

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrSimlandi™

Adalimumab injection

Read this carefully before you start taking Simlandi and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Simlandi.

Simlandi is a biosimilar biologic drug (biosimilar) to the reference biologic drug HUMIRA. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

Simlandi treatment should be started and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), Ankylosing spondylitis (AS), adult Crohn's disease (CD), adult ulcerative colitis (UC), adult and adolescent hidradenitis suppurativa (HS), psoriasis (Ps), or adult and pediatric uveitis, and familiar with the Simlandi efficacy and safety profile.

Serious Warnings and Precautions

- **Allergic reactions:** If you/your child develop a severe rash, swollen face or difficulty breathing while taking adalimumab, call your/your child's doctor right away.
- **Hepatoplenic T-cell lymphoma:** Very rare reports of hepatosplenic T-cell lymphoma (HSTCL), a rare serious lymphoma that is often fatal, have been identified in patients treated with adalimumab. Most patients had also been treated with other medications for Crohn's disease and the majority were in adolescent and young adult males. The link between HSTCL and adalimumab is not clear.
- **Other cancers:** There have been very rare cases of certain kinds of cancer in patients taking adalimumab or other TNF- blockers. Some patients receiving adalimumab have developed types of cancer called non-melanoma skin cancer. Tell your/your child's doctor if you/your child have a bump or open sore that does not heal. People with more serious rheumatoid arthritis that have had the disease for a long time may have a higher than average risk of getting a kind of cancer that affects the lymph system, called lymphoma. If you/your child take adalimumab or other TNF-blockers, your/your child's risk may increase. There have been cases of lymphoma and other cancers, including unusual types, in children, adolescents and young adults taking TNF-blocking agents, including adalimumab, which sometimes resulted in death. For children

and adults taking TNF-blocker medicines, the chances of developing lymphoma or other cancers may increase.

- **Lupus-like symptoms:** Some patients have developed lupus-like symptoms that got better after their treatment was stopped. If you/your child have chest pains that do not go away, shortness of breath, joint pain or a rash on your/your child's cheeks or arms that gets worse in the sun, call your/your child's doctor right away. Your/your child's doctor may decide to stop your/your child's treatment.
- **Nervous system diseases:** There have been rare cases of disorders that affect the nervous system of people taking adalimumab or other TNF-blockers. Signs that you/your child could be experiencing a problem affecting your/your child's nervous system include: numbness or tingling, problems with your/your child's vision, weakness in your/your child's legs, and dizziness.
- **Serious infections:** There have been rare cases where patients taking adalimumab or other TNF-blocking agents have developed serious infections. Some of these cases have been life-threatening. Such infections include tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis). Infection causes include tuberculosis, legionellosis (a serious form of bacterial pneumonia), listeriosis (an infection that usually develops after eating food contaminated by bacteria called listeria), and very rare cases of hepatitis B infection relapse.
- **Blood problems:** In some instances, patients treated with TNF-blocking agents may develop low blood counts, such as anemia (low red blood cells) or low platelets. If you/your child develop symptoms such as persistent fever, bleeding, or bruising, you should contact your/your child's doctor right away.

What is Simlandi used for?

Simlandi is a medicine that is used in:

- adults with rheumatoid arthritis, which is an inflammatory disease of the joints.
- adults with psoriatic arthritis, which is an inflammatory disease of the joints and skin.
- adults with ankylosing spondylitis, which is a form of arthritis.
- adults with Crohn's disease, which is an inflammatory disease of the digestive tract.
- pediatrics with polyarticular juvenile idiopathic arthritis who are 2 years of age and older and require a full 40 mg dose based on body weight.
- adults with ulcerative colitis, which is an inflammatory disease of the bowel (colon).
- adults or adolescents (12 to 17 years of age, weighing ≥ 30 kg) with moderate to severe hidradenitis suppurativa (HS) who have not responded to antibiotics. HS is a painful, progressive, chronic inflammatory skin disease that causes nodules, abscesses, sinus tracts and fistulas under the breasts, underarms, buttocks and groin.
- adults with psoriasis, which is an inflammatory disease of the skin. The doctor prescribed Simlandi to

- reduce the signs and symptoms of your plaque psoriasis.
- adults with uveitis, which is an inflammatory disease of the eye.
- children (weighing ≥ 30 kg) with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.

