NOVARTIS

Cosentyx Derm - Cosentyx in Pso - PsO dosing - HCP

Prescribing information

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Cosentyx® (secukinumab) PsO dosing

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 is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of conditions for which Cosentyx is indicated.[1]

Information on the Cosentyx safety profile may be found on the Safety profile page of this website and the Cosentyx Summary of product Characteristics.[1]

Cosentyx flexible dosing schedule for eligible adult patients with moderate to severe PsO

The recommended dose of Cosentyx in adults with PsO is 300 mg delivered at Weeks 0, 1, 2, 3 and 4, followed by a monthly maintenance dose.[1]

Based on clinical response, patients with PsO weighing ≥90 kg may benefit from a maintenance dose of 300 mg every 2 weeks.[1] Each 300 mg dose is given as one subcutaneous injection of 300 mg or as two subcutaneous injections of 150 mg.

- Body weight <90 kg
- Body weight ≥90 kg

For patients who weigh <90 kg, the recommended Cosentyx dose is 300 mg with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing.[1]

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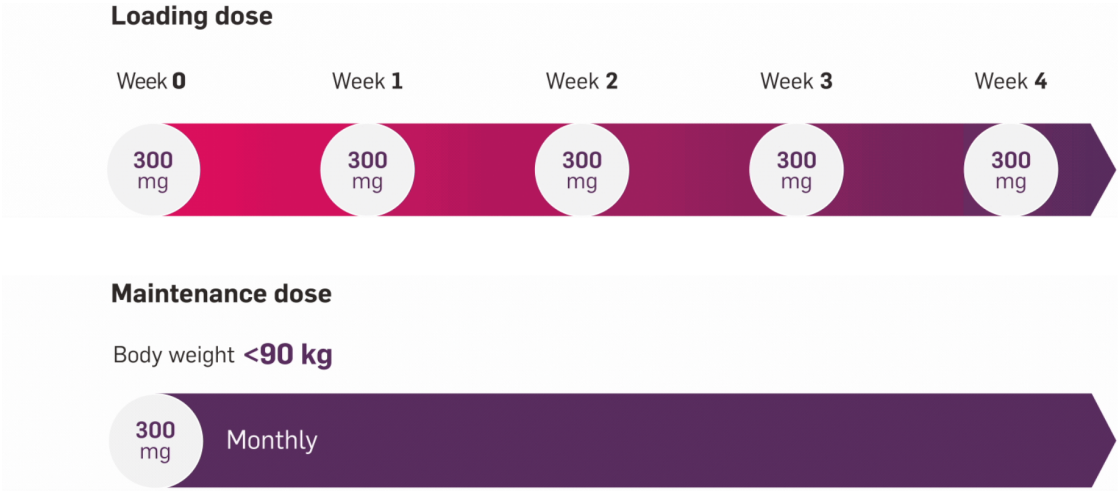

For patients who weigh ≥90 kg, the recommended Cosentyx dose is 300 mg at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Maintenance dosing may be up-titrated for patients weighing ≥90 kg to 300 mg every 2 weeks depending on clinical response.[1]

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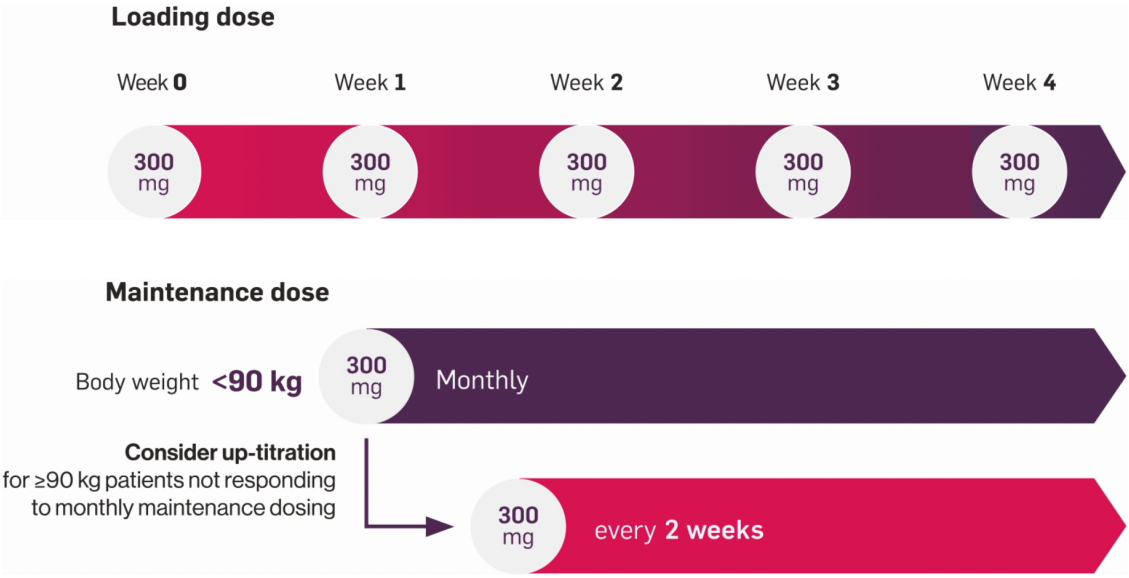

