.

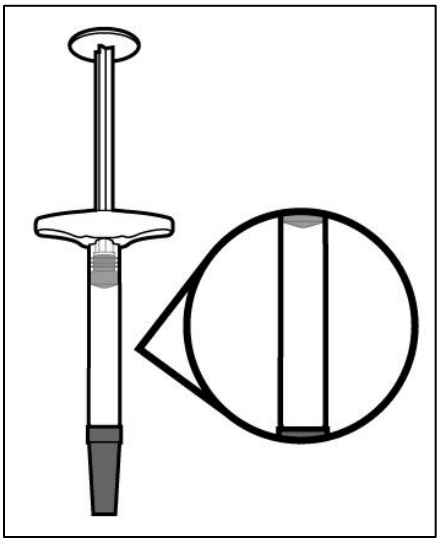

Figure B

4. Wait 30 minutes.

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

Do not warm the syringe 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

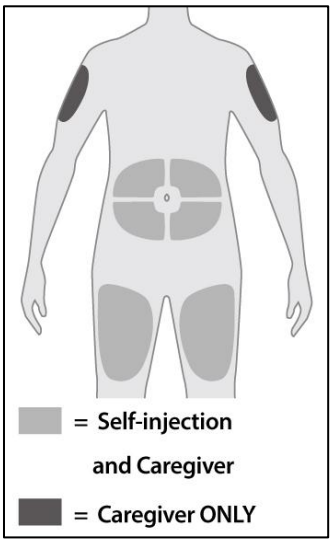

Figure C

6. Wash your hands.

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.

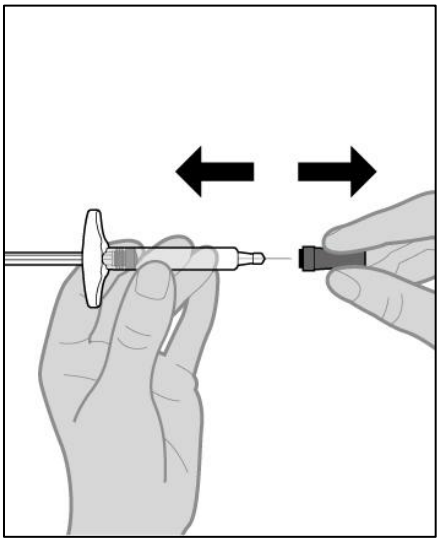

Figure D

9. Insert the syringe into the injection site (see *Figure E*).

a. Hold the syringe by its body in one hand between your thumb and index finger.
b. Using your other hand, gently pinch a fold of skin you cleaned.
c. With a quick and "dart-like" motion, insert the needle completely into the fold of the skin at a 45-degree angle.

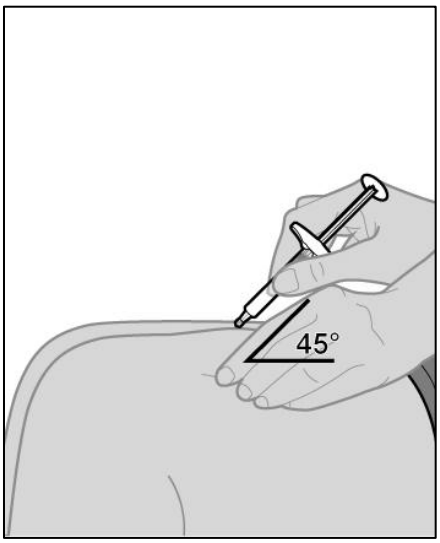

Figure E

10. Give the injection (see *Figure F*).

a. After the needle is inserted, let go of the pinched skin.
b. Push the plunger down slowly and as far as it will go until the syringe is empty.

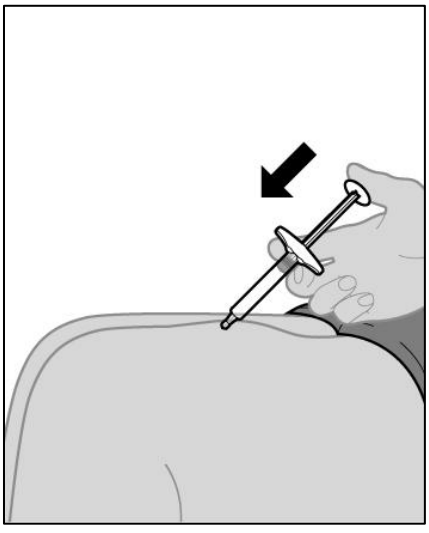

Figure F

11. Remove the needle from the injection site (see *Figure G*).

a. Remove the needle from the skin at the same angle it was inserted.
b. Gently press a cotton ball or gauze over the injection site and hold for 10 seconds.
c. Apply an adhesive bandage, if necessary.

