



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

**Public Summary**

**Summary for ARTG Entry:** 61598 XENICAL orlistat 120mg capsule blister pack

**ARTG entry for** Medicine Registered  
**Sponsor** Roche Products Pty Ltd  
**Postal Address** PO Box 255, DEE WHY, NSW, 2099  
 Australia  
**ARTG Start Date** 11/04/2000  
**Product category** Medicine  
**Status** Active  
**Approval area** Non-Prescription Medicines

**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. XENICAL orlistat 120mg capsule blister pack**

<b>Product Type</b>	Single Medicine Product	<b>Effective date</b>	18/06/2015
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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**

Xenical is indicated for the treatment of obese patients with a body mass index (BMI)  $\geq 30$ , and overweight patients with a BMI  $\geq 27$  in the presence of other risk factors, in conjunction with a mildly hypocaloric diet.

**Warnings**

No Warnings included on Record

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	Not recorded	3 Years	Store below 25 degrees Celsius	Not recorded	Protect from Light
Blister Pack	Not recorded	3 Years	Store below 25 degrees Celsius	Not recorded	Protect from Heat Protect from Moisture

**Pack Size/Poison information**

**Pack Size**

- 21 capsules
- 84 capsules
- 42 capsules
- 9 capsules

**Poison Schedule**

- (S3) Pharmacist Only Medicine
- (S3) Pharmacist Only Medicine
- (S3) Pharmacist Only Medicine
- (S3) Pharmacist Only Medicine

**Components**

1.

**Dosage Form**

Capsule, hard

**Route of Administration**

Oral

**Visual Identification**

Hard gelatin capsule, opaque turquoise, imprinted with black ink "XENICAL Roche 120".

**Active Ingredients**

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Orlistat

120 mg

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