Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	400550	STELARA ustekinumab 45 mg/ 0.5 mL solution for injection pre-filled pen (One-Press patient-controlled injector)

ARTG entry for	Medicine Registered
Sponsor	Janssen-Cilag Pty Ltd
Postal Address	Locked Bag 2070, NORTH RYDE, NSW, 1670 Australia
ARTG Start Date	9/11/2023
Product Category	Medicine
Status	Active
Approval Area	Drug Safety Evaluation Branch

Medicine under additional monitoring

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1 . STELARA ustekinumab 45 mg/ 0.5 mL solution for injection pre-filled pen (One-Press patient-controlled injector)

Product Type	Single Medicine Product	**Effective Date**	9/11/2023

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Plaque Psoriasis,,Adults -,STELARA is indicated for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.,,Psoriatic Arthritis (PsA),,STELARA, alone or in combination with methotrexate, is indicated for the treatment of signs and symptoms of active psoriatic arthritis in adult patients (18 years and older) where response to previous non-biological DMARD therapy has been inadequate.,,Crohn's Disease,,STELARA is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a TNF alpha antagonist or have medical contraindications to such therapies.,,Ulcerative Colitis,,STELARA is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

This product is included in the Black Triangle Scheme

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Syringe	Glass Type I Clear	36 Months	Store at 2 to 8 degrees Celsius	Neither child resistant closure nor restricted flow insert	Refrigerate Do not Freeze Do not Shake Protect from Light

Pack Size/Poison information

Pack Size	Poison Schedule
1	(S4) Prescription Only Medicine

Components

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1 . STELARA ustekinumab 45 mg/ 0.5 mL solution for injection pre-filled pen (One-Press patient-controlled injector)

Dosage Form	Injection, solution
Route of Administration	Subcutaneous
Visual Identification	Pre-filled pen containing pre-filled syringe. The solution is clear to slightly opalescent, colourless to light yellow

Active Ingredients	
Ustekinumab	**45 mg**

Other Ingredients (Excipients)
histidine hydrochloride monohydrate
histidine
polysorbate 80
sucrose
water for injections

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