Do not rub the injection site.

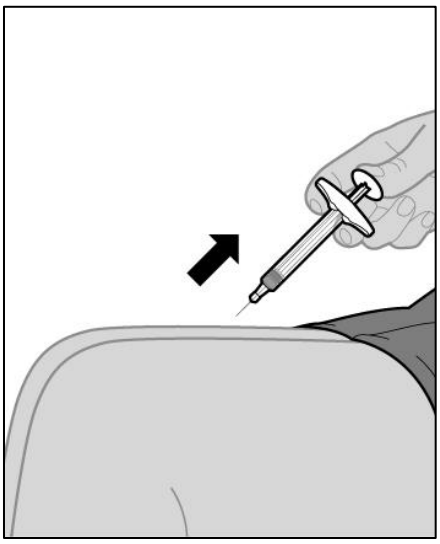

Figure G

After the injection

12. Dispose of the syringe (see *Figure H*).

a. Put the used syringe 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 syringe.

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

Figure H

Instructions for use

Read carefully these instructions before using the REMSIMA syringe with safety guard.

Consult your healthcare provider if you have questions about using the REMSIMA® syringe.

Important information

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

About the REMSIMA® syringe with safety guard

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

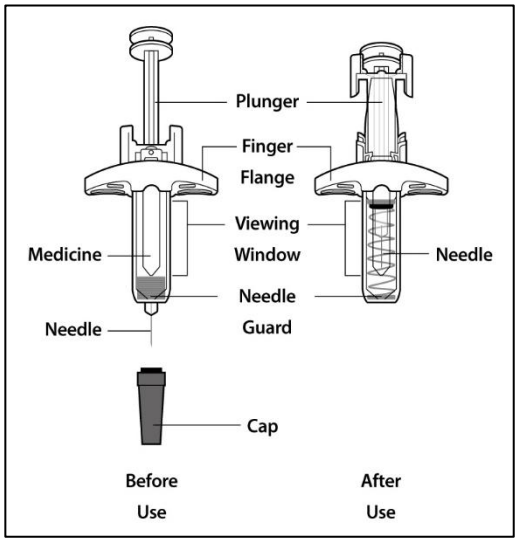

Figure A

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

Prepare for the injection

1. Gather the supplies for the injection.

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

e. Remove the syringe from the carton stored in your refrigerator by holding the middle of the syringe body.

f. Ensure you have the following supplies:
   - Syringe
   - Alcohol swab
   - Cotton ball or gauze*
   - Adhesive bandage*
   - Sharps disposal container*

**Items not included in the carton*

2. Inspect the syringe.

Do not use the syringe if:

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

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

Do not use the syringe 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.

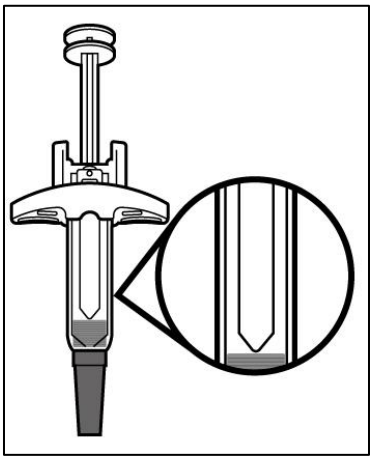

Figure B

4. Wait 30 minutes.

b. Leave the syringe at room temperature for 30 minutes to allow it to naturally warm up.

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

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

b. 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

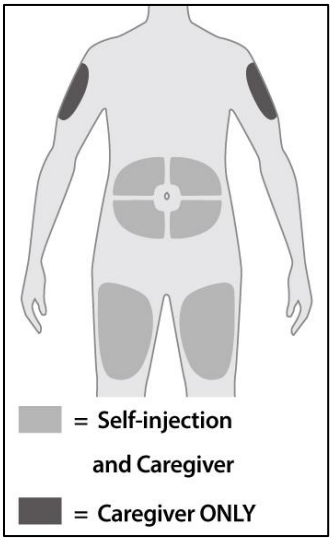

Figure C

6. Wash your hands.

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

7. Clean the injection site.

c. Clean the injection site with an alcohol swab.

d. 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*).