Patients with rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, hidradenitis suppurativa, psoriasis, or uveitis may be given other medicines for their disease before they are given Simlandi. If you have adult ulcerative colitis or you have Crohn's disease, you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Simlandi to reduce the signs and symptoms of your disease.

How does Simlandi work?

Simlandi is a recombinant fully human immunoglobulin G1 (IgG1) kappa monoclonal antibody (mAb) that specifically binds to tumor necrosis factor- α (TNF) and blocks its interaction with the p55 (TNFR1) and p75 (TNFR2) cell surface TNF receptors, thereby neutralizing the effect of TNF in inflammatory conditions. Simlandi is approved as a biosimilar to Humira (adalimumab).

People with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, adult ulcerative colitis, hidradenitis suppurativa or psoriasis have too much of TNF-alpha in their bodies. The extra TNF-alpha in your/your child's body can attack normal healthy body tissues and cause inflammation, especially in the tissues of your bones, cartilage, joints, digestive tract and skin. By binding to TNF-alpha, adalimumab decreases the inflammation process of these diseases.

Simlandi helps reduce the signs and symptoms of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis and psoriatic arthritis (such as pain and swollen joints), may help improve your/your child's ability to perform daily activities (such as getting dressed, walking and climbing stairs), and may help prevent further damage to your/your child's bones and joints. In addition, Simlandi helps reduce the signs and symptoms of ankylosing spondylitis (back pain and morning stiffness), and adult Crohn's disease or adult ulcerative colitis (abdominal pain and diarrhea).

Simlandi is also used to treat inflammatory lesions (nodules and abscesses) in adults and adolescents (12 to 17 years of age, weighing ≥ 30 kg) with hidradenitis suppurativa.

Simlandi also helps reduce the signs and symptoms of psoriasis (such as pain, itching and scaly patches on skin).

Simlandi helps control uveitis by reducing the risk of inflammation and loss of vision in adult and pediatric patients.

Simlandi, however, can also lower your/your child's body's ability to fight infections. Taking Simlandi can make you/your child more prone to getting infections or make any infection you/your child have worse.

What are the ingredients in Simlandi

Medicinal ingredient:

Adalimumab

Non-medicinal ingredients:

Polysorbate 80, sodium chloride, sucrose, and water for injection.

Simlandi comes in the following dosage forms:

40 mg in 0.4 mL sterile solution (100 mg/mL) for injection
(Pre-filled Syringe with needle guard and Autoinjector)

80 mg in 0.8 mL sterile solution (100 mg/mL) for subcutaneous injection
(Pre-filled Syringe with needle guard)

Do not use Simlandi if:

- you/your child has a known hypersensitivity (allergy) to adalimumab or any of its components. For a complete listing, (see **6 DOSAGE FORMS, COMPOSITION AND PACKAGING**).
- you/your child has a severe infection such as sepsis (an infection of the blood), tuberculosis (a serious infection usually affecting the lungs) and opportunistic infections (infections that can occur when your defence system against infections is weak (See **Serious Warnings and Precautions Box**).
- you/your child has moderate to severe heart failure (when the heart does not pump normally (see **Serious Warnings and Precautions Box**).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Simlandi. Talk about any health conditions or problems you may have, including if:

- you are taking anakinra or abatacept (other biologic drugs);
- a surgery is planned for you in the near future;
- you suffer from congestive heart failure (see **Do not use Simlandi if**);
- you suffer from any form of cytopenia (a condition where you do not have enough blood cells);
- you have lasting fever, bruising, bleeding or paleness;
- you develop lupus-like symptoms (such as rash, fever, fatigue, headache, painful joints)
- you have a history of tuberculosis;
- you have a history of fungal infections;
- you have a history of hepatitis B (an infection of the liver)

- you have a history of cancer such as leukemia (a cancer of the blood);
- you have a history of lymphoma (a cancer affecting the white blood cells)

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Other warnings you should know about:

If you/your child received Simlandi while pregnant, your/her baby may be at higher risk for getting an infection for up to approximately five months after the last dose of Simlandi received during pregnancy. It is important that you tell your/her baby's doctors and other healthcare professionals about your/her Simlandi use during pregnancy so they can decide when your/her baby should receive any vaccine.

