Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 343262 ENHERTU trastuzumab deruxtecan 100 mg powder for injection vial

ARTG entry for	Medicine Registered (Provisional)
Sponsor	AstraZeneca Pty Ltd
Postal Address	PO Box 131, NORTH RYDE, NSW, 1670 Australia
ARTG Start Date	8/10/2021
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 . ENHERTU trastuzumab deruxtecan 100 mg powder for injection vial

Product Type Single Medicine Product **Effective Date** 8/10/2021

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

Provisionally Registered Indications

ENHERTU is indicated for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens.,This indication is approved via the provisional approval pathway, based on overall response rate and duration of response. Full registration for this indication depends on verification and description of clinical benefit in a confirmatory trial.

Provisionally Registered Conditions

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
Vial	Glass Type I Coloured	36 Months	Store at 2 to 8 degrees Celsius	Neither child resistant closure nor restricted flow insert	Refrigerate Do not Freeze

Pack Size/Poison information

Pack Size	Poison Schedule
1 vial	(S4) Prescription Only Medicine

Components

1 . ENHERTU trastuzumab deruxtecan 100 mg powder for injection vial

Dosage Form Injection, powder for

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Route of Administration	Intravenous Infusion
Visual Identification	White to yellowish-white lyophilized powder.

Active Ingredients	
trastuzumab deruxtecan	**100 mg**

Other Ingredients (Excipients)
histidine hydrochloride monohydrate
histidine
polysorbate 80
sucrose

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