Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	327905	ZOLGENSMA onasemnogene abeparvovec 2 x e13 vg/mL injection for intravenous infusion 8.3 mL vial
ARTG entry for	Medicine Registered	
Sponsor	Novartis Pharmaceuticals Australia Pty Ltd	
Postal Address	PO Box 101, NORTH RYDE, NSW, 1670 Australia	
ARTG Start Date	4/03/2021	
Product Category	Medicine	
Status	Active	
Approval Area	Drug Safety Evaluation Branch	

Medicine under additional monitoring

Conditions

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

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 February 1992, other than condition No. 8 and condition No. 9.

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 February 1992, other than condition No. 11.

Except where the sponsor has been contracted by an overseas partry to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

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, other than condition No. 8 and condition No. 9.

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, other than condition No.11

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.

The therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:

Products

1 . ZOLGENSMA onasemnogene abeparvovec 2 x e13 vg/mL injection for intravenous infusion 8.3 mL vial

Product Type	Single Medicine Product	**Effective Date**	17/05/2024

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

ZOLGENSMA (onasemnogene abeparvovec) is indicated for the treatment of paediatric patients less than 9 months of age with symptomatic or pre-symptomatic spinal muscular atrophy with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene and 1 to 3 copies of the SMN2 gene.

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	Other composite material	12 Months	Store between minus 60 - minus 80 degrees	Child resistant closure	Store in Original Container

Pack Size/Poison information

Pack Size	Poison Schedule
7 vials of 8.3 mL each	(S4) Prescription Only Medicine
8 vials of 8.3 mL each	(S4) Prescription Only Medicine
3 vials of 8.3 mL each	(S4) Prescription Only Medicine
6 vials of 8.3 mL each	(S4) Prescription Only Medicine
4 vials of 8.3 mL each	(S4) Prescription Only Medicine
9 vials of 8.3 mL each	(S4) Prescription Only Medicine
5 vials of 8.3 mL each	(S4) Prescription Only Medicine
2 vials of 8.3 mL each	(S4) Prescription Only Medicine

Components

1 . ZOLGENSMA onasemnogene abeparvovec 2 x e13 vg/mL injection for intravenous infusion 8.3 mL vial

Dosage Form	Injection, intravenous infusion
Route of Administration	Intravenous
Visual Identification	When thawed, the vial contents are clear to slightly opaque, colourless to faint white solution.

Active Ingredients

onasemnogene abeparvovec	**1 U**

Other Ingredients (Excipients)

hydrochloric acid
magnesium chloride hexahydrate
poloxamer
sodium chloride
trometamol
water for injections