

Your

JAMP Care™ guide

to Pr Simlandi™
(adalimumab)



Your JAMP Care guidebook

This patient guidebook has been designed by JAMP Care to help you learn about your new treatment. We encourage you take the time to read through and get acquainted with Simlandi.

If you are new to adalimumab treatment (including Simlandi)

We encourage you to read through your guidebook and take note of any questions you may have for your doctor, or your JAMP Care *Single Point of Contact* in the notes section on page 26. Please take note of the robust package of benefits that you are entitled to (see the back cover). Get in touch with your *Single Point of Contact* or call JAMP Care to learn more about any of these services.

If you are switching to Simlandi from a different adalimumab treatment

You and your doctor recently made the decision to switch your treatment to Simlandi. Thank you for putting your trust in us. With JAMP Care you will continue to receive the treatment you need, plus the support that we can offer. Please take note of the robust package of benefits that you are entitled to (see the back cover). Get in touch with your *Single Point of Contact* or call JAMP Care to learn more about any of these services.

Let's get started

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Simlandi is a biosimilar biologic drug (biosimilar).

What is a biosimilar?

- A biosimilar is a type of biologic drug that has the same safety and efficacy as an existing biologic drug already approved for clinical use.
- While traditional pharmaceuticals are created chemically, biologics originate from living cells. They are typically larger and more complex in their structure, making it difficult-to-impossible to make generic alternatives for them.
- Biosimilars take substantial expertise and investment to bring to market and are subject to rigorous regulatory and approval standards.
- Biosimilar drugs offer a solution to reducing prescription drug costs to patients, and our public healthcare systems, without compromising effectiveness or safety. This also increases access to medication for more patients.

Who is Simlandi for?

Simlandi is used to treat:



Adults with rheumatoid arthritis – an inflammatory disease of the joints.



Adults with psoriatic arthritis – an inflammatory disease of the joints and skin.



Adults with ankylosing spondylitis – a form of arthritis.



Pediatric patients 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 Crohn's disease – an inflammatory disease of the digestive tract.



Adults with ulcerative colitis – 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 – a painful, progressive, chronic inflammatory skin disease that causes nodules, abscesses, sinus tracts and fistulas under the breasts, underarms, buttocks and groin.



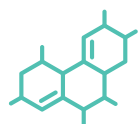
Adults with psoriasis – an inflammatory disease of the skin. The doctor prescribed Simlandi to reduce the signs and symptoms of your plaque psoriasis.



Adults with uveitis – 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.

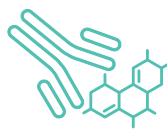
How does Simlandi work?



Too much TNF-alpha in the body causes inflammation



Simlandi is given subcutaneously. The Simlandi molecules (also called adalimumab) grab onto TNF-alpha



By binding TNF-alpha, Simlandi decreases inflammation in affected tissues.

See "What does Simlandi do" below.

People with the conditions listed on the next page (except uveitis) 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.

Interested in learning more?

Here are some of the finer details.

- Simlandi is a recombinant fully-human immunoglobulin G1 (IgG1) kappa monoclonal antibody (mAb).



Antibodies are like detectives hunting for a criminal: they're molecules that have the special ability of grabbing onto other molecules they encounter and stopping them from doing their bidding - but they only have a warrant for a very specific criminal.



In this case, **Simlandi** (the antibody) binds to tumor necrosis factor- α (**TNF**) and stops TNF from interacting with its "**receptor**" molecules, TNF-receptor 1 and TNF-receptor 2 (also known as p55 and p75). These are "cell surface receptors" that are found on the outside of certain cells.



Normally, when these **receptors are activated by TNF**, they send a signal that **triggers inflammation**. When Simlandi binds TNF, it neutralizes the effect of TNF in inflammatory conditions.

What does Simlandi do?



Rheumatoid arthritis

- Simlandi helps reduce signs and symptoms such as pain and swollen joints.
- Simlandi may help improve your ability to perform daily activities such as getting dressed, walking and climbing stairs.
- Simlandi may help prevent further damage to your bones and joints.



Psoriatic arthritis

- Simlandi helps reduce signs and symptoms such as pain and swollen joints.
- Simlandi may help improve your ability to perform daily activities such as getting dressed, walking and climbing stairs.
- Simlandi may help prevent further damage to your bones and joints.



