

29 March 2022



RE: Shortage of QLAIRA estradiol valerate/dienogest tablets composite pack and alternative supply arrangement under Section 19A of the *Therapeutic Goods Act*.

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Australia

Dear Healthcare Professional,

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This notification is sent by LINK to inform your organisation that due to the shortage of Australian registered **QLAIRA estradiol valerate/dienogest tablets composite pack (AUST R 149319)**, LINK has arranged the supply of an alternative product, **QLAIRA estradiol valerate/dienogest film coated tablets composite pack in wallet pack (Jenapharm GmbH Germany)**, registered and marketed in Germany.

QLAIRA estradiol valerate/dienogest film coated tablets composite pack in wallet pack (Jenapharm GmbH Germany), is NOT registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act, 1989* until **31 July 2022**.

QLAIRA estradiol valerate/dienogest film coated tablets composite pack in wallet pack (Jenapharm GmbH Germany), are indicated for:

- Oral contraception.
- Treatment of heavy and/or prolonged menstrual bleeding in women without organic pathology who desire oral contraception.

The s19A approved *German* product is identical in active ingredient, strength and excipient ingredients to the Australian registered product.

Please refer to the Australian Product Information for **QLAIRA estradiol valerate/dienogest tablets composite pack (AUST R 149319)** (available at <https://www.ebs.tga.gov.au>) when prescribing and administering **QLAIRA estradiol valerate/dienogest film coated tablets composite pack in wallet pack (Jenapharm GmbH Germany)**.

QLAIRA estradiol valerate/dienogest film coated tablets composite pack in wallet pack (Jenapharm GmbH Germany), are registered in *Germany* with the outer package and package insert in both German. The active ingredient, strength and dosage form included on the wallet label are in German.

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **QLAIRA estradiol valerate/dienogest film coated tablets composite pack in wallet pack (Jenapharm GmbH Germany)**, should be reported by healthcare professionals and patients to Link Healthcare Medical Information. This information can also be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

Link Healthcare Medical Information can be contacted by phone on 1800 181 060 or via email at medinfo@linkhealthcare.com.au.

Link Healthcare Customer Service contact details

Link Healthcare Customer Service can be contacted via phone on 1800 181 060 or via email at customerservice@linkhealthcare.com.au. Please contact Link Healthcare Customer Service for further information.

We would appreciate if you could distribute this information to those in your organisation who would be affected by the shortage of the Australian registered **QLAIRA estradiol valerate/dienogest tablets composite pack (AUST R 149319)**.

Yours sincerely,



Charlotte Griffin

Medicine Access Associate