Public Summary

Summary for ARTG Entry:	395373 Guanfacine 3 TAKEDA, guanfacine (as hydrochloride) 3 mg modified release tablet blister pack
ARTG entry for	Medicine Registered
Sponsor	Takeda Pharmaceuticals Australia Pty Ltd
Postal Address	Grosvenor Place Level 39 225 George Street, Sydney, NSW, 2000 Australia
ARTG Start Date	2/12/2022
Product Category	Medicine
Status	Active
Approval Area	Drug Safety Evaluation Branch

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 . Guanfacine 3 TAKEDA, guanfacine (as hydrochloride) 3 mg modified release tablet blister pack

Product Type	Single Medicine Product	**Effective Date**	13/05/2024

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

indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6-17 years old, as monotherapy (when stimulants or atomoxetine are not suitable, not tolerated or have been shown to be ineffective) or as adjunctive therapy to psychostimulants (where there has been a sub-optimal response to psychostimulants). must be used as part of a comprehensive ADHD management programme, typically including psychological, educational and social measures.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	PVC/PCTFE (Aclar)/Al	4 Years	Store below 25	Child resistant closure	Not recorded

degrees Celsius

Pack Size/Poison information

Pack Size	Poison Schedule
28	(S4) Prescription Only Medicine

Components

1 . Guanfacine 3 TAKEDA, guanfacine (as hydrochloride) 3 mg modified release tablet blister pack

Dosage Form	Tablet, modified release
Route of Administration	Oral
Visual Identification	Round, green tablets debossed with '3MG' on one side and '503' on the other side.

Active Ingredients

guanfacine hydrochloride	**3.42 mg**

Other Ingredients (Excipients)

colloidal anhydrous silica
crospovidone
fumaric acid
glycerol dibehenate
hypromellose
indigo carmine aluminium lake
iron oxide yellow
lactose
methacrylic acid - ethyl acrylate copolymer (1:1)
microcrystalline cellulose
polysorbate 80
povidone
sodium lauryl sulfate