



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

**Summary for ARTG Entry:** 206042 TEMOZOLOMIDE AMNEAL temozolomide 5 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 5 mg capsule sachet**

<b>Product Type</b>	Single Medicine Product	<b>Effective date</b>	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**

<b>Pack Size</b>	<b>Poison Schedule</b>
20 Capsules	(S4) Prescription Only Medicine
5 Capsules	(S4) Prescription Only Medicine

**Components**

**1. TEMOZOLOMIDE AMNEAL temozolomide 5 mg capsule sachet**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification** Green/White hard capsule, size 3, printed in black ink with 'TMZ' on the cap and '5' on the body.

**Active Ingredients**

**Temozolomide** 5 mg

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