

Provisional Consent to the Distribution of a New Medicine

Pursuant to section 23(1) of the Medicines Act 1981, the Minister of Health hereby provisionally consents to the sale, supply or use in New Zealand of the new medicine set out in the Schedule hereto:

Schedule

Product:	Alyacen 1/35
Active Ingredients:	Ethinylestradiol 0.035mg Norethisterone 1mg
Dosage Form:	Tablet
New Zealand Sponsor:	ORSPEC Pharma Management Limited
Manufacturer:	Glenmark Pharmaceuticals Limited, Bardez, India

Note: This consent is given subject to the following conditions:

- Provisional consent is granted for one year to address an urgent shortage in the market and only applies to batch number 20240218.
- The medicine may only be marketed or distributed when no other norethisterone/ethinyl estradiol 1mg/0.035mg tablet medicine with consent under section 20 or section 23 of the Medicines Act 1981 is available in the New Zealand market, or to meet PHARMAC supply obligations.

Note: This consent is valid for one year from the date of publication of this notice.

Dated this 16th day of October 2024.

CHRIS JAMES, Group Manager, Medsafe, Ministry of Health (pursuant to delegation given by the Minister of Health on 11 September 2013).