



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	128710	NALTREXONE GH naltrexone hydrochloride 50mg film coated tablets blister pack
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	Generic Health Pty Ltd	
<b>Postal Address</b>	Suite 2 Level 2 / 19-23 Prospect Street, Box Hill, VIC, 3128 Australia	
<b>ARTG Start Date</b>	31/08/2007	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . NALTREXONE GH naltrexone hydrochloride 50mg film coated tablets blister pack

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	10/08/2023
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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**  
NALTREXONE GH is indicated for use within a comprehensive treatment programme for alcohol dependence. NALTREXONE GH is also indicated as adjunctive therapy in the maintenance of formerly opioid-dependent patients who have ceased the use of opioids such as diamorphine (heroin) and morphine.

**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/PVDC/Al	2 Years	Store below 25 degrees Celsius	Not recorded	Not recorded

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
30 tablets	(S4) Prescription Only Medicine

#### Components

##### 1 . Medicine component

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral
<b>Visual Identification</b>	The Naltrexone 50mg filmcoated tablets are beige, capsule-shaped tablets with a score on each side.

**Active Ingredients**

naltrexone hydrochloride	50 mg
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**Other Ingredients (Excipients)**

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colloidal anhydrous silica  
crospovidone  
hypromellose  
iron oxide black  
iron oxide red  
iron oxide yellow  
lactose monohydrate  
macrogol 4000  
magnesium stearate  
microcrystalline cellulose  
powdered cellulose  
titanium dioxide

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