BEFORE you/your child use Simlandi, talk to the doctor or pharmacist if:

- you/your child have or have had any kind of infection including an infection that is in only one place in your/your child's body (such as an open cut or sore), or an infection that is in your/your child's whole body (such as the flu). Having an infection could put you/your child at risk for serious side effects from Simlandi. If you are unsure, ask your/your child's doctor.
- You/your child have a history of infections that keep coming back or other conditions that might increase your/your child's risk of infections, including fungal infections.
- you/your child have ever had tuberculosis, or if you/your child have been in close contact with someone who has had tuberculosis. If you/your child develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats) call your/your child's doctor right away. Your/your child's doctor will need to examine you/your child for tuberculosis and perform a skin test.
- you/your child resided or travelled to areas where there is a greater risk for certain kinds of infections such as tuberculosis, histoplasmosis, coccidioidomycosis, blastomycosis, or parasitic infections. These infections are caused by a bacteria or a fungus that can affect the lungs or other parts of your/your child's body. If you/your child take Simlandi, these may become active or more severe. If you don't know if you/your child have lived in or travelled to an area where these infections are common, ask your/your child's doctor.
- you/your child have ever had liver injury or hepatitis B virus infection or are at risk of developing this infection. Signs and symptoms include the following: yellowing of the skin or eyes (jaundice), feeling of sickness, tiredness, loss of appetite, joint pain, fever, dark brown-coloured urine, vomiting, and abdominal pain. If you/your child experience any of these signs and symptoms, contact your/your child's doctor immediately. These symptoms may occur several months after starting therapy with Simlandi.
- you/your child experience any numbness or tingling or have ever had a disease that affects your/your child's nervous system like multiple sclerosis or Guillain-Barré syndrome.

- you/your child have or have had heart failure.
- you/your child are scheduled to have major surgery or dental procedures.
- you/your child are scheduled to be vaccinated for anything. It is recommended that pediatric patients, if possible, be brought up to date with all immunizations according to current guidelines before starting Simlandi.
- you/your child are taking other medicines for your/your child's rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis, or other conditions. You/your child can take other medicines provided your/your child's doctor has prescribed them or has told you it is acceptable that you/your child take them while you/your child are taking Simlandi. It is important that you tell your/your child's doctor about any other medicines you/your child are taking for other conditions (for example, high blood pressure medicine) before you/your child start taking Simlandi.
- you are taking other medicines for your Crohn's disease or other conditions. You can take other medicines provided your doctor has prescribed them or has told you it is acceptable that you take them while you are taking Simlandi. It is important that you tell the doctor about any other medicines you are taking for other conditions before you start taking Simlandi.
- you/your child are taking any over-the-counter drugs, herbal medicines and vitamin and mineral supplements.
- you/your child are pregnant or could become pregnant.
- you/your child are breast-feeding or plan to breast-feed.

If you are not sure or have any questions about any of this information, ask your/your child's doctor.

The following may interact with Simlandi:

Other TNF-blockers such as:

- etanercept (Enbrel®),
- abatacept (Orencia®)
- anakinra (Kineret®)
- infliximab (Remicade®)
- certolizumab pegol ((Cimzia®)
- golimumab (Simponi®)

How to take Simlandi

Simlandi is administered by injection under the skin (by subcutaneous injection).

For instructions on the use of Simlandi, each carton contains the following:

- this Patient Medication Information Leaflet,
- a detailed, illustrated Information for the User,
- a Quick Reference Guide.

For step-wise instructions explaining how to inject Simlandi, please also refer to the detailed, illustrated Information for the User for both the pre-filled syringe and the Autoinjector.

For quick reference, you may also use the Quick Reference Guide for the pre-filled syringe and the Autoinjector.