Tailor the dosing of Cosentyx based on clinical response of your eligible patients with PsO

You can **tailor** the **dosing** of Cosentyx based on the **clinical response** of your patients with PsO weighing ≥90 kg. In the A2324 Q2W clinical trial, **FAST** (Week 16) and observed **LONG-LASTING** (Week 52) skin clearance was seen in patients (≥90 kg) treated with Cosentyx 300 mg Q2W vs 300 mg Q4W.[2]

Primary endpoint of PASI 90 response at Week 16 for Cosentyx 300 mg Q2W vs Q4W was met (73.2% vs 55.5%; p=0.0003).[2]

PASI 90 response to Year 1 (exploratory endpoint)[2]

Image

Adapted from Augustin M, et al. 2022.[2]

A2324 Q2W was a multicentre, double-blind, parallel-group trial on patients with moderate to severe PsO weighing ≥90 kg (N=331) treated with Cosentyx 300 mg Q2W or Q4W.

FAST

Image

73%

of **patients ≥90 kg** achieved **PASI 90** with Cosentyx 300 mg **Q2W at Week 16**, which was significantly higher than those patients treated with Cosentyx 300 mg **Q4W** (72.8% vs 50.0%, respectively; one-sided p-value p=0.0003; primary endpoint).[2]

LONG-LASTING

Image

76%

of **patients ≥90 kg** achieved **PASI 90** (exploratory endpoint) with Cosentyx 300 mg Q2W **at Year 1** (76.4% vs 52.4%, respectively; p<0.05; exploratory endpoint).[2]

Please note the p value of p=0.0003 is related to the primary endpoint. For the exploratory

endpoint at Week 52, the p value is <0.05.

The recommended dose is 300 mg of Cosentyx with initial dosing at Weeks 0, 1, 2, 3 and 4 followed by monthly maintenance dosing. Based on clinical response, a maintenance dose of 300 mg Q2W may provide additional benefit for patients with a body weight of 90 kg or higher.[1]

Cosentyx pre-filled injections for eligible patients with moderate to severe PsO

Video

6 mins 37 secs

UnoReady® 300 mg pen video

Video - 15 Jul 2024

6 mins 37 secs

UnoReady® 300 mg pen video

See more details

Hide details

Video

5 mins 56 secs

SensoReady® 150 mg pen video

Video - 15 Jul 2024

5 mins 56 secs

SensoReady® 150 mg pen video

See more details

Hide details

Image

75 mg pre-filled syringe

Cosentyx (secukinumab) offers a range of pre-filled injections. The pre-filled syringes are available in three dosages: 75 mg, 150 mg, and 300 mg; the pre-filled pens are available in

two dosages: 150 mg and 300 mg. The 150 mg and 300 mg solution for injection in pre-filled syringe and in pre-filled pen are not indicated for administration to paediatric patients with a weight <50 kg.[1]

Image

In the MATURE study at 28 weeks, **100% of patients were 'satisfied' or 'very satisfied'** with using the UnoReady® 300 mg pen (n=37: 32.4% and 67.6%, respectively).*[3]

