COSENTYX® Safety and tolerability profiles

COSENTYX® (secukinumab) is indicated for the treatment of:[1]

- Moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy
- Severe plaque psoriasis in pediatric patients 12 to less than 18 years of age who are candidates for systemic therapy or phototherapy and have a body weight ≥50 kg
- Adult patients with active psoriatic arthritis when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. COSENTYX® can be used alone or in combination with methotrexate
- Adult patients with active ankylosing spondylitis who have responded inadequately to conventional therapy

Pr Cosentyx®
secukinumab

Tolerability profile

Adverse drug reactions reported by ≥2% of patients[1]

	Psoriasis		Psoriatic arthritis			Ankylosing spondylitis	
	ERASURE*, FIXTURE†, FEATURE‡ & JUNCTURE§ (through Week 12)		FUTURE 1¶ & FUTURE 2†† (through Week 16)			MEASURE 2‡‡ (through Week 16)	
Adverse reaction	COSENTYX® 300 mg (n=690)	Placebo (n=694)	COSENTYX® (FUTURE 1) 150 mg (n=202)	COSENTYX® (FUTURE 2) 150 mg (n=100)	Placebo (n=300)	COSENTYX® 150 mg (n=72)	Placebo (n=271)
Nasopharyngitis	11.4%	8.6%	9.4%	4.0%	5.7%	11.1%	5.2%
Diarrhea	4.1%	1.4%	0%	0%	0%	0%	0%
Upper respiratory tract infection	2.5%	0.7%	6.4%	8.0%	5.7%	1.4%	2.2%
Oral herpes	0%	0%	2.5%	0%	1.0%	2.8%	0.4%
Pharyngitis	0%	0%	2.0%	0%	0%	0%	0%
Rhinitis	0%	0%	0%	2.0%	0%	0%	0%
Conjunctivitis	0%	0%	0%	2.0%	0%	0%	0%

Adapted from COSENTYX® Product Monograph.

The safety profile observed in FUTURE 5§§ was generally similar to that observed in FUTURE 1 and FUTURE 2.[1]

IMMUNOGENICITY

<1% of COSENTYX® patients developed secukinumab antibodies at 52 weeks (about half were neutralizing but not associated with loss of efficacy).[1]

Safety profile

The most frequently reported adverse drug reactions were upper respiratory tract infections (most frequently nasopharyngitis, pharyngitis and rhinitis). Most of the events were mild or moderate in severity.[1]

In the placebo-controlled period of the phase 3 studies, the proportion of patients who discontinued treatment due to adverse events was:

Approximately 1.2% of COSENTYX® patients and 1.2% of placebo patients in plaque psoriasis trials[1]

1.6% of COSENTYX® patients and 2.7% of placebo patients in psoriatic arthritis trials[1]

2.0% of COSENTYX® patients and 3.7% of placebo patients in ankylosing spondylitis trials[1]

Adverse reactions that occurred at rates less than 1% in the placebo-controlled period of the plaque psoriasis studies through Week 12 included: sinusitis, tinea pedis, conjunctivitis, tonsillitis, oral candidiasis, and neutropenia. No new less common adverse reactions were identified in the clinical trials in psoriatic arthritis and ankylosing spondylitis.[1]

Note: In the FIXTURE study, <1% of COSENTYX® patients experienced injection site reactions (0.7% in the combined COSENTYX® groups vs. 11.1% in the etanercept group; significance not assessed).[2]*

* ERASURE was a randomized, double-blind, placebo-controlled, multicenter trial. Patients were randomized to receive COSENTYX® 150 mg (n=245), COSENTYX® 300 mg (n=245) or placebo (n=248). COSENTYX® injections were administered once weekly at Weeks 0, 1, 2 and 3, then monthly from Week 4 to Week 48.

† FIXTURE was a phase III randomized, 52-week, double-blind, placebo-controlled, active-comparator controlled, multicentre trial. Patients were randomized in a 1:1:1:1 ratio to receive COSENTYX® 150 mg (n=327), COSENTYX® 300 mg (n=327), etanercept 50 mg (n=326) or placebo (n=326). COSENTYX® injections were administered once weekly at Weeks 0, 1, 2 and 3, then monthly from Week 4 to Week 48. Etanercept injections were administered twice weekly for 12 weeks, then once weekly from Week 12 to Week 51.[1]

‡ FEATURE was a randomized , double-blind, controlled, multicenter trial. Patients were randomized to receive COSENTYX® 150 mg (n=59), COSENTYX® 300 mg (n=59) or placebo (n=59). COSENTYX® injections were administered once weekly at Weeks 0, 1, 2 and 3, then monthly from Week 4 to Week 12.

