Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	317240 XOFLUZA baloxavir marboxil 20 mg film-coated tablet blister pack
ARTG entry for	Medicine Registered
Sponsor	Roche Products Pty Ltd
Postal Address	30-34 Hickson Road, Sydney, NSW, 2000 Australia
ARTG Start Date	21/02/2020
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"

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 . XOFLUZA baloxavir marboxil 20 mg film-coated tablet blister pack

Product Type Single Medicine Product **Effective Date** 22/09/2023

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

Treatment of influenza,Xofluza is indicated for the treatment of uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours and who are:,· otherwise healthy, or,· at high risk of developing influenza complications.,Prophylaxis of influenza,Xofluza is indicated for the post-exposure prophylaxis of influenza in patients aged 12 years of age and older following contact with an individual who has confirmed influenza.,Vaccination is the preferred method of routine prophylaxis against infection with influenza virus.

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
Blister Pack	Al/Al	60 Months	Store below 30 degrees Celsius	Child resistant closure	Protect from Light Protect from Moisture Store in Original Container

Pack Size/Poison information

Pack Size	Poison Schedule
2 tablets	(S4) Prescription Only Medicine

Components

1 . XOFLUZA baloxavir marboxil 20 mg film-coated tablet blister pack

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	White to light yellow, oblong-shaped film-coated tablets debossed with a symbol and 772 on one side and 20 on the other side.

Active Ingredients

baloxavir marboxil	**20 mg**

Other Ingredients (Excipients)

croscarmellose sodium
hypromellose
lactose monohydrate
microcrystalline cellulose
povidone
purified talc
sodium stearylfumarate
titanium dioxide

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