

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<sup>3</sup>



**150+** 

clinical trials across indications\*4





8 years

of real-world experience, worldwide across indications  $^{\scriptscriptstyle 5}$ 

Image



8

indications<sup>1,2</sup>

Cosentyx has 5-years of a <u>consistent safety profile</u> across 24 studies in <u>PsO and</u> PsA<sup>6</sup>

# 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<sup>7</sup>

Please refer to the Cosentyx Summary of Product Characteristics (SmPC) for full safety information, and the safety profile page <a href="here">here</a>.

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

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AEs of select interest (EAIR per 100 PY)	1 year	2 years	3 years	4 years	5 years	6 years	Cumulative rate
Serious infections <sub>Cases</sub>	<b>2.0</b> n=149	<b>1.7</b> n=475	<b>0.7</b> n=649	<b>1.3</b> n=1841	<b>1.3</b> n=2285	<b>1.1</b> n=2226	1.3 n=8719
Malignant or unspecified tumours <sub>Cases</sub>	<b>0.2</b> n=15	<b>0.2</b> n=50	<b>0.2</b> n=225	<b>0.3</b> n=422	<b>0.3</b> n=520	<b>0.3</b> n=573	0.3 n=1896
MACE Cases	<b>0.2</b> n=15	<b>0.1</b> n=39	<b>0.2</b> n=151	<b>0.2</b> n=238	<b>0.2</b> n=264	<b>0.1</b> n=287	0.2 n=1031
Total IBD Cases	<b>0.2</b> n=12	<b>0.2</b> n=46	<b>0.2</b> n=185	<b>0.3</b> n=340	<b>0.2</b> n=312	<b>0.1</b> n=261	<b>0.2</b> 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).

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



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<sup>†1,2,4</sup>



No new safety signals have been identified in more than 680,000 PY across AS, <u>PsA</u> and <u>PsO indications</u><sup>7</sup>



No trend towards increased rates of major adverse cardiovascular events (MACE), or malignancy reported in clinical trials and  ${\rm RWE}^{{\rm \ddagger7.8}}$ 

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Cosentyx

Cosentyx in PSO

Cosentyx in HS

Safety profile

**Mechanism of action** 

Therapeutic indications¹ Cosentyx is indicated for the treatment of moderate to severe plaque psorial adults, children and adolescents from the age of 6 years who are candidate therapy; active psoriatic arthritis (PsA) in adult patients (alone or in combin methotrexate [MTX]) when the response to previous disease-modifying antitherapy has been inadequate; active ankylosing spondylitis (AS) in adults we	es for systemic lation with i-rheumatic drug who have
responded inadequately to conventional therapy; active non-radiographic a spondyloarthritis (nr-axSpA) with objective signs of inflammation as indicate	

C-reactive protein and/or magnetic resonance imaging evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs; active moderate to

years and older (alone or in combination with MTX) whose disease has responded

inadequately to, or who cannot tolerate, conventional therapy; active juvenile psoriatic

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

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.

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.
- ClinicalTrials.gov. Search results for 'secukinumab', completed, terminated and active, not recruiting trials. Available at: <a href="https://clinicaltrials.gov/search?term=Secukinumab,&aggFilters=status:com">https://clinicaltrials.gov/search?term=Secukinumab,&aggFilters=status:com</a> [Accessed July 2024].
- 5. European Medicines Agency. European public assessment report. Medicine overview. Cosentyx (secukinumab). <a href="https://www.ema.europa.eu/en/documents/overview/cosentyx-epar-medicine-o....">https://www.ema.europa.eu/en/documents/overview/cosentyx-epar-medicine-o....</a> [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.

<sup>\*</sup>Not limited to licensed indications.

<sup>&</sup>lt;sup>†</sup>In paediatric PsO, JPsA and ERA.

<sup>&</sup>lt;sup>‡</sup>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.<sup>8</sup>

Adverse events should be reported. Reporting forms and information can be found at <a href="https://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a>. Adverse events should also be reported to Novartis online through the pharmacovigilance intake (PVI) tool at <a href="https://www.novartis.com/report">www.novartis.com/report</a>, or alternatively email <a href="mailto:medinfo.uk@novartis.com">medinfo.uk@novartis.com</a> or call 01276 698370.

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