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

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

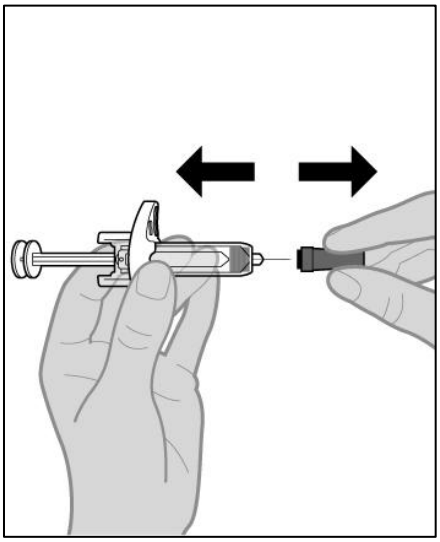

Figure D

9. Insert the syringe into the injection site (see *Figure E*).

d. Hold the syringe by its body in one hand between your thumb and index finger.

e. Using your other hand, gently pinch a fold of skin you cleaned.

f. With a quick and "dart-like" motion, insert the needle completely into the fold of the skin at a 45-degree angle.

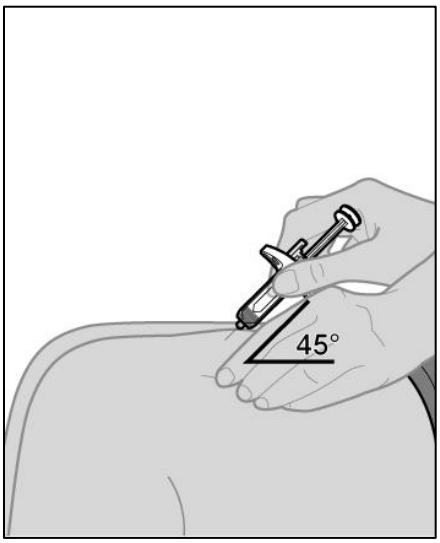

Figure E

10. Give the injection (see *Figure F*).

c. After the needle is inserted, let go of the pinched skin.

d. Push the plunger down slowly and as far as it will go until the syringe is empty.

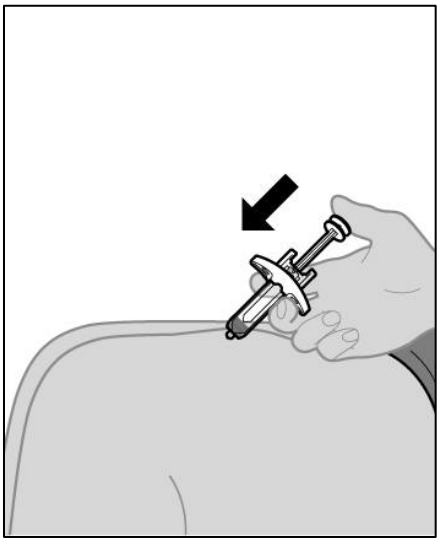

Figure F

11. Remove the needle from the injection site (see *Figure G*).

d. Remove the needle from the skin at the same angle it was inserted.
e. Gently press a cotton ball or gauze over the injection site and hold for 10 seconds.
f. Apply an adhesive bandage, if necessary.

Do not rub the injection site.

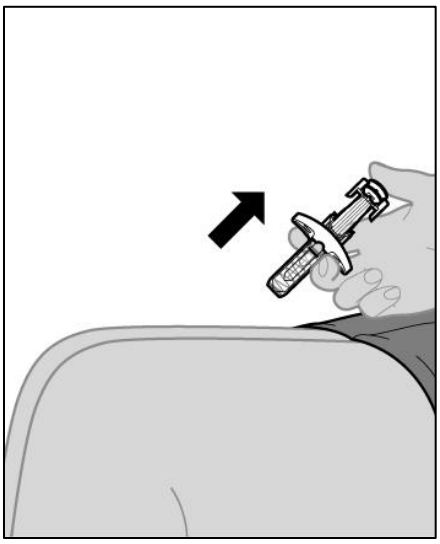

Figure G

After the injection

12. Dispose of the syringe (see *Figure H*).

d. Put the used syringe in an approved sharps disposal container immediately after use.
e. 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.
f. When your sharps disposal container is almost full, it should be disposed of in accordance with local requirements.

Do not recap the syringe.

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

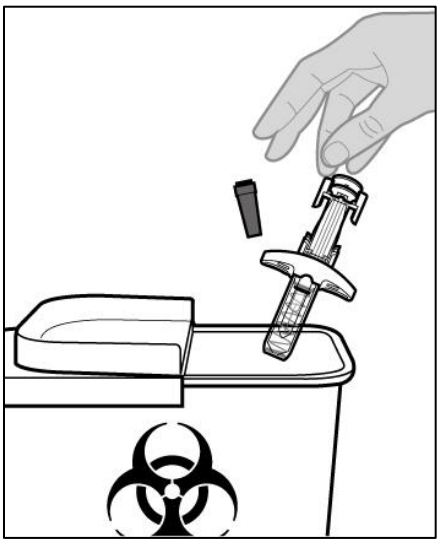

Figure H