*MATURE was a 52-week, randomised, double-blind, placebo controlled study that evaluated efficacy, safety, tolerability and PK of Cosentyx in patients with moderate to severe PsO via one 300 mg/2 ml UnoReady pen injection (n=41) or two 150 mg/1 ml pre-filled syringe injections (n=41) vs placebo. Patients self-administered treatment at Weeks 0, 1, 2, 3, 4 and 8 followed by Q4W dosing starting at Week 12 up to Week 48. The co-primary endpoints of PASI 75 and IGA mod 2011 0/1 response rates at Week 12 were met ($p<0.0001$ for both).[3]

What your eligible patients should know when switching to the Cosentyx UnoReady® 300 mg pen

The Cosentyx UnoReady® pen delivers the potential benefits of Cosentyx 300 mg in one injection. In the MATURE study at 28 weeks 100% of patients (n=41) were 'satisfied' or 'very satisfied' with using the UnoReady® pen.[1,3,4]

There are some differences between using the Cosentyx SensoReady® and UnoReady® pen that eligible patients should be aware of:[†4,5]

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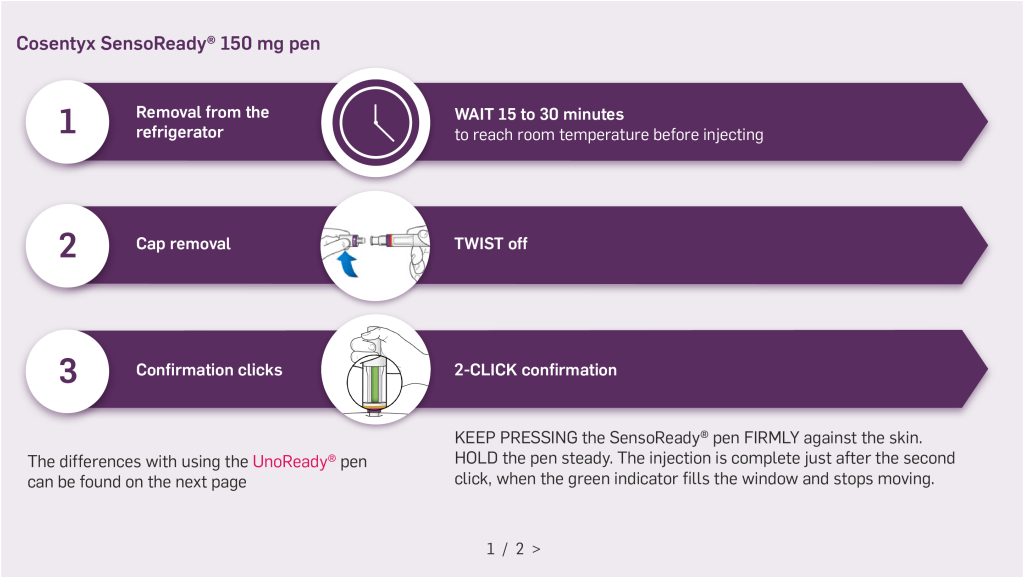

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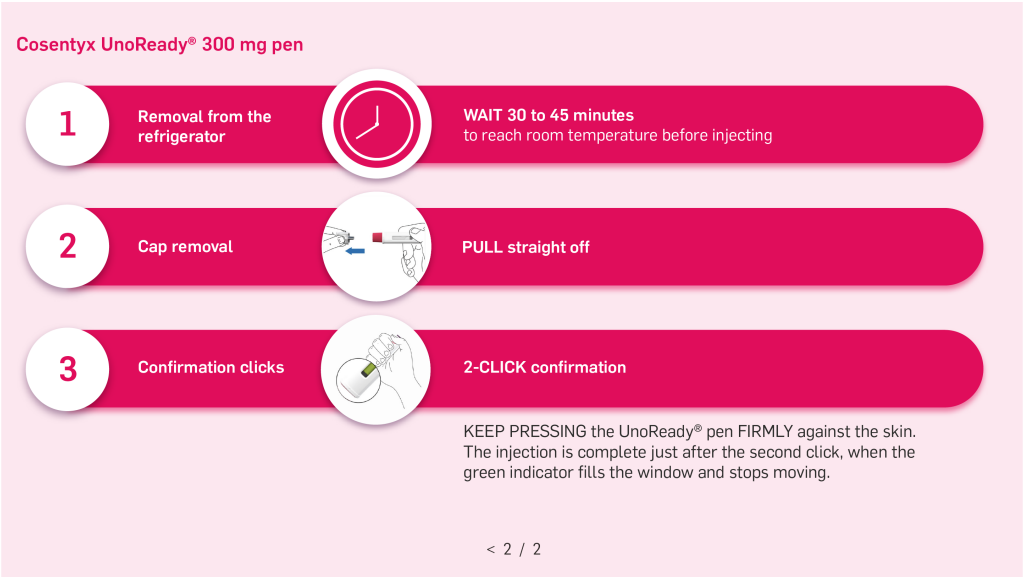

