

Extracts from Cosentyx

secukinumab

Novartis

Section: 10(c) Immunomodifiers - Immunology


Use in pregnancy: C*

Permitted in sport

Use: Interleukin-17A inhibitor. Adults greater than or equal to 18 yrs: treatment of mod-severe plaque psoriasis in candidates for systemic therapy or phototherapy, psoriatic arthritis in patients with inadequate response to prior DMARD, ankylosing spondylitis

Contraindications: Clinically important, active infections (see Prec)

Precautions: Infection incl recurrent history, chronic (should not use with active TB, consider pretreatment anti-TB therapy with latent infection); monitor for infection; IBD (monitor for new onset, exacerbation); latex sensitivity; hepatic, renal impairment (no data); pregnancy, lactation, children < 18 yrs

Adverse Reactions: **TGA Report Form**  URTIs (esp mild-mod nasopharyngitis, rhinitis, pharyngitis); rhinorrhoea; oral herpes; cutaneous, mucosal candidiasis; major CV event; headache; incr cholesterol, TGs, ALT, AST; nausea; diarrhoea; urticaria; neutropenia; anti-drug Abs incl neutralising; mild-mod dysmenorrhoea, menorrhagia, metrorrhagia; anaphylaxis (rare); others, see full PI

Interactions: Live vaccines (should not admin concurrently; not recommended in newborns, infants for 16 wks after last dose during pregnancy); CYP450 substrates with narrow TI eg warfarin (poss, consider therapeutic monitoring)

Cosentyx Prefilled Syringe (Solution for injection) Rx (S4) CMI

Secukinumab (rch) IgG_{1k} human monoclonal Ab; latex derivative cap; clear, colourless-slightly yellow

Dose: Admin by SCI (avoid psoriasis affected inj site). Plaque psoriasis: 300 mg (2 x 150 mg) at wks 0, 1, 2, 3 then mthly starting wk 4. Psoriatic arthritis: 150 mg at wks 0, 1, 2, 3 then mthly starting wk 4; anti-TNFalpha inadequate responder or concomitant mod-severe plaque psoriasis: 300 mg (2 x 150 mg) at wks 0, 1, 2, 3 then mthly starting wk 4; may admin +/- methotrexate.

Ankylosing spondylitis: 150 mg at wks 0, 1, 2, 3 then mthly starting wk 4

Pack 150 mg/mL 1 mL [2] (AUSTR218799) (534900010001)

Cosentyx Prefilled Pen (Solution for injection) Rx (S4) CMI

Secukinumab (rch) IgG_{1k} human monoclonal Ab; latex derivative cap; clear, colourless-slightly yellow

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Ankylosing spondylitis: 150 mg at wks 0, 1, 2, 3 then mthly starting wk 4

Pack 150 mg/mL 1 mL [1] : Authority - PBS/RPBS (Rp 2) (AUSTR218800) (534900020013: 10898N NV)

[Approved indication(s) for authority] Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencing... [\[more...\]](#))

PBS: \$804.06

Pack 150 mg/mL 1 mL [1] : Authority - PBS/RPBS (Rp 2) (AUSTR218800) (534900020014: 10893H NV)

[Approved indication(s) for authority] Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of... [\[more...\]](#))

PBS: \$804.06

Pack 150 mg/mL 1 mL [1] : Authority - PBS/RPBS (Rp 5) (AUSTR218800) (534900020015: 10906B NV)

[Approved indication(s) for authority] Ankylosing spondylitis

Treatment Phase: Initial 3 (grandfather treatment)

Clinical criteria:

Patient must have confirmed ankylosing spondylitis, defined radiographically (plain X-ray) of... [\[more...\]](#)

PBS: \$804.06

Pack 150 mg/mL 1 mL [1] : Authority - PBS/RPBS (Rp 5) (AUSTR218800) (534900020016: 10906B NV)

[Approved indication(s) for authority] Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis, AND

Patient must have received... [\[more...\]](#)

PBS: \$804.06

Pack 150 mg/mL 1 mL [1] : Authority - PBS/RPBS (Rp 5) (AUSTR218800) (534900020017: 10906B NV)

[Approved indication(s) for authority] Ankylosing spondylitis

Treatment Phase: Initial 3 or Continuing treatment - balance of supply

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis,... [\[more...\]](#)

PBS: \$804.06

Pack 150 mg/mL 1 mL [1] : Authority - PBS/RPBS (Rp 5) (AUSTR218800) (534900020030: 10895K NV)

[Approved indication(s) for authority] Severe active psoriatic arthritis

Treatment Phase: Initial 3 - grandfather treatment

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, AND... [\[more...\]](#)

PBS: \$804.06

Pack 150 mg/mL 1 mL [1] : Authority - PBS/RPBS (Rp 5) (AUSTR218800) (534900020031: 10895K NV)

[Approved indication(s) for authority] Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Please note that the extract below should be read in the context of the entire document.

