



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 206044 TEMOZOLOMIDE AMNEAL temozolomide 100 mg capsule sachet

ARTG entry for Medicine Registered
Sponsor Juno Pharmaceuticals Pty Ltd
Postal Address Level 2 6 Bond Street, South Yarra, VIC, 3141
 Australia
ARTG Start Date 14/06/2013
Product category Medicine
Status Active
Approval area Drug Safety Evaluation Branch

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. TEMOZOLOMIDE AMNEAL temozolomide 100 mg capsule sachet

Product Type	Single Medicine Product	Effective date	12/09/2016
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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 newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and then as adjuvant treatment., Treatment of recurrence of anaplastic astrocytoma and glioblastoma multiforme following standard therapy., Temozolomide is also indicated as a first-line treatment for patients with advanced metastatic malignant melanoma.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Sachet	Other composite material	24 Months	Store below 25 degrees Celsius	Child resistant closure	Store in Original Container

Pack Size/Poison information

Pack Size	Poison Schedule
20 Capsules	(S4) Prescription Only Medicine
5 Capsules	(S4) Prescription Only Medicine

Components

1. TEMOZOLOMIDE AMNEAL temozolomide 100 mg capsule sachet

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	Pink/White hard capsule, size 3, printed in black ink with 'TMZ' on the cap and '100' on the body.

Active Ingredients

Temozolomide	100 mg
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