Previous Next

[†]After proper training in subcutaneous injection technique, patients may self-inject Cosentyx or may be injected by a caregiver if a physician determines that this is appropriate. However, the physician should ensure appropriate follow-up of patients. Patients or caregivers should be instructed to inject the full amount of Cosentyx according to the instructions provided in the package leaflet. Comprehensive instructions for administration are given in the package leaflet.[1]

Cosentyx dosing schedule for paediatric PsO

In paediatric PsO treatment, the recommended Cosentyx dose varies depending on the child’s body weight.[1]

The dosing schedule of Cosentyx begins with the initial dose at Weeks 0, 1, 2, 3 and 4, followed by a monthly maintenance dose. Each dose of Cosentyx, whether 75 mg, 150 mg,

or 300 mg, is administered as a single subcutaneous injection. The 300 mg dose may be given as one 300 mg injection or two 150 mg injections.[1]

- Body weight <50 kg
- Body weight ≥50 kg

If your patient weighs under 50 kg, the dosing regimen for Cosentyx involves a weekly 75 mg subcutaneous injection during the initial 4-week phase, followed by a monthly maintenance dose of 75 mg. The Cosentyx injection doses are administered as a single 75 mg subcutaneous injection.[1]

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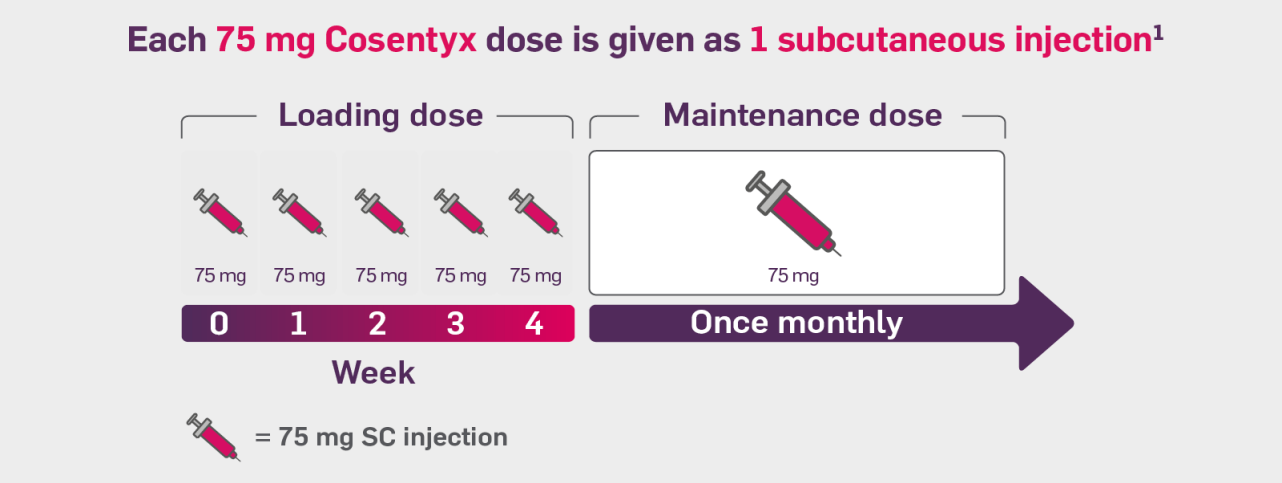
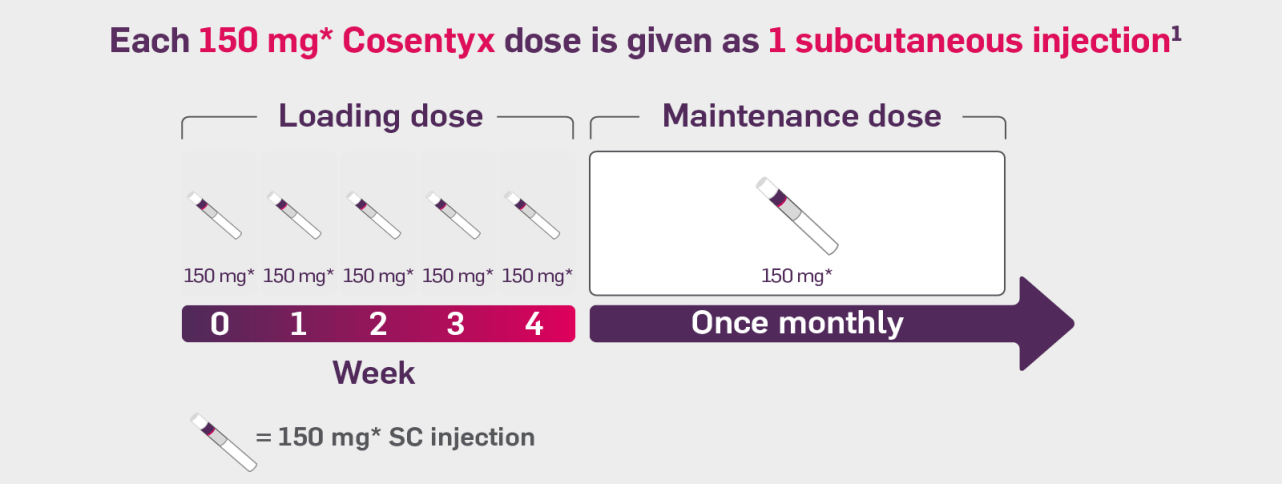


