

Cosentyx Rheum - Efficacy in JIA - HCP

[Prescribing information](#)

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 **Cosentyx**[®]
secukinumab

Cosentyx[®] (secukinumab): Efficacy in juvenile idiopathic arthritis (JIA)

Cosentyx, alone or in combination with methotrexate (MTX), is indicated for the treatment of active enthesitis-related arthritis (ERA) in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy; active juvenile psoriatic arthritis (JPsA) in patients 6 years and older (alone or in combination with MTX) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy.¹

[Full indication for Cosentyx can be found here](#)

Cosentyx is the first and only fully human IL-17A inhibitor approved for use in children as young as 6 years old with JPsA and ERA¹⁻³

Cosentyx helps to reduce systemic inflammation in JIA by direct and effective inhibition of IL-17A⁴⁻⁶

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IN JUNIPERA, Cosentyx demonstrated...⁴

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- A significantly longer time to flare vs placebo in paediatric patients with ERA and JPsA⁴**
- FAST and LASTING joint relief as early as Week 12, sustained up to 2 years⁴**
- FAST and LASTING resolution of enthesitis and dactylitis as early as Week 12, sustained up to 2 years⁷**
- A generally well-tolerated safety profile, consistent with that seen in adult indications^{1,4}**

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In treatment period 2 (TP2), Cosentyx demonstrated a significantly longer time to flare vs placebo in paediatric patients with ERA and JPsA*⁴

See below for study design.

Days	Cosentyx 75/150 mg SC (n=37)	Placebo (n=38)
0	0	0
57	0	10
113	10	25
169	20	35
225	30	45
281	40	55
337	50	65
393	60	75
449	70	85
505	80	95
561	90	100
617	95	100
673	100	100

Adapted from Brunner HI, et al. 2022.⁴

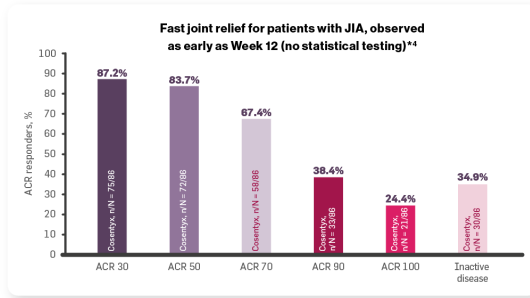
- The risk of flare was reduced by 72% for up to 2 years for patients on Cosentyx compared with placebo (27% vs 55%; HR 0.28; 95% CI: 0.13 to 0.63; p<0.001).⁴**
- Paediatric patients with ERA and JPsA on Cosentyx showed a significantly longer time to flare than those on placebo, from Week 12 up to Week 104 (27% [n/N = 10/37] vs 55% [n/N = 21/38], respectively; p<0.001).⁴**

The primary endpoint of time to disease flare with Cosentyx vs placebo in TP2 was met (p<0.001).⁴

Patients who did not experience a disease flare in TP2, were censored at the date of their last non-missing flare evaluation in TP2.

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It was observed that Cosentyx had a fast and lasting response in JIA (as early as Week 12, sustained up to 2 years; no statistical testing)⁴



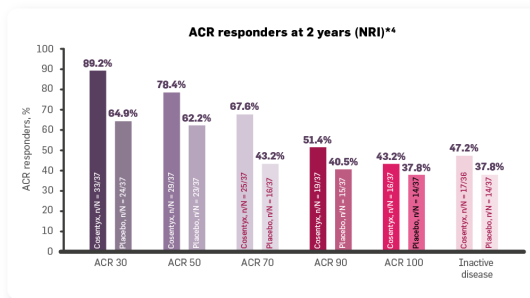
Adapted from Brunner HI, et al. 2022.⁴

Key secondary endpoints in the JUNIPERA study included ACR 30/50/70/90 and 100.⁴

By Week 12, over **80%** of Cosentyx patients in the JUNIPERA study achieved **ACR50** response (83.7%, n/N=72/86, CI: 73.9, 90.5).¹⁴

Inactive disease, a preferred treatment target in JIA and key secondary endpoint, was achieved by **35%** of Cosentyx patients (N=30) at Week 12.⁴

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Adapted from Brunner HI, et al. 2022.⁴

In JUNIPERA TP2, more patients with JIA achieved and maintained **JIA-ACR 30/50/70/90/100 scores**,¹ a key secondary endpoint, with Cosentyx (N=37) compared with placebo (N=38) at Week 104 (89%, 78%, 68%, 51%, and 43% vs 65%, 62%, 43%, 41%, and 38%, respectively).⁴

(observational data; no statistical testing)

Image

Fast acting resolution of enthesitis and dactylitis in JIA⁷ (observational data; no statistical testing)

In children with JPsA:⁷

68% complete resolution of enthesitis at Week 12 (n=15/22)

63% complete resolution of dactylitis at Week 12 (n=10/16)

In children with ERA:⁷

74% complete resolution of enthesitis at Week 12 (n=34/46)

60% complete resolution of dactylitis at Week 12 (n=3/5)

Image

A generally well-tolerated safety profile, consistent with that seen in adult indications^{1,4}

Most frequent TEAEs	Cosentyx (n=86)	Cosentyx (n=37)	Placebo (n=38)	Entire total Cosentyx exposure period (n=86)
	TP1 ¹ n (%)	TP2 ² n (%)	n (%)	n (%)
Nasopharyngitis	5 (5.8)	14 (37.8)	6 (15.8)	27 (31.4)
Diarrhoea	1 (1.2)	9 (24.3)	2 (5.3)	17 (19.8)
Nausea	6 (7.0)	7 (18.9)	3 (7.9)	19 (22.1)
Upper respiratory tract infection	6 (7.0)	6 (16.2)	6 (15.8)	19 (22.1)
Cough	1 (1.2)	7 (18.9)	4 (10.5)	13 (15.1)
Arthralgia	2 (2.3)	6 (16.2)	3 (7.9)	12 (14.0)
Oropharyngeal pain	5 (5.8)	4 (10.8)	2 (5.3)	12 (14.0)
Headache	5 (5.8)	3 (8.1)	3 (7.9)	12 (14.0)
Fever	2 (2.3)	6 (16.2)	2 (5.3)	12 (14.0)

Adapted from Brunner HI, et al. 2022.⁴

See study design below for TP1 and TP2 definitions.