§ JUNCTURE was a randomized , double-blind, controlled, multicenter trial. Patients were randomized to receive COSENTYX® 150 mg (n=61), COSENTYX® 300 mg (n=60) or placebo (n=61). COSENTYX® injections were administered once weekly at Weeks 0, 1, 2 and 3, then monthly from Week 4 to Week 12.

¶ FUTURE 1 was a randomized, double-blind, placebo-controlled, multicenter trial. Patients were randomized to receive COSENTYX® IV loading dose (10 mg/kg) or placebo at Weeks 0, 2 and 4 followed by COSENTYX® 75 mg (n=202), COSENTYX® 150 mg (n=202) or placebo (n=202) administered once monthly.

†† FUTURE 2 was a randomized, double-blind, placebo-controlled, multicenter trial. Patients were randomized to receive COSENTYX® SC loading dose (75mg, 150 mg or 300 mg) or placebo at Weeks 0, 1, 2, 3 and 4 followed by COSENTYX® 75 mg (n=99), COSENTYX® 150 mg (n=100), COSENTYX® 300 mg (n=100) or placebo (n=98) administered once monthly.

‡‡ MEASURE 2 was a randomized, double-blind, placebo-controlled, multicenter trial. Patients randomized to COSENTYX® received 75 mg (n=73) or 150 mg (n=72) SC at Weeks 0, 1, 2, 3, and 4 followed by the same dose every month. At Week 16, patients who were randomized to placebo (n=74) at baseline were re-randomized to receive COSENTYX® (either 75 mg or 150 mg) SC every month.

§§ FUTURE 5 was a randomized, double-blind, placebo-controlled, multicenter trial. Patients were randomized to receive COSENTYX® 150 mg (n=220), 300 mg (n=222), or placebo (n=332) SC at Weeks 0, 1, 2, 3 and 4 followed by the same dose every month, or a once monthly injection of COSENTYX® 150 mg (n=222). Patients treated with placebo received COSENTYX®, either 150 mg or 300 mg, SC, per baseline randomization, at Week 16 or Week 24 based upon responder status.

Important safety information

Indication and clinical use:

COSENTYX® (secukinumab) is indicated for the treatment of:

- Moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy
- Severe plaque psoriasis in pediatric patients 12 to less than 18 years of age who are candidates for systemic therapy or phototherapy and have a body weight ≥50 kg
- Adult patients with active psoriatic arthritis when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. COSENTYX® can be used alone or in combination with methotrexate
- Adult patients with active ankylosing spondylitis who have responded inadequately to conventional therapy

Geriatric patients ≥65 years of age: although limited in patient number, no differences in safety or efficacy were observed between older and younger patients.

Pediatrics <18 years of age: safety and effectiveness in pediatric patients with severe plaque psoriasis below the age of 12 years have not been established. Safety and effectiveness in pediatric patients with the principal diagnosis of psoriatic arthritis or ankylosing spondylitis below the age of 18 years have not been established.

Contraindications:

- Severe hypersensitivity to the active substance or any of its components

Relevant warnings and precautions:

- Infections: could potentially increase risk of infections; caution in patients with a chronic infection or history of recurrent infections; patients should be evaluated for tuberculosis prior to initiation of treatment with COSENTYX®
- Caution in patients with active inflammatory bowel disease
- Caution in latex-sensitive patients: natural rubber latex derivatives in the removable cap of the prefilled syringe/COSENTYX® SensoReady® pen
- Consider completion of all age-appropriate immunizations according to current guidelines prior to treatment; should not be used with live vaccinations; can be used with those that are inactivated or non-live
- Hypersensitivity reactions: rare cases of anaphylaxis and cases of urticaria occurred in COSENTYX®-treated patients in clinical trials
- Pregnancy: should only be used if the potential benefit justifies the potential risk to the fetus
- Nursing women: caution should be exercised

For more information:

Consult the Product Monograph at www.novartis.ca/CosentyxMonograph for important information relating to adverse reactions, drug interactions and dosing information which has not been discussed in this piece. The Product Monograph is also available by calling 1-800-363-8883.

References: 1. COSENTYX® Product Monograph. Novartis Pharmaceuticals Canada Inc. January 20, 2021. **2.** Langley RG, Elewski BE, Lebwohl M, *et al*. Secukinumab in plaque psoriasis--results of two phase 3 trials. *N Engl J Med*. 2014 Jul 24;371(4):326-38. doi: 10.1056/NEJMoa1314258.

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