The 150 mg and 300 mg solution for injection, available in pre-filled syringe and pen formats, is not indicated for paediatric patients with a weight below 50 kg. Cosentyx may be available in other strengths and/or presentations depending on the individual treatment needs.[1]

If your patient weighs over 50 kg, the recommended Cosentyx dosing schedule begins with a weekly subcutaneous injection of 150 mg during the initial dosing phase, followed by a monthly maintenance dose of 150 mg. This dose can be increased to 300 mg if deemed beneficial for certain patients. The Cosentyx 300 mg dose can be administered as a single subcutaneous injection or as two separate injections of 150 mg each.[1]

Image



Cosentyx may be available in other strengths and/or presentations depending on the individual treatment needs.[1]

Cosentyx dosing precautions and considerations

The efficacy of Cosentyx across its various indications has been established through clinical studies. Based on the available evidence, a clinical response is normally achieved within

the first 16 weeks of treatment, however, if your patients don’t demonstrate a response to the prescribed Cosentyx dose within this timeframe, consideration should be given to discontinuing the treatment. Some patients with an initial partial response may subsequently improve with continued treatment beyond 16 weeks.[1]

Image

Cosentyx dosing and special populations

No dose adjustments are required for elderly individuals aged 65 and over. The safety and efficacy of Cosentyx in children below the age of 6 years have not yet been established. Cosentyx has not been studied in patients with renal or hepatic impairment and therefore no dose recommendations can be made in these populations.[1]

There are no adequate data from the use of Cosentyx in pregnant women. As a precautionary measure, it is preferable to avoid the use of Cosentyx during pregnancy. Because of the potential for adverse reactions in nursing infants from Cosentyx, a decision on whether to discontinue breast-feeding during treatment and up to 20 weeks after treatment or to discontinue therapy with Cosentyx must be made taking into account the benefit of breast-feeding to the child and the benefit of therapy to the woman.[1]

Image

Cosentyx missed dose

Encourage your patient to promptly consult with you in the event that they miss a scheduled dose, so that you may determine when they should take the subsequent Cosentyx injection dose.[4]

Image

Cosentyx overdose

In clinical studies, doses of Cosentyx up to 30 mg per kg (approximately 2,000 to 3,000 mg) have been administered intravenously without encountering dose-limiting toxicity. In the rare event of a Cosentyx overdose, patients should be monitored for any adverse reactions and their symptoms treated appropriately.[1]

Image

Cosentyx safety considerations

Contraindications
Cosentyx is contraindicated in:
Patients with hypersensitivity to the active substance or to any of the excipients
Clinically important, active infection, e.g., active tuberculosis

Infections
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 Cosentyx in patients with a chronic infection or a history of recurrent infection. Please see the SmPC for the full information.