- There was only **one reported injection-site reaction** (n/N = 1/48)⁴
- **No patients developed anti-drug antibodies** during treatment⁴
- No deaths were reported in the study. 11 patients (12.8%) reported nonfatal serious adverse events and 8 (9.3%) patients discontinued study treatment due to adverse events throughout the entire study period (3 patients with Cosentyx [6.3%] and 5 with placebo [13.2%])⁴

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Click on the arrows for supporting data

[Click this link for more information on the safety profile of Cosentyx.](#)

*JUNIPERA was a Phase III, double-blind, placebo-controlled, randomised withdrawal study in biologic-naïve paediatric ERA and JPsA patients with active disease (N=86). Patients received Cosentyx 75/150 mg depending on weight <50/≥50 kg respectively, at baseline and Weeks 1, 2, 3 and 4 and then every 4 weeks until Week 100. The primary endpoint was the time to disease flare[§] with Cosentyx vs placebo in TP2. Key secondary endpoints included JIA ACR20/50/70/90/100 responses, inactive disease status, JIA ACR CRVs, JADAS-27-C reactive protein and total enthesitis and dactylitis counts. Safety profile analysis was calculated for the entire study period in the overall population. In Treatment Period 1, all patients received open-label treatment with Cosentyx until Week 12. In Treatment Period 2, JIA ACR30 responders at Week 12 were randomised 1:1 to continue Cosentyx or begin placebo in the double-blind period up to Week 100. Patients who experienced a flare received open-label Cosentyx up to Week 104 (Treatment Period 3).⁴

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Safety profile

Image



Dosing

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Mechanism of action

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HCP resources

Therapeutic Indications¹

Cosentyx is indicated for the treatment of moderate to severe plaque psoriasis (PsO) in adults, children and adolescents from the age of 6 years who are candidates for systemic therapy; active psoriatic arthritis (PsA) in adult patients (alone or in combination with methotrexate [MTX]) when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate; active ankylosing spondylitis (AS) in adults who have responded inadequately to conventional therapy; active nonradiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs; active moderate to severe hidradenitis suppurativa (HS; acne inversa) in adults with an inadequate response to conventional systemic HS therapy; active enthesitis-related arthritis (ERA) in patients 6 years and older (alone or in combination with MTX) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy; active juvenile psoriatic

arthritis (JPsA) in patients 6 years and older (alone or in combination with MTX) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy.¹

[†]In Treatment Period 1, all patients received Cosentyx until Week 12. Key secondary endpoints included ACR 30/50/70/90 and 100. At Week 1, 33.7%, 22.1%, 8.1%, 2.3% and 1.2% of children with JIA were JIA ACR 30, 50, 70, 90 and 100 responders, respectively.⁴ At Week 12, 87%, 84%, 67%, 38% and 24% of children with JIA were JIA-ACR 30, 50, 70, 90 and 100 responders, respectively. A total of 34.9% of patients with JIA reached inactive disease status at Week 12.⁴

[‡]The JIA ACR30/50/70/90/100 response as per the JIA-ACR response criteria is defined as 30/50/70/90/100% improvement in three or more of six CRVs, with no more than one of the remaining CRVs worsening by >30%.¹

[§]Disease flare was defined as $\geq 30\%$ worsening from baseline in ≥ 3 of the 6 JIA ACR response criteria, >30% improvement relative to the end of Week 12.⁴

ACR, American College of Rheumatology; AS, ankylosing spondylitis; axSpA, axial spondyloarthritis; CI, confidence interval; CRP, C-reactive protein; CRV, core set variable; DMARD, disease modifying anti-rheumatic drug; ERA, enthesitis-related arthritis; HR, hazard ratio; IL-17A, interleukin 17A; JADAS, juvenile arthritis disease activity score; JIA, juvenile idiopathic arthritis; JPsA, juvenile psoriatic arthritis; MoA, mechanism of action; MRI, magnetic resonance imaging; MTX, methotrexate; nr-axSpA, non-radiographic axial spondyloarthritis; NSAID, non-steroidal anti-inflammatory drug; PsA, psoriatic arthritis; PsO, plaque psoriasis; TP2, Treatment Period 2.

References

1. Cosentyx® (secukinumab) Summary of Product Characteristics.
2. Taltz (ixekizumab) Summary of Product Characteristics.
3. Bimzelx (bimekizumab) Summary of Product Characteristics.
4. Brunner HI, et al. *Ann Rheum Dis* 2022;82:154–160.
5. Paroli M, et al. *Medicina* 2022;58:1552.
6. Tsukazaki H, et al. *Int J Mol Sci* 2020;21:6401.
7. Novartis Data on File. CAIN457F2304. Data Analysis Report. January 2022.

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Adverse events should be reported. Reporting forms and information can be found at

www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report, or alternatively email medinfo.uk@novartis.com or call 01276 698370.

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