



MENARINI

17 December 2015

URGENT NOTICE

Re: Short supply of COGENTIN benztropine mesylate 2mg/2mL injection ampoule (AUST R 10452)

Dear Healthcare Professional,

A. Menarini Australia Pty Ltd (Menarini) wish to advise that there is currently a lack of supply of Cogentin (benztropine mesylate) 2 mg/2 mL injection.

The lack of supply has come about due to two issues. Firstly, we have been advised that the finished product manufacturer of Cogentin is currently unable to source enough supply of the drug substance - benztropine. All benztropine on-hand has failed release testing due to low assay. Secondly, the finished product manufacturer is unable to acquire additional benztropine from the same manufacturer because the manufacturer will no longer manufacture benztropine. The finished product manufacturer has started the process of qualifying an alternate benztropine supplier; however, as this process is subject to US FDA approval, it would take at least 18 months before supply of Cogentin finished product to Australia can recommence. Unfortunately, the finished product manufacturer is unable to provide more precise guidance as to the timing of finished product availability.

To ensure parenteral benztropine is available in Australia, Menarini have received authorisation from the Therapeutic Goods Administration (TGA) under section 19A of the *Therapeutic Goods Act 1989* to supply an alternate brand of parenteral benztropine. Menarini recognise that availability of parenteral benztropine meets an important public health need in Australia.

Cogentin is indicated for the following use¹:

COGENTIN is recommended for all forms of parkinsonism - including arteriosclerotic, post-encephalitic, idiopathic, as well as drug-induced extrapyramidal disorders (except tardive dyskinesia). It can be effective at any stage of the disease, even when a patient has become bedridden. COGENTIN often is helpful in patients who have become unresponsive to other agents. COGENTIN is a powerful anticholinergic agent which is mainly effective in relieving tremor and rigidity. Therapy is directed toward control of disturbing symptoms to permit the patient maximum integration of function with minimum discomfort.

In non-drug-induced parkinsonism, partial control of symptoms is usually achieved.

Cogentin is used for the treatment of acute dystonic reactions.^{1,2} Cogentin is PBS listed for Emergency Drug Supplies as part of a Prescriber Bag Item.

Alternate brand of parenteral benztropine

In order to address the lack of registered parenteral benztropine Menarini will supply an alternate brand of benztropine injection. This alternate product has not been assessed for safety and efficacy by the TGA but is approved in Canada. It has the following details:

Trade name: Benztropine Omega

Dosage form and strength: 2 mg/2 mL Vials

Storage conditions: Protect product from freezing; Store between 15°C to 30°C

Shelf life: 36 months

Pack size: 10 vials

The main differences between the Benztropine Omega brand compared with the Cogentin brand are the following:

	Benztropine Omega	Cogentin
Dosage form	Clear glass vials (with white flip-off lid, aluminium crimp and latex- free stopper)	Clear glass ampoules
Pack size	10	5
Storage conditions	Protect product from freezing Store between 15°C to 30°C	Protect from light Protect product from freezing Store below 30°C

Dosage and administration

The dosage and administration of Benztropine Omega is the same as for Cogentin. Before prescribing or administering Cogentin or Benztropine Omega, please review the full TGA approved Cogentin Product Information¹ available from: <http://www.menarini.com.au/pi>

Should you have any enquiries please contact Medical Information on 1800 644 542 during office hours, Monday to Friday 9.00 am to 5.00 pm. We anticipate that Benztropine Omega stock will be available from your wholesaler upon depletion of Cogentin stock during December 2015 or January 2016, depending on individual wholesaler stock levels. To order the product, please contact your preferred wholesaler.

Sincerely,



Dr. Elna Fourie
Associate Medical Director
A. Menarini Australia Pty Ltd

References:

1. Cogentin Injection Product Information, June 2013
2. Campbell D. The management of acute dystonic reactions. *Australian Prescriber* 2001;24(1): 19-20