



**Australian Government**

**Department of Health**

Therapeutic Goods Administration

# OTC medicine monograph: Pholcodine

Version 1.1, September 2014

**TGA** Health Safety  
Regulation

## About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <<http://www.tga.gov.au>>.

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## Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	OTC Medicines Evaluation /OMA	10/06/2014
V1.1	Revision to additional instructions as per outcome of RASML consultation on OTC oral cough medicines	OTC Medicines Evaluation /OMA	09/09/2014

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## Introduction

This OTC Medicine Monograph outlines the requirements for Australian market authorisation of oral liquid preparations containing pholcodine as a single active ingredient when applied for as an OTC new medicine N2 application. Proposed medicines must comply with all aspects of the monograph relevant to their strength and dosage form to qualify for evaluation as an N2 application.

This monograph should be read in conjunction with the document [Requirements for OTC new medicine N2 applications](#).

## Active substance

This monograph only applies to pholcodine (CAS no. 509-67-1) as a single active ingredient and excludes preparations containing any salts and derivatives of pholcodine.

## Dosage form and strengths

Acceptable dosage forms and strengths are shown in the table below.

Active substance	Dosage strengths	Dosage form
Pholcodine	1, 2 and 3 mg/mL	Oral liquid

## Indications

### Therapeutic indications for inclusion in the Australian Register of Therapeutic Goods (ARTG)

Required indication is *“Cough suppressant for the temporary relief of non-productive, dry cough”*.

### Label indications

Required label indication is *“Temporary relief of dry cough”*.

Further description of the cough may be included by selecting one or more of the following:

- non-productive.
- irritating.
- stubborn.
- tickly.

## Directions for use

Dosages must be as shown in the table below.

## Adults and children 6 years and over

Dosage strength	Age	Single dose	Dose interval	Maximum daily dose
1 mg/mL	Adults and children 12 years and over	10-15 mL (10-15 mg)	Every 6 to 8 hours as necessary	4 doses
	Children 6-11 years (only on the advice of a doctor, pharmacist or nurse practitioner)	5-10 mL (5-10 mg)	Every 6 to 8 hours as necessary	4 doses
	Do not use in children under 6 years of age.			
2 mg/mL	Adults and children 12 years and over	5-7.5 mL (10-15 mg)	Every 6 to 8 hours as necessary	4 doses
	Children 6-11 years (only on the advice of a doctor, pharmacist or nurse practitioner)	2.5-5 mL (5-10 mg)	Every 6 to 8 hours as necessary	4 doses
	Do not use in children under 6 years of age.			
3 mg/mL	Adults and children 12 years and over	5 mL (15 mg)	Every 6 to 8 hours as necessary	4 doses
	Children 6-11 years (only on the advice of a doctor, pharmacist or nurse practitioner)	2.5 mL (7.5 mg)	Every 6 to 8 hours as necessary	4 doses
	Do not use in children under 6 years of age.			

### Additional instruction

The following instruction is also required:

If coughing persists, consult your doctor or pharmacist.

### Labels

Labelling must comply with all relevant Australian requirements, as detailed in the document [Requirements for OTC new medicine N2 applications](#), including all required warning statements.

## Quality requirements

In addition to the quality requirements outlined in the document [Requirements for OTC new medicine N2 applications](#), the following specific requirements apply to pholcodine monograph medicines:

### Finished product specifications

In addition to other requirements specified in the document [Requirements for OTC new medicine N2 applications](#), the finished product specifications must comply, at a minimum, with the relevant set of requirements below.

The requirements below include all relevant BP general monograph requirements. Further reference to these is not required. Reference to the BP monograph below refer to the **current** monograph at the time of application.

#### Oral liquid

The tests and limits in the **BP monograph *Pholcodine Linctus*** with the addition of:

- oral liquid appearance;
- tests and limits for pH;
- individual unspecified impurities (NMT 1.0%); and total impurities (NMT 3.0%);
- content of any preservatives included in the formulation, and
- microbiological quality in compliance with TGO 77.

#### Container/measuring device

- Pholcodine medicines must be sold in containers that comply with *Therapeutic Goods Order No 80, Child Resistant Packaging Requirements for Medicines*.
- If a measuring device is to be supplied with the medicine, calibrations must be exclusively in metric units and must allow all the doses shown on the labels to be measured accurately. Details of the calibrations on the measuring device must be provided with the submission (a sample may also be requested). Further considerations and requirements regarding measuring devices are detailed in [ARGOM Appendix 2: Guidelines on quality aspects of OTC applications, 8. Finished product container](#).

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