Ankylosing spondylitis

- Simlandi helps reduce signs and symptoms including back pain and morning stiffness.



Polyarticular juvenile idiopathic arthritis

- Simlandi helps reduce signs and symptoms such as pain and swollen joints.
- Simlandi may help improve your/your child's ability to perform daily activities such as getting dressed, walking and climbing stairs.
- Simlandi may help prevent further damage to your/your child's bones and joints.



Adult Crohn's disease

- Simlandi helps reduce signs and symptoms including abdominal pain and diarrhea.



Adult ulcerative colitis

- Simlandi helps reduce signs and symptoms including abdominal pain and diarrhea.



Hidradenitis suppurativa

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



Psoriasis

- Simlandi helps reduce signs and symptoms such as pain, itching and scaly patches on skin.



Uveitis

- Simlandi helps control uveitis by reducing the risk of inflammation and loss of vision in adult and pediatric patients (2 years of age, weighing more than ≥ 30 kg).

Simlandi 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.

For more information about the diseases covered above, refer to the resources, page 25.

How to administer Simlandi

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

Your/your child's doctor or assistant will train you how to inject your medication. 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.

For step-by-step instructions and additional resources

- Visit the JAMP Care website, at www.JAMPCare-support.ca
- Refer to the detailed, illustrated *Information for the User* document (found in the carton with your medication)

For quick reference

- Refer to the *Quick Reference Guide* (also found in the carton with your medication).

Watch the patient injection video

Scan the QR code with your smartphone camera:



Do you need injection training, support, or a refresher?

Speak with your *Single Point of Contact*, or contact JAMP Care at

1-855-310-5102

jampcare@supportprogram.com



Dosage formats of Simlandi

Simlandi is available in three different dosage formats



Autoinjector, 40 mg

Prefilled autoinjector containing 40 mg of adalimumab in 0.4 mL sterile solution (concentration: 100 mg/mL).



Prefilled syringe, 40 mg

Prefilled syringe with needle guard containing 40 mg of adalimumab in 0.4 mL sterile solution (concentration: 100 mg/mL).



Prefilled syringe, 80 mg

Prefilled syringe with needle guard containing 80 mg of adalimumab in 0.8 mL sterile solution (concentration: 100 mg/mL).

How much Simlandi to take



Adults with Rheumatoid Arthritis

The recommended dose is 40 mg administered every other week subcutaneously.



Adults with Psoriatic Arthritis

The recommended dose is 40 mg administered every other week subcutaneously.



Adults with Ankylosing Spondylitis

The recommended dose is 40 mg administered every other week subcutaneously.



Polyarticular juvenile idiopathic arthritis, weighing ≥ 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 prefilled syringe are not designed to deliver a portion of the 40 mg dose.



Adults with Crohn's Disease

Recommended induction dose: 160 mg at Week 0, followed by 80 mg at Week 2 subcutaneously. 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.

Recommended maintenance dose: 40 mg every other week subcutaneously beginning at Week 4.



Adults with Ulcerative Colitis

Recommended induction dose: 160 mg at Week 0, followed by 80 mg at Week 2 subcutaneously. 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.

Recommended maintenance dose: 40 mg every other week subcutaneously beginning at Week 4.

How much Simlandi to take



Adults with Hidradenitis Suppurativa

Recommended initial dose: 160 mg, followed by 80 mg two weeks later administered subcutaneously. 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.

Recommended maintenance dose: 40 mg every week beginning four weeks after the initial dose.



Adolescents, 12 to 17 years of age weighing ≥ 30 kg, with Hidradenitis Suppurativa

The recommended initial dose is 80 mg subcutaneously (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.



Adults with Psoriasis

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 subcutaneously. The first dose of 80 mg can be given as two 40 mg injections or one 80 mg injection.



Adults with 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 subcutaneously. The first dose of 80 mg can be given as two 40 mg injections or one 80 mg injection.



Pediatric Uveitis, weighing ≥ 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 prefilled syringe are not designed to deliver a portion of the 40 mg dose.