Patient must have a documented history of severe active psoriatic arthritis, AND

Patient must have... [\[more...\]](#)

PBS: \$804.06

Pack 150 mg/mL 1 mL [1] : [Authority - PBS/RPBS](#) (Rp 5) (AUSTR218800) (534900020032: 10895K NV)

[\[Approved indication\(s\) for authority\]](#) Severe active psoriatic arthritis

Treatment Phase: Initial 3 (grandfather treatment) or

Continuing treatment - balance of supply

Clinical criteria:

Patient must have received... [\[more...\]](#)

PBS: \$804.06

Pack 150 mg/mL 1 mL [1] x 4 : [Authority - PBS/RPBS](#) (AUSTR218800) (534900020011: 10890E NV)

[\[Approved indication\(s\) for authority\]](#) Active ankylosing spondylitis

Treatment Phase: Initial treatment - initial 1 (new patients or patients recommencing treatment after a break of 5 years or more)

Clinical criteria:

The... [\[more...\]](#)

PBS: \$3,168.94

Pack 150 mg/mL 1 mL [1] x 4 : [Authority - PBS/RPBS](#) (AUSTR218800) (534900020012: 10890E NV)

[\[Approved indication\(s\) for authority\]](#) Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencing treatment after a break of less than 5 years)

Clinical criteria:

Patient must have a... [\[more...\]](#)

PBS: \$3,168.94

Pack 150 mg/mL 1 mL [1] x 4 : [Authority - PBS/RPBS](#) (AUSTR218800) (534900020023: 10900Q NV)

[\[Approved indication\(s\) for authority\]](#) Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must... [\[more...\]](#)

PBS: \$3,168.94

Pack 150 mg/mL 1 mL [1] x 4 : [Authority - PBS/RPBS](#) (AUSTR218800) (534900020024: 10900Q NV)

[\[Approved indication\(s\) for authority\]](#) Severe psoriatic arthritis

Treatment Phase: initial treatment - Initial 2 (change or recommencing treatment after a break of less than 5 years)

Clinical criteria:

Patient must have a... [\[more...\]](#)

PBS: \$3,168.94

Pack 150 mg/mL 1 mL [2] : [Authority - PBS/RPBS](#) (Rp 2) (AUSTR218800) (534900020018: 10901R NV)

[\[Approved indication\(s\) for authority\]](#) Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or
Initial 2 (change or recommencing... [\[more...\]](#))

PBS: \$1,585.75

Pack 150 mg/mL 1 mL [2] : [Authority - PBS/RPBS](#) (Rp 2) (AUSTR218800) (534900020010: 10494H NV)

[\[Approved indication\(s\) for authority\]](#) Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or... [\[more...\]](#)

PBS: \$1,585.75

Pack 150 mg/mL 1 mL [2] : [Authority - PBS/RPBS](#) (Rp 5) (AUSTR218800) (534900020001: 10425Q NV)

[\[Approved indication\(s\) for authority\]](#) Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, AND... [\[more...\]](#)

PBS: \$1,585.75

Pack 150 mg/mL 1 mL [2] : [Authority - PBS/RPBS](#) (Rp 5) (AUSTR218800) (534900020002: 10425Q NV)

[\[Approved indication\(s\) for authority\]](#) Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the... [\[more...\]](#)

PBS: \$1,585.75

Pack 150 mg/mL 1 mL [2] : [Authority - PBS/RPBS](#) (Rp 5) (AUSTR218800) (534900020003: 10425Q NV)

[\[Approved indication\(s\) for authority\]](#) Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Face, hand, foot - balance of supply

Clinical criteria:

Patient must have received insufficient... [\[more...\]](#)

PBS: \$1,585.75

Pack 150 mg/mL 1 mL [2] : [Authority - PBS/RPBS](#) (Rp 5) (AUSTR218800) (534900020027: 10899P NV)

[\[Approved indication\(s\) for authority\]](#) Severe active psoriatic arthritis

Treatment Phase: Initial 3 - grandfather treatment

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, AND... [\[more...\]](#)

PBS: \$1,585.75

Pack 150 mg/mL 1 mL [2] : [Authority - PBS/RPBS](#) (Rp 5) (AUSTR218800) (534900020028: 10899P NV)

[\[Approved indication\(s\) for authority\]](#) Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, AND

Patient must have... [\[more...\]](#)

Please note that the extract below should be read in the context of the entire document.

PBS: \$1,585.75

Pack 150 mg/mL 1 mL [2] : [Authority - PBS/RPBS](#) (Rp 5) (AUSTR218800) (534900020029: 10899P NV)

[Approved indication(s) for authority] Severe active psoriatic arthritis

Treatment Phase: Initial 3 (grandfather treatment) or

Continuing treatment - balance of supply

Clinical criteria:

Patient must have received... [\[more...\]](#)

PBS: \$1,585.75

Pack 150 mg/mL 1 mL [2] x 4 : [Authority - PBS/RPBS](#) (AUSTR218800) (534900020019: 10910F NV)

[Approved indication(s) for authority] Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or... [\[more...\]](#)

PBS: \$6,189.98

Pack 150 mg/mL 1 mL [2] x 4 : [Authority - PBS/RPBS](#) (AUSTR218800) (534900020020: 10910F NV)

[Approved indication(s) for authority] Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break of less than 5 years)

Clinical criteria:... [\[more...\]](#)

PBS: \$6,189.98

Pack 150 mg/mL 1 mL [2] x 4 : [Authority - PBS/RPBS](#) (AUSTR218800) (534900020021: 10910F NV)

[Approved indication(s) for authority] Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5... [\[more...\]](#)

PBS: \$6,189.98

Pack 150 mg/mL 1 mL [2] x 4 : [Authority - PBS/RPBS](#) (AUSTR218800) (534900020022: 10910F NV)

[Approved indication(s) for authority] Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)

Clinical criteria:... [\[more...\]](#)

PBS: \$6,189.98

Pack 150 mg/mL 1 mL [2] x 4 : [Authority - PBS/RPBS](#) (AUSTR218800) (534900020025: 10894J NV)

[Approved indication(s) for authority] Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must... [\[more...\]](#)

PBS: \$6,189.98

Pack 150 mg/mL 1 mL [2] x 4 : [Authority - PBS/RPBS](#) (AUSTR218800) (534900020026: 10894J NV)

[Approved indication(s) for authority] Severe psoriatic arthritis

Treatment Phase: initial treatment - Initial 2 (change or recommencing treatment after a break of less than 5 years)

Clinical criteria:

Patient must have a... [\[more...\]](#)

PBS: \$6,189.98