Please carefully read the following instructions and the illustrated instructions in the **Information for the User** and follow them step-by-step. You will be assisted by your/your child's doctor or assistant on the technique of injection. Do not attempt to inject until you are sure that you understand how to prepare and give the injection. After proper training, the injection can be self-administered or given by another person, for example, a healthcare professional, a family member or friend.

The injection should not be mixed in the same syringe with any other medicine.

Setting Up

- Remove one dosing tray containing a Simlandi Autoinjector or Pre-filled Syringe with needle guard from the carton in the refrigerator.
 - Do not shake or drop the Autoinjector or pre-filled syringe.
 - Do not use the Autoinjector or pre-filled syringe if it is frozen or if it has been left in direct sunlight.
 - If you are using the Autoinjector, only remove the caps **immediately** before injection.
- Set up the following on a clean, flat working surface:
 - One Simlandi Autoinjector
 - The alcohol swab provided

-OR-

- One pre-filled syringe of Simlandi for injection
 - The alcohol swab provided
- If you do not have all of the pieces you need to give yourself/your child an injection, call your pharmacist. Use only the items provided in the carton your Simlandi prescription comes in.

- Make sure that the name Simlandi appears on the dosing tray and on the Autoinjector or pre-filled syringe label.
- Check the expiry date on the Autoinjector or pre-filled syringe. Do not use the product if the date has passed the month and year shown.
- Make sure the liquid in the Autoinjector or pre-filled syringe is clear and colourless. Do not use the Autoinjector or pre-filled syringe if the liquid is cloudy or if flakes or particles can be seen.
- Have a puncture-proof container nearby for disposing the used Autoinjector, pre-filled syringe and needles.

FOR YOUR/YOUR CHILD'S PROTECTION, IT IS IMPORTANT THAT YOU FOLLOW THESE INSTRUCTIONS

Choosing and Preparing the Injection Site

- Wash your hands thoroughly.
- Choose a site on the front of your/your child's thighs or abdomen. If you choose your/your child's abdomen, you should avoid the area two inches around your/your child's navel.
- Choose a different site each time you give yourself/your child an injection. Each new injection should be given at least one inch from the site you used before. Do **NOT** inject into areas where the skin is tender, bruised, red or hard or where you/your child have scars or stretch marks.
- You may find it helpful to keep notes on the location of previous injections.
- Wipe the injection site where Simlandi is to be injected with the alcohol swab provided, using a circular motion. Do **NOT** touch this area again before giving the injection.

Preparing the Dose for Injection

Simlandi Autoinjector

- Hold the Autoinjector with the clear cap pointing up. Check the appearance of the solution through the window on the side of the Autoinjector to make sure the liquid is clear and colourless. Do not use the Autoinjector if the liquid is cloudy or discoloured or has flakes or particles in it. Do not use if frozen or if it has been left in direct sunlight.

Simlandi Pre-filled syringe

- Remove the needle cover from the syringe, taking care not to touch the needle with your fingers or allowing it to touch any surface.
- Turn the syringe so the needle is facing up and slowly push the plunger in to push the air in the syringe out through the needle. If a small drop of liquid comes out of the needle, this is acceptable.

Injecting Simlandi

Simlandi Autoinjector

- Only remove the clear cap **immediately** before injection. Throw the clear cap away; do not put the clear cap back on the Autoinjector, as this could damage the needle.
- Turn the Autoinjector so that the orange needle sleeve points to the injection site.
- Squeeze the skin at the injection site to make a raised area and hold it firmly.
- Place the orange needle sleeve straight up (90° angle) from the injection site and hold the Autoinjector so that you can see the window.
- Push and keep pushing the Autoinjector down onto the injection site.
 - The first “click” will signal the start of the injection.
 - The injection may take 10 seconds to complete after this first “click”
- Keep pushing the Autoinjector down onto the injection site.
- The injection is complete when the orange indicator has stopped moving and you may hear a second “click”.

DO NOT lift up or let go of the pressure from the injection site until you have confirmed that the injection is complete.

- When the injection is completed, slowly pull the Autoinjector from the skin. The orange needle sleeve will cover the needle tip

If there are more than a few drops of liquid on the injection site, call your healthcare provider for help.