Tips for remembering to take your injection

Always inject Simlandi the way your healthcare provider has trained you

To manage your risk of side effects, it is critical to take your medication exactly as instructed by your healthcare provider.

- **Administer Simlandi on a day of the week when you already have another activity planned** (e.g., the day you go to your dance class)
- **Choose a weekday**
 - Your routine is less likely to change, making it easier to remember your injection
- **When scheduling your injections**
 - Plan out your entire year on a calendar
 - Mark your injection dates and dates when you will need to refill your prescription
 - Avoid waiting until you are out of your medication to renew your prescription
 - Check in with your pharmacy a few days before pickup so they are stocked for your arrival
- **Set an alarm**
 - On your smartphone, watch, or in your day-planner
- **Ask for help**
 - Find a reliable family member or friend who can call or check on you daily to remind you

What to do if you forget to take your medication

If you miss a dose of Simlandi, take it as soon as you remember.

Then take the next dose on your regular schedule.

S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

Overdose

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

Storing Simlandi



Store Simlandi
between 2-8°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 prefilled syringe.
- Do not use beyond the expiration date.
- When needed, for example when you/your child are travelling, a Simlandi autoinjector or prefilled 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, Simlandi must be used within 14 days, even if it is put back in the refrigerator.
- Remember to record the date when Simlandi is first removed from the refrigerator.
- If not used within 14 days, Simlandi must be discarded.
- Care should be taken to avoid dropping or crushing the product as it contains a glass syringe.
- Keep Simlandi and all medicines out of reach and sight of children.

Travelling with Simlandi

Travel tips

It is very important to keep your condition and its treatment in mind when you travel so you can continue to benefit from Simlandi treatment. Next time you are planning a trip, remember to review these handy tips on how to travel with Simlandi. Remember you must always take Simlandi as directed, even when travelling.

- Follow the storage tips outlined on the previous page.
- When packing, bring enough Simlandi to last your entire trip. Pack an extra Simlandi prescription in case of damage to or loss of your medication.
- As you adjust to your new travel routines, remember to follow your dosing schedule, and administer Simlandi on time.
- Speak to your travel agent about any special needs or mobility issues before booking:
 - Request a room with a refrigerator to properly store Simlandi.
 - Consider asking for seats with ample legroom, that are closer to washrooms, or are adapted to families.
 - You can request accommodations with elevators, rooms on ground floors, or specially adapted rooms.
- Talk to your travel agent or airline if you need to arrange refrigeration when you travel for long durations or in warm countries.
- For short trips (e.g., by car), transport Simlandi in your cooler bag. Remember to include the cold gel packs to help maintain the proper temperature.
- For longer trips (e.g., by plane), the Simlandi Pen or prefilled syringe can be stored at room temperature (up to 25°C) for a single maximum period of 14 days. If you do not use it within 14 days, it must be discarded.
- Once you get to your destination, you may be able to use the mini-bar in your hotel room to store Simlandi:
 - Bring a thermometer with you to make sure the mini-bar temperature is between 2°C and 8°C. If in doubt, ask the hotel staff if they can arrange refrigeration for you.
 - Store Simlandi away from the freezer section and avoid direct contact with ice.

Travelling with Simlandi

When travelling by plane

- Review foreign policies when travelling with medications with your airline or travel agent. Some countries require passengers to declare medications in their possession upon arrival.
- Let your airline know that you need to keep Simlandi refrigerated before, during and after your flights.
- Verify with your airline that the Simlandi and the cold gel packs you use to keep Simlandi at the proper temperature are exempt from liquid restrictions at security. Keep the original Simlandi box as proof.
- It is important to keep Simlandi in its original packaging with the pharmacy label and your name. This can help at airport security to identify the product as your prescription and its requirement for proper refrigerated storage.
- At airports, everyone is entitled to private security screening. This can help you if you want to maintain confidentiality about your condition and treatment.
- If you have any problems, ask to speak to a supervisor, showing them your pharmacy prescription and your doctor's note. You can find a downloadable letter on the JAMP Care website.
- Liquid and gel-based prescription medications are exempt from the on-board liquid restrictions in Canada. You should store these medications in a carry-on baggage and declare them during security screening.
- Some security procedures might allow “visual inspection” of medication upon request to avoid X-ray screening of your luggage.
- For peace of mind, plan extra time for security procedures as staff may have additional questions regarding your medication.

