INDICATIONS AND CLINICAL USE:[1]

Indications:

Adults

- **Rheumatoid Arthritis (RA):** reducing the signs and symptoms, inducing major clinical response and clinical remission, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Simlandi can be used alone or in combination with methotrexate (MTX) or other disease-modifying anti-rheumatic drugs (DMARDs).
- **Polyarticular Juvenile Idiopathic Arthritis (JIA):** in combination with methotrexate, reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients, 2 years of age and older, weighing ≥ 30 kg, who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Simlandi can be used as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is not appropriate.
- **Psoriatic Arthritis (PsA):** reducing the signs and symptoms of active arthritis and inhibiting the progression of structural damage and improving the physical function in adult psoriatic arthritis patients. Simlandi can be used in combination with methotrexate (MTX) in patients who do not respond adequately to methotrexate alone.
- **Ankylosing Spondylitis (AS):** reducing the signs and symptoms in adult patients with active ankylosing spondylitis who have had an inadequate response to conventional therapy.
- **Adult Crohn's Disease (CD):** reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy, including corticosteroids and/or immunosuppressants. Simlandi is indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.

BIOJAMP

- **Adult Ulcerative Colitis (UC):** for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response to conventional therapy including corticosteroids and/or azathioprine or 6-mercaptopurine (6-MP) or who are intolerant to such therapies. The efficacy of Simlandi in patients who have lost response to or were intolerant to TNF blockers has not been established.

- **Adult Hidradenitis Suppurativa (HS):** for the treatment of active moderate to severe hidradenitis suppurativa in adult patients who have not responded to conventional therapy (including systemic antibiotics).

- **Plaque Psoriasis (Ps):** for the treatment of adult patients with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy. For patients with chronic moderate plaque psoriasis, Simlandi should be used after phototherapy has been shown to be ineffective or inappropriate.

- **Adult Uveitis:** for the treatment of non-infectious uveitis (intermediate, posterior and panuveitis) in adult patients with inadequate response to corticosteroids or as corticosteroid sparing treatment in corticosteroid-dependent patients.

Pediatrics

- **Polyarticular JIA:** in combination with methotrexate, reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients, from 2 years of age, weighing ≥ 30 kg, who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Simlandi can be used as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is not appropriate.

- **Adolescent Hidradenitis Suppurativa (HS):** for the treatment of active moderate to severe hidradenitis suppurativa in adolescent patients (from 12 to 17 years of age weighing ≥ 30 kg), who have not responded to conventional therapy (including systemic antibiotics).

- **Pediatric Uveitis:** for the treatment of chronic non-infectious anterior uveitis in pediatric patients from 2 years of age and weighing ≥ 30 kg, who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.

BIOJAMP

Clinical use Pediatrics (<18 years of age):

- **Polyarticular JIA:** Adalimumab has not been studied in pediatric patients with polyarticular JIA less than 2 years of age or in pediatric patients with a weight below 10 kg. Simlandi is available for pediatric polyarticular juvenile patients who require the full 40 mg dose based on body weight. The auto-injector and pre-filled syringe are not designed to deliver a portion of the full 40 mg dose and must not be used in pediatric patients who require < 40 mg dose.
- **Adolescent Hidradenitis Suppurativa:** There are no clinical trials with adalimumab in adolescent patients with hidradenitis suppurativa (HS). The dosage of Simlandi in these patients has been determined based on pharmacokinetic/pharmacodynamic modelling and simulation.
- **Pediatric Uveitis:** Adalimumab has not been studied in pediatric patients with uveitis less than 2 years of age. Very limited data are available for pediatric patients with uveitis between 2 and < 3 years of age.

Geriatrics (>65 years of age):

Evidence from clinical studies and experience suggests that use of adalimumab in the geriatric population is not associated with differences in effectiveness.

CONTRAINDICATIONS:

- Patients with known hypersensitivity to adalimumab or any of its components.
- Patients with severe infections such as sepsis, tuberculosis and opportunistic infections.
- Patients with moderate to severe heart failure (NYHA class III/IV).

MOST SERIOUS WARNINGS AND PRECAUTIONS:

- **Hepatosplenic T-cell lymphoma (HSTCL):** Very rare post-marketing reports of hepatosplenic T-cell lymphoma (HSTCL), a rare aggressive lymphoma that is often fatal, have been identified in patients treated with adalimumab.
- **Infections:** Serious infections due to bacterial, mycobacterial, invasive fungal, viral, parasitic, or other opportunistic infections have been reported in patients receiving TNF-blocking agents. Sepsis, rare cases of tuberculosis, candidiasis, listeriosis, legionellosis and pneumocystis have also been reported. Other serious infections seen in clinical trials include pneumonia, pyelonephritis, septic arthritis and septicemia. Hospitalization or fatal outcomes associated with infections have been reported. Many of the serious infections have occurred in patients on concomitant immunosuppressive therapy that, in addition to their underlying disease, could predispose them to infections.
- **Pediatric malignancy:** Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF-blockers, including adalimumab.

BIOJAMP

OTHER RELEVANT WARNINGS AND PRECAUTIONS

- Concomitant administration with other biologic DMARDs (e.g., anakinra and abatacept) or other TNF antagonists could increase risk for infections and other potential pharmacological interactions.
- Patients who require surgery while taking adalimumab should be closely monitored for infections, and appropriate actions should be taken.
- Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with adalimumab.
- Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF-blocking agents.
- If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with Simlandi, treatment should be discontinued.
- TNF-blocking agents have been associated with rare cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of demyelinating disease.
- Reports of serious allergic reactions, including anaphylaxis, have been received following adalimumab administration.

BIOJAMP

FOR MORE INFORMATION:

Please consult the product monograph at **https://pdf.hres.ca/dpd_pm/00064183.PDF** for important information relating to adverse reactions, drug interactions, dosing information, overdosage, storage and stability and special handling instructions, which have not been exhaustively discussed in this piece.

REFERENCES:

1. Text: Product Monograph PrSimlandi™ / PrSimlandi™, JAMP Pharma Corporation, January 5, 2022 https://health-products.canada.ca/dpd-bdpp/dispatch-repartition do;jsessionid=8A5F2E0968E3A66DCDC42F2B4C76139A

2. Nash P, Vanhoof J, Hall S, et al. Randomized Crossover Comparison of Injection Site Pain with 40 mg/0.4 or 0.8 mL Formulations of Adalimumab in Patients with Rheumatoid Arthritis. Rheumatol Ther. 2016;3(2):257-270. doi:10.1007/s40744-016-0041-3

BIOJAMP