

Cosentyx Rheum - Efficacy in JIA - HCP

[Prescribing information](#)

Image



Image



 **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.

Time to disease flare*

Days	0	57	113	169	225	281	337	393	449	505	561	617	673
Patients with disease flare (%)	0	10	20	30	35	40	45	50	55	60	65	70	75
Legend	—	—	—	—	—	—	—	—	—	—	—	—	—
Group	—	—	—	—	—	—	—	—	—	—	—	—	—
n	97	94	92	90	88	86	84	82	80	78	76	74	72
Group	—	—	—	—	—	—	—	—	—	—	—	—	—
n	38	32	28	22	21	20	19	19	18	16	15	15	0

Adapted from Brunner HI, et al. 2022.⁴

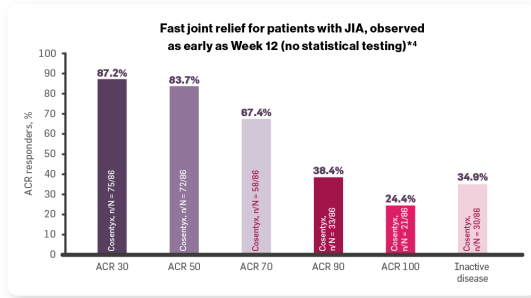
- The risk of flare was reduced by 72% for up to 2 years for patients on Cosentyx compared with placebo (27% vs 55%; HR 0.28; 95% CI: 0.13 to 0.63; p<0.001).⁴**
- Paediatric patients with ERA and JPsA on Cosentyx showed a significantly longer time to flare than those on placebo, from Week 12 up to Week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



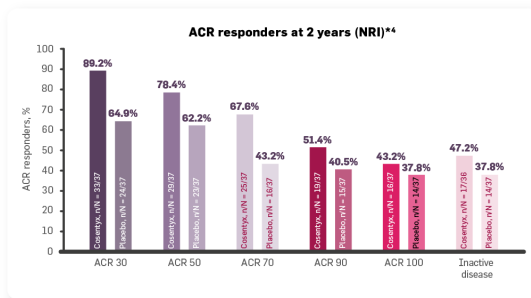
Adapted from Brunner HI, et al. 2022.⁴

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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