Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	372650 LAGEVRIO molnupiravir 200 mg capsules bottle
ARTG entry for	Medicine Registered (Provisional)
Sponsor	Merck Sharp & Dohme (Australia) Pty Ltd
Postal Address	North Ryde Post Business Centre, Locked Bag 2234, NORTH RYDE BC, NSW, 1670 Australia
ARTG Start Date	20/01/2022
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 . LAGEVRIO molnupiravir 200 mg capsules bottle

Product Type	Single Medicine Product	**Effective Date**	22/11/2023

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

Provisionally Registered Indications

LAGEVRIO (molnupiravir) has provisional approval for the treatment of adults with COVID- 19 who do not require initiation of oxygen due to COVID-19 and who are at increased risk for hospitalisation or death [see Section 5.1 PHARMACODYNAMIC PROPERTIES - Clinical Trials].,The decision to approve this indication has been made on the basis of the analysis of efficacy and safety data from a Phase 3 trial. Continued approval of this indication depends on additional data.

Provisionally Registered Conditions

Extend the provisional registration period to 18 January 2026 for the provisionally registered indication as described in the letter dated 01 September 2023 from CESA, PMAB (PM-2023-03380-1-2) D23-3163058

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
Bottle	HDPE	36 Months	Store below 30 degrees Celsius	Child resistant closure	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
40 capsules per bottle	(S4) Prescription Only Medicine

Components

1 . LAGEVRIO molnupiravir 200 mg capsules bottle

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	Swedish Orange opaque capsule with the corporate logo and 82 printed with white ink

Active Ingredients

molnupiravir	**200 mg**

Other Ingredients (Excipients)

croscarmellose sodium
ethanol absolute
hyprolose
hypromellose
iron oxide red
isopropyl alcohol
magnesium stearate
microcrystalline cellulose
potassium hydroxide
propylene glycol
purified water
Shellac
strong ammonia solution
tert-butyl alcohol
titanium dioxide

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