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.

Cosentyx Summary of Product Characteristics (SmPC) can be found here.

The Cosentyx legacy

Image

patients treated globally and counting, across indications[2]

Image

150+

clinical trials across indications*[3]

Image

10 years

of real-world clinical experience, worldwide across indications†[4]

Image

8

indications[1]

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

RWE shows a consistent safety profile across indications with long-term use of Cosentyx over 9 years[5]

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 data in a PSUR including exposure in clinical trials and marketing experience):[5]

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AEs of select interest (EAIR per 100 PY)	1 year	2 years	3 years	4–6 years	7–9 years	Cumulative rate
Serious infections	2.6	1.6	0.7	1.2	0.3	0.7
Cases	n=238	n=707	n=649	n=6,352	n=3,783	n=12,588
Malignant or unspecified tumours	0.2	0.2	0.2	0.3	0.1	0.2
Cases	n=17	n=71	n=225	n=1,515	n=1,663	n=3,555
MACE	0.2	0.1	0.2	0.1	0.1	0.1
Cases	n=21	n=55	n=151	n=789	n=888	n=2,081
Total IBD	0.2	0.2	0.2	0.2	0.1	0.1
Cases	n=16	n=83	n=185	n=913	n=627	n=1,933
Exposure (PY)	9,288	45,420	93,744	531,985	1,201,975	1,882,445

Adapted from Novartis Data on File, 2025.[5]

Successive time periods of PSUR shown with cumulative rate: 26 Dec 2014 to 25 June 2015; 26 June 2015 to 25 Dec 2015; 26 Dec 2015 to 25 June 2016; 26 June 2016 to 25 Dec 2016; 26 Dec 2016 to 25 Dec 2017; 26 Dec 2017 to 25 Dec 2018; 26 Dec 2018 to 25 Dec 2019; 26 Dec 2019 to 25 Dec 2020; 26 Dec 2020 to 25 Dec 2023.[5]

Cosentyx is contraindicated in patients with clinically important, active infection, e.g. active tuberculosis.[1]

Cosentyx has the potential to increase the risk of infections. Serious infections have been observed in patients receiving Cosentyx in the post-marketing setting. Caution should be exercised when considering the use of secukinumab in patients with a chronic infection or a history of recurrent infection. Cases of inflammatory bowel disease have been reported with Cosentyx, therefore, it is not recommended in patients with IBD. Please refer to the SmPC for full safety details.[1]

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

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Consistent safety profile in clinical trials, including those for paediatric JIA (n=86) and PsO (n=162) patients as young as 6 years old[‡1]

Image

Consistent safety profile in more than **1.8 million PY** across AS, PsA and PsO indications[5]

Image

No trend towards **increased rates of major adverse cardiovascular events (MACE), or malignancy** reported in clinical trials and RWE[5]

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 PsO in adults, children and adolescents from the age of 6 years who are candidates for systemic therapy; active PsA in adult patients (alone or in combination with MTX) when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate; active AS in adults who have responded inadequately to conventional therapy; active 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 HS (acne inversa) in adults with an inadequate response to conventional systemic HS therapy; active 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 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]

*Not limited to licensed indications.
†Since first indication in eligible adults with moderate to severe PsO.[4]
‡In paediatric PsO, JPsA and ERA.

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) Summary of Product Characteristics.

2. Novartis Data on File. Secukinumab (SEC018). February 2025.

3. 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 June 2025].

4. European Medicines Agency. Summary of positive opinion EMA/CHMP/670627/2015. Available at: https://www.ema.europa.eu/en/documents/smop/chmp-post-authorisation-summary-positive-opinion-cosentyx_en.pdf [Accessed June 2025].

5. Novartis Data on File. Secukinumab (SECO20). April 2025.

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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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