NOVARTIS

Cosentyx Rheum - Efficacy in JIA - HCP

Prescribing information

Image

Image

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 indications 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 ERA[1–3]

Cosentyx helps to reduce systemic inflammation in JIA by direct and effective inhibition of IL-17A[4–6]

Discover the MOA

IN JUNIPERA, Cosentyx demonstrated...[4]

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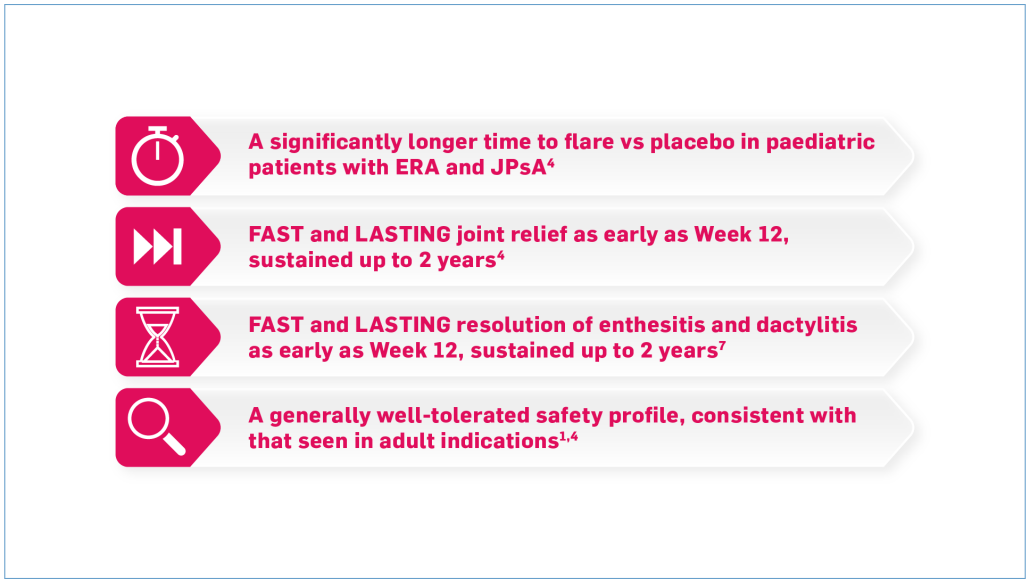

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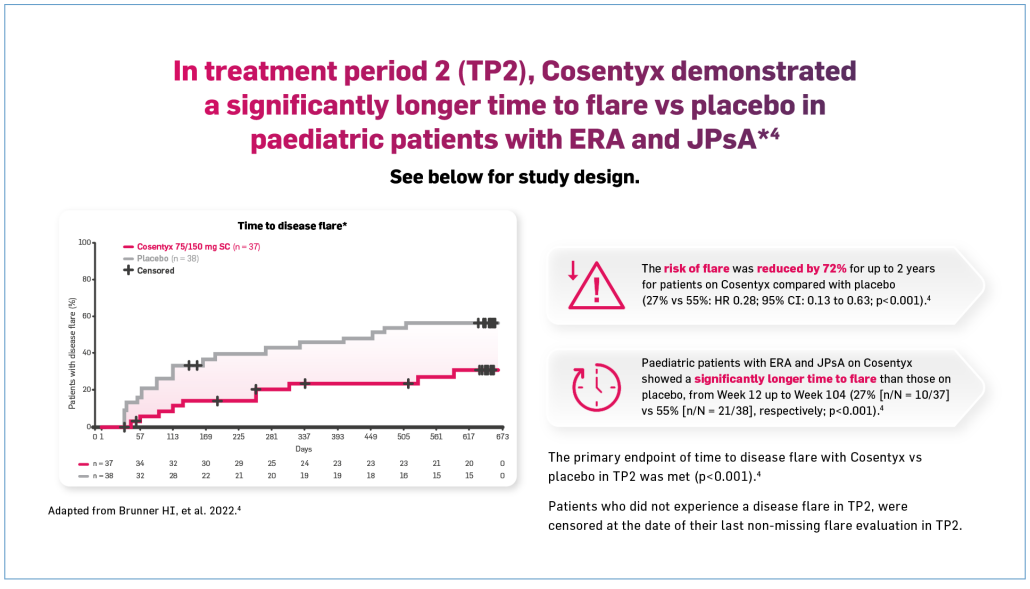

