

VARIATION IN SUPPLY: CLOMID (clomiphene citrate) 50 mg tablets, AUST R 10103

Dear Doctor,

Sanofi would like to inform you of a temporary supply shortage of Australian approved Clomid, indicated for the treatment of ovulatory failure in carefully selected infertile women who wish to become pregnant¹.

The shortage is due to issues we are experiencing with sourcing of the active ingredient, and has led to disruptions in the production of Clomid at our current manufacturing site. Sanofi is making every effort to resolve the issue, however, at this stage we cannot speculate on when supply of Australian approved Clomid will resume.

As an interim solution for the shortage of Australian approved Clomid, Sanofi has sourced European approved Clomid which will be supplied during this shortage period. This product has been approved for supply under s19A of the Therapeutic Goods Act 1989, and is not registered in Australia.

The Australian and European versions of Clomid are the same with regard to the indications, active ingredient, strength, presentation and pack size (10 tablets); however the two products differ slightly in their formulations. The Clomid manufactured for the European market has European-specific labelling, and does not contain the statement “*Prescription Only Medicine*” on the pack. However please note that Clomid remains a Schedule 4 (prescription-only medicine) under the Poisons Standard.

PBS Reimbursement

European approved Clomid will be reimbursed under the Pharmaceutical Benefits Scheme (PBS) in the same way Australian approved Clomid is, as a restricted benefit. Prescriptions should be written in the normal manner.

Adverse Event Reporting

Reporting any suspected adverse events is important for the continued monitoring of the safety of all medicines. You are encouraged to report any suspected adverse events via the TGA Australian Adverse Drug Reaction Reporting System portal or directly to Sanofi at ae@sanofi.com

If you would like further information regarding Clomid please contact:

Medical enquiries	Sanofi Medical Information	1800 818 806
Enquiries relating to supply	Sanofi Customer Service	1800 640 791

I apologise for the inconvenience this variation in supply of Clomid may cause and appreciate your understanding and support during this period. As further information becomes available, we will be in contact with you to provide an update.

Yours faithfully,



Dr Jamshed A. Ahmed

Country Medical Chair, Australia & New Zealand

1. *Clomid Product Information January 2016*