What to pack in addition to your Simlandi

- Sharps disposal container
- Cooler bag
- Ice packs
- Alcohol pads/swabs
- Cotton balls or gauze pads
- Other prescription medications (as required)

Travel letter

Ask your *Single Point of Contact* for a Simlandi travel letter that includes important information for the airline regarding Simlandi's format, storage and transport.





Important information about Simlandi

When it should not be used

Do not take Simlandi if you:

- Are allergic to adalimumab or to any of its components
- Have a severe infection such as sepsis, tuberculosis and opportunistic infections
- Have moderate to severe heart failure

Interactions with Simlandi

As with most medicines, interactions with other drugs are possible. Tell your doctor or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with Simlandi:

- Etanercept (Enbrel®)
- Abatacept (Orencia®)
- Anakinra (Kineret®)
- Infliximab (Remicade®)
- Certolizumab pegol (Cimzia®)
- Golimumab (Simponi®)

Warnings and precautions

BEFORE you use Simlandi talk to your doctor or pharmacist if you:

- Have or have had any kind of infection including an infection that is in only one place in your body, or an infection that is in your whole body
- Have a history of infections that keep coming back or other conditions that might increase your risk of infections, including fungal infections
- Have ever had tuberculosis, or if you have been in close contact with someone who has had tuberculosis
- Resided or travelled to areas where there is greater risk for certain kinds of infections such as tuberculosis, histoplasmosis, coccidioidomycosis, blastomycosis, or parasitic infections
- Have ever had injury or hepatitis B virus infection or are at risk of developing this infection

- Experience any numbness or tingling or have ever had a disease that affects your nervous system like multiple sclerosis or Guillain-Barré syndrome
- Have or have had heart failure
- Are scheduled to have major surgery or dental procedures
- Are scheduled to be vaccinated for anything
- Are taking other medicines
- Are pregnant or could become pregnant
- Are breast-feeding or plan to breast-feed

Side effects and what to do about them

Like all medicines, Simlandi can have side effects.

Tell your doctor IMMEDIATELY if you 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)

Talk to your doctor AS SOON AS POSSIBLE if you 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



Important information about Simlandi

Talk to your doctor AS SOON AS POSSIBLE if you notice any of the following:

- 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

Serious side effects and what to do about them

Talk to your healthcare professional if you experience a SEVERE case of:

- Headache
- Abdominal pain

Talk to your healthcare professional EVERY TIME you experience a case of:

- Injection site reaction
- Cough and cold symptoms, including sore throat
- Rash
- Nausea
- Fever

STOP taking Simlandi and get IMMEDIATE MEDICAL HELP if you experience:

- Pneumonia
- 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)

This is not a complete list of side effects. For any unexpected effects while taking Simlandi, contact your doctor or pharmacist.

Resources

For more information about the diseases covered in this brochure, take a look at the following websites:

Arthritis Society of Canada



Canadian Spondylitis Association



Canadian Hidradenitis Suppurativa Foundation



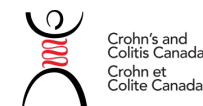
Canadian Psoriasis Network



Canadian Dermatology Association



Crohn's and Colitis Canada



Canadian Association of Psoriasis Patients



Fighting Blindness Canada



ACT4Biosimilars



Notes











Notes

Support. Confidence. Community. Simplicity.



As you start your treatment with Simlandi, you can rely on our support – every step of the way. JAMP Care is an established Patient Support Program designed to be easy to use with unsurpassed responsiveness.

Our comprehensive package of services includes:

-  **A single point of contact**
-  **Laboratory and vaccination services included**
-  **Fast reimbursement navigation support**
-  **Financial assistance**
-  **Clinical testing and vaccinations**
-  **Routine blood work**
-  **Medication delivery**
-  **Educational materials**
-  **Injection training at-home or in-clinic**
-  **Nutrition counselling available on demand**



For help accessing any of these services, speak with your *Single Point of Contact* or contact JAMP Care at:

 **1-855-310-5102**

 **jampcare@supportprogram.com**



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SIM-002-SE22-E