Inflammatory bowel disease (including Crohn's disease and ulcerative colitis)
Cases of new or exacerbations of inflammatory bowel disease have been reported with Cosentyx. Cosentyx is not recommended in patients with IBD. If a patient develops signs or symptoms of IBD or experiences an exacerbation of pre-existing IBD, Cosentyx should be discontinued and appropriate medical management should be initiated.

Hypersensitivity reactions
Rare cases of anaphylactic reactions and angioedema have been observed in patients receiving Cosentyx. If an anaphylactic reaction, angioedema or other serious allergic reaction occurs, administration of Cosentyx should be discontinued immediately and appropriate therapy initiated.

Vaccinations

Live vaccinations should not be given concurrently with Cosentyx. Please see the SmPC for full information regarding vaccinations.

Latex-sensitive individuals – Cosentyx 150 mg solution for injection in pre-filled syringe and 150 mg solution for injection in pre-filled pen only
The removable needle cap of Cosentyx 150 mg in the pre-filled syringe and 150 mg pre-filled pen contains a derivative of natural rubber (latex). Use in latex-sensitive individuals has not been studied and there is therefore a potential risk of hypersensitivity reactions which cannot be completely ruled out.

Concomitant immunosuppresive therapy
In psoriasis studies, the safety and efficacy of Cosentyx in combination with immunosuppressants, including biologics, or phototherapy have not been evaluated. Cosentyx was administered concomitantly with MTX, sulfasalazine and/or corticosteroids in arthritis studies (including in patients with PsA and AS). Caution should be exercised when considering concomitant use of other immunosuppressants and Cosentyx.

Hepatitis B reactivation
Hepatitis B virus reactivation can occur in patients treated with Cosentyx. In accordance with clinical guidelines for immunosuppressants, testing patients for HBV infection is to be considered before initiating treatment with Cosentyx. Patients with evidence of positive HBV serology should be monitored for clinical and laboratory signs of HBV reactivation during Cosentyx treatment. If reactivation of HBV occurs while on Cosentyx, discontinuation of the treatment should be considered, and patients should be treated according to clinical guidelines.[1]

Cosentyx is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of conditions for which Cosentyx is indicated.

This is not an exhaustive list of warnings and precautions. Please refer to the Cosentyx SmPC for full information.

The most frequently reported adverse reactions are upper respiratory tract infections (17.1%) (most frequently nasopharyngitis, rhinitis).[1]

Discover additional information regarding the Cosentyx safety profile

Find out more

Image

Cosentyx

Image

Cosentyx in PsO

Image

PsO with PsA

Image

Cosentyx in HS

Image

Heritage

Image

Safety profile

Image

Mechanism of action

Cosentyx is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of conditions for which Cosentyx is indicated. Please refer to the Cosentyx SmPC for full product information and administration, including dosing in special populations, before prescribing.[1]

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]

AS, ankylosing spondylitis; ERA, enthesitis-related arthritis; HBV, hepatitis B virus; HS, hidradenitis suppurativa; IGA mod 2011/01, Investigator's Global Assessment modified 2011 Investigator's Global Assessment modified 2011; JPsA, juvenile psoriatic arthritis; MTX, methotrexate; nr-axSpA, non-radiographic axial spondyloarthritis; PASI, psoriasis area and severity index; PK, pharmacokinetics; PsA, psoriatic arthritis; PsO, plaque psoriasis; Q2W, every 2 weeks; Q4W, every 4 weeks; SmPC, Summary of Product Characteristics.

References

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

2. Augustin M, et al. *Br J Dermatol* 2022;186:942-954.

3. Sigurgeirsson B, et al. *Dermatol Ther* 2022;35(3):e15285.

4. Cosentyx 300 mg solution for injection pre-filled pen. Patient Information Leaflet.

5. Cosentyx 150 mg solution for injection pre-filled pen. Patient Information Leaflet.

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