- After completing the injection, place a cotton ball or gauze pad on the skin of the injection site
- DO NOT RUB**
Slight bleeding at the injection site is normal.
- Put your used needles, Autoinjector and sharps in an approved disposal container.

Simlandi Pre-Filled Syringe

- Holding the prefilled syringe in one hand, gently pull the needle cover off with the other hand.
 - Throw the needle cover away and never recap
 - Do not touch the needle with your finger or let the needle touch anything.
 - You may see a drop of liquid at the end of the needle. This is normal
- Hold the body of the prefilled syringe in one hand between the thumb and index finger, like a pencil.
 - Do not pull back on the plunger at any time.
- Gently squeeze the area of cleaned skin at the injection site with your other hand and hold firmly.
- Insert the needle into the squeezed area of skin at about a 45o angle using a quick dart-like movement.
- After the needle is in, let go of the skin.
- Slowly push the plunger all the way in until all of the liquid is injected and the prefilled syringe is empty.

- Slowly lift your finger from the plunger. The plunger will move up with your finger and retract (remove) the needle from the injection site into the needle guard.
 - The needle will not retract unless all the liquid is injected.
 - Speak to your doctor or pharmacist if you think you have not given the full dose.
- After completing the injection, place a cotton ball or gauze pad on the skin of the injection site,
 - DO NOT RUB**
 - Slight bleeding at the injection site is normal.
- Put your used needles, syringe and sharps in an approved disposal container.
- Other items may be put in the household trash.

Disposing of Supplies

- You should always check with your/your child's healthcare provider (e.g., doctor, nurse, or pharmacist) for instructions on how to properly dispose of used needles and syringes (including the Autoinjector). Do **NOT** use the same needle and syringe more than once. You should follow any special provincial or local laws regarding the proper disposal of needles and syringes. **Do NOT throw used needles or syringes (including the Autoinjector) in the household trash or recycling bin.**
- Dispose of used needles and syringes (including the Autoinjector) in a container made especially for this purpose (sharps container), or a hard plastic container with a screw-on cap or metal container with a plastic lid labelled "Used Syringes". Do not use glass or clear plastic containers.
- Always keep the container out of the reach of children.
- When the container is about two-thirds full, tape the cap or lid down so it does not come off and dispose of it as instructed by your/your child's doctor, nurse or pharmacist. **DO NOT THROW THE CONTAINER IN THE HOUSEHOLD TRASH OR RECYCLING BIN.**
- The used alcohol pads may be placed in the trash, unless otherwise instructed by your/your child's doctor, nurse or pharmacist.

Usual Dose:

Adults with Rheumatoid Arthritis, Psoriatic Arthritis or Ankylosing Spondylitis:

- The recommended dose is 40 mg administered every other week as a subcutaneous injection.

Adults with Crohn's Disease or Ulcerative Colitis:

- The recommended induction dose is 160 mg at Week 0, followed by 80 mg at Week 2 administered by subcutaneous injection. The first dose of 160 mg can be given in one day (four 40 mg injections or two 80 mg injections) or split over two consecutive days (two 40 mg injections or one 80 mg injection each day). The second dose of 80 mg at Week 2 is given as two 40 mg injections or one 80 mg injection in one day.
- The recommended maintenance dose regimen is 40 mg every other week beginning at Week

4.

Adults with Hidradenitis Suppurative:

- The recommended initial dose is 160 mg, followed by 80 mg two weeks later administered by subcutaneous injection. The first dose of 160 mg at Week 0 can be given in one day (four 40 mg injections or two 80 mg injections) or split over two consecutive days (two 40 mg injections or one 80 mg injection each day) or split over two consecutive days (two 40 mg injections or one 80 mg injection each day). The second dose of 80 mg at Week 2 is given as two 40 mg injections or one 80 mg injection in one day.
- The recommended maintenance dose regimen is 40 mg every week beginning four weeks after the initial dose.

Adults with Psoriasis or Uveitis:

- The recommended dose is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose administered by subcutaneous injection. The first dose of 80 mg can be given as two 40 mg injections or one 80 mg injection.

