NOVARTIS

Cosentyx Derm - Heritage - HCP

Prescribing information

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Cosentyx® (secukinumab) heritage

Cosentyx® (secukinumab) 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 moderate to severe hidradenitis suppurativa (HS; acne inversa) in adults with an inadequate response to conventional systemic HS therapy.[1]

Full indications for Cosentyx can be found here

The Cosentyx legacy

Image

1,000,000

patients treated globally and counting, across indications[3]

Image

150+

clinical trials across indications*[4]

Image

8 years

of real-world experience, worldwide across indications[5]

Image

8

indications[1,2]

Cosentyx has 5-years of a consistent safety profile across 24 studies in PsO and PsA[6]

Confidence to prescribe Cosentyx to your eligible patients – Cosentyx real-world evidence (RWE)

RWE shows a consistent safety profile with long-term use of Cosentyx over 6 years[7]

Please refer to the Cosentyx Summary of Product Characteristics (SmPC) for full safety information, and the safety profile page **here**.

No trend towards increased AE rates over time (pooled AS, PsA, PsO):[7]

Image

AEs of select interest (EAIR per 100 PY)	1 year	2 years	3 years	4 years	5 years	6 years	Cumulative rate
Serious infections Cases	2.0 n=149	1.7 n=475	0.7 n=649	1.3 n=1841	1.3 n=2285	1.1 n=2226	1.3 n=8719
Malignant or unspecified tumours Cases	0.2 n=15	0.2 n=50	0.2 n=225	0.3 n=422	0.3 n=520	0.3 n=573	0.3 n=1896
MACE Cases	0.2 n=15	0.1 n=39	0.2 n=151	0.2 n=238	0.2 n=264	0.1 n=287	0.2 n=1031
Total IBD Cases	0.2 n=12	0.2 n=46	0.2 n=185	0.3 n=340	0.2 n=312	0.1 n=261	0.2 n=1291
Exposure (PY)	7450	28,549	93,744	137,325	182,024	212,636	680,470

<1% incidence rate of IBD, which is within expected background incidence rate (per 100 PY).[6]

For further adverse events, please refer to the Cosentyx SmPC.

Image

No new safety signals in clinical trials, including those for paediatric juvenile idiopathic arthritis (JIA, n=81) and PsO (n=162) patients as young as 6 years old[†1,2,4]

Image

No new safety signals have been identified in **more than 680,000 PY** across AS, PsA and PsO indications[7]

Image

No trend towards **increased rates of major adverse cardiovascular events (MACE), or malignancy** reported in clinical trials and RWE[‡7,8]

Image

Cosentyx

Image

Cosentyx in PSO

Image

Cosentyx in HS

Image

Safety profile

Image

Mechanism of action

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 non-radiographic 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.

*Not limited to licensed indications.
†In paediatric PsO, JPsA and ERA.
‡The pooled clinical trial safety data for Cosentyx involved 7300+ patients and 21 randomised controlled clinical trials, including long-term exposure of up to 5 years in PsO and PsA and up to 4 years in AS. The post-marketing data are from the Cosentyx Periodic Safety Update Report (PSUR) submitted to global health authorities.[8]

AE, adverse event; AS, ankylosing spondylitis; axSpA, axial spondyloarthritis; EAIR, exposure-adjusted incidence rate; HS, hidradenitis suppurativa; IBD, inflammatory bowel disease; JIA, juvenile idiopathic arthritis; JPsA, juvenile psoriatic arthritis; MACE, major adverse cardiovascular event; MTX, methotrexate; PsA, psoriatic arthritis; PsO, psoriasis; PSUR, Periodic Safety Update Report; PY, patient-years; RWE, real-world evidence.

References

1. Cosentyx® (secukinumab) GB Summary of Product Characteristics.

2. Cosentyx® (secukinumab) NI Summary of Product Characteristics

3. Novartis Data on File. Secukinumab (Sec008). February 2023.

4. ClinicalTrials.gov. Search results for ‘secukinumab’, completed, terminated and active, not recruiting trials. Available at: https://clinicaltrials.gov/search?term=Secukinumab,&aggFilters=status:com [Accessed July 2024].

5. European Medicines Agency. European public assessment report. Medicine overview. Cosentyx (secukinumab). https://www.ema.europa.eu/en/documents/overview/cosentyx-epar-medicine-o.... [Accessed July 2024].

6. Gottlieb AB, et al. *Acta Derm Venereol* 2022;102:adv00698.

7. Novartis data on file. Cosentyx PSUR; 26 December 2019–25 December 2020. February 2021.

8. Deodhar A et al. *Arthritis Res Ther* 2019;21(1):111.

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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