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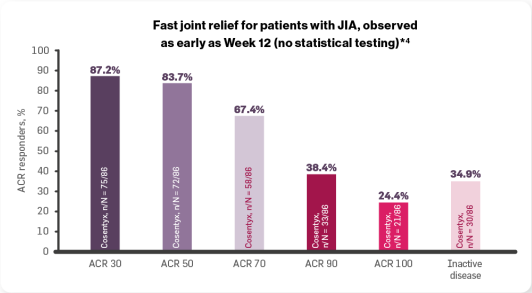
It was observed that Cosentyx had a fast and lasting response in JIA (as early as Week 12, sustained up to 2 years; no statistical testing)[4]



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).[†4]

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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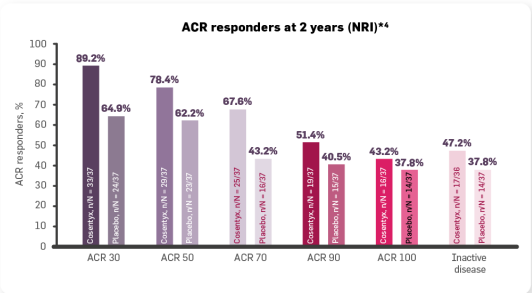

Adapted from Brunner HI, et al. 2022.[4]

In JUNIPERA TP2, more patients with JIA achieved and maintained **JIA-ACR 30/50/70/90/100 scores**,[‡] 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 JIA[7] (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)

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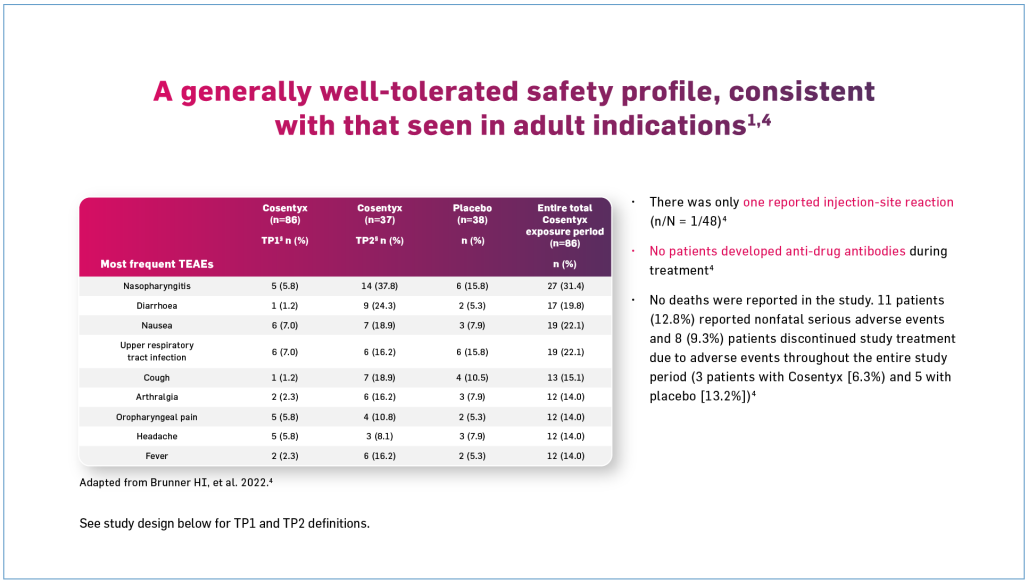

Previous Next

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

Image

Mechanism of action

Image

HCP resources

Therapeutic Indications[1]

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 ≥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.

UK | January 2025 | FA-11313556

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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