Adolescents, 12 to 17 years of age weighing \geq 30 kg, with Hidradenitis Suppurativa:

- The recommended initial dose is 80 mg administered by subcutaneous injection (two 40 mg injections or one 80 mg injection), followed by 40 mg every other week starting one week later. Depending on your/your child's response, the doctor may increase the dose to 40 mg every week.

Polyarticular juvenile idiopathic arthritis, weighing \geq 30 kg:

- The recommended dose of SIMLANDI is 40 mg subcutaneously every other week. SIMLANDI is only available for children who require the full 40 mg dosage. The autoinjector and pre-filled syringe are not designed to deliver a portion of the 40 mg dose.

Pediatric uveitis, weighing \geq 30 kg:

- The recommended dose of SIMLANDI is 40 mg subcutaneously every other week. SIMLANDI is only available for children who require the full 40 mg dosage. The autoinjector and pre-filled syringe are not designed to deliver a portion of the 40 mg dose.

Overdose:

If you think you, or a person you are caring for, have taken too much Simlandi, contact a health care professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you/your child forget to give yourself/your child an injection, you/your child should inject the missed dose of Simlandi as soon as you/your child remember. Then administer the next dose as you would have on the originally scheduled date.

What are the possible side effects from using Simlandi?

These are not all the possible side effects you may have when taking Simlandi.

Like all medicines, Simlandi can cause side effects. Most side effects are mild to moderate. However, some may be serious and require treatment.

Tell your/your child's doctor immediately if you/your child experience any of the following:

- severe rash, hives or other signs of allergic reaction
- swollen face, hands, feet
- trouble breathing, swallowing
- sudden weight gain; this is possibly indicative of new or worsening heart failure
- bruising or bleeding very easily, looking very pale; this could mean a blood problem such as low red blood cells (anemia) or low platelets (other cells found in the blood)

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

- signs of infection such as fever, fatigue, wounds, dental problems, burning on urination
- feeling weak or tired
- coughing
- tingling
- numbness
- double vision
- arm or leg weakness
- arm or leg pain, swelling or redness
- bump or open sore that does not heal
- red scaly patches or raised bumps that are filled with pus; this could be new or worsening hidradenitis suppurativa, new or worsening psoriasis or a skin infection
- alopecia (loss of hair)
- changes in the colour of the skin
- changes in the colour of your/your child's urine (dark or red)
- worsening of the appearance of a scar
- night sweats
- weight loss
- pain in the abdomen or chest

If you experience any side effects not listed here, contact your healthcare professional.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN
--

AND WHAT TO DO ABOUT THEM			
Symptom/effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON Injection site reaction		√	
COMMON Cough and cold symptoms, including sore throat Headache Rash Nausea Pneumonia Fever Abdominal pain	√ √	√ √ √ √ √	√
RARE Tuberculosis Other serious infections Nerve disorder Appendicitis Blood clots: abdominal pain, chest pain, leg or arm pain with redness and swelling Bladder infection Hepatitis (jaundice, [yellow skin, dark urine], abdominal pain, tiredness)		√ √ √ √ √ √ √	√ √ √ √ √ √

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional

Reporting Side Effects

You can report any side suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 2 and 8°C (in a refrigerator) in the original carton until ready to use. **DO NOT FREEZE Simlandi.** Protect from light. Refrigerated Simlandi remains stable until the expiration date printed on the Autoinjector or pre-filled syringe. Do not use beyond the expiration date.

When needed, for example when you/your child are travelling, a Simlandi Autoinjector or pre-filled syringe can be stored at room temperature (up to 25°C/77°F) for a single maximum period of 14 days.

Once taken out of the refrigerator for room temperature storage, a Simlandi Autoinjector or pre-filled syringe must be used within 14 days, even if it is put back in the refrigerator. If not used within 14 days, the Simlandi Autoinjector or pre-filled syringe must be discarded. You should record the date when the Simlandi autoinjector or pre-filled syringe is first removed from the refrigerator.

Care should be taken to avoid dropping or crushing the product as it contains a glass syringe.

Keep Simlandi and all other medicines out of the reach and sight of children.

If you want more information about Simlandi:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drugproduct-database.html>), the manufacturer's website [<https://www.jamppharma.com>], or by calling 1-866-399-9091 #2.

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