16 October 2024

Unavailability of BREVINOR-1® 28 Day (Ethinylestradiol 35 micrograms and Norethisterone 1 milligram) tablets and alternative supply arrangement under Provisional Consent for ALYACEN 1/35 (Norethindrone and Ethinyl Estradiol Tablets USP, 1 mg/0.035 mg).

Dear Healthcare Professional,

This communication is sent by ORSPEC Pharma Management Limited to notify your organisation that due to the unavailability of **BREVINOR-1® 28 Day (Ethinylestradiol 35 micrograms and Norethisterone 1 milligram) tablets,** ORSPEC Pharma has arranged for the supply of an alternative product which has been granted provisional consent under section 23 of the Medicines Act 1981 by Medsafe.

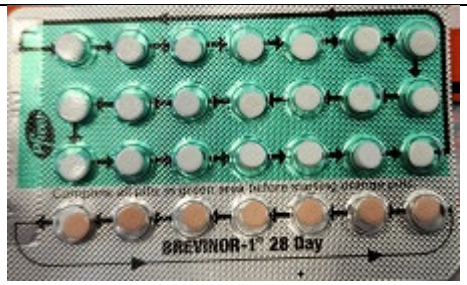
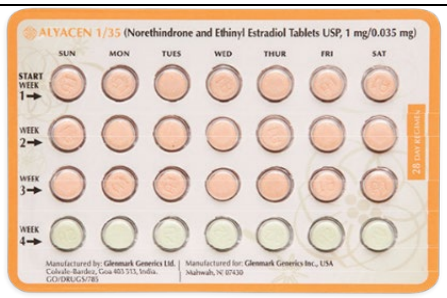
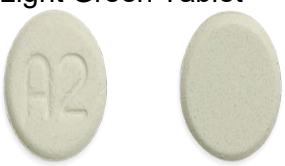
ALYACEN 1/35 (Norethindrone Tablets and Ethinyl Estradiol, USP 1 mg/0.035 mg) are approved for use of the following indication:

- *Contraception.*

The difference in nomenclature of the active ingredient used for **ALYACEN 1/35 (Norethindrone Tablets and Ethinyl Estradiol, USP 1 mg/0.035 mg)** vs **BREVINOR-1® 28 Day (Ethinylestradiol 35 micrograms and Norethisterone 1 milligram)** is due to variations in naming conventions between the U.S. (where **norethindrone and ethinyl estradiol** is used) and other regions such as Australia, and New Zealand (where **norethisterone and ethinylestradiol** is used). Both names refer to the same chemical substance with the same molecular formula.

ALYACEN 1/35 are also registered by the U.S. Food and Drug Administration (FDA) and are packaged in English. Please note the following similarities between, **BREVINOR-1® 28 Day** and **ALYACEN 1/35** to be supplied as per the Provisional Consent:

	BREVINOR-1® 28 Day (Ethinylestradiol 35 micrograms and Norethisterone 1 milligram)	**ALYACEN 1/35 (Norethindrone Tablets and Ethinyl Estradiol, USP 1 mg/0.035 mg)**
Dosage	On the first day of the menstrual cycle, i.e. the first day of bleeding, the woman is instructed to take a white active tablet corresponding to the day of the week from the green area of the Brevinor-1® 28 Day pack. Thereafter one white active tablet is taken daily, following the arrows on the pack, until all 21 white tablets have been taken. The woman should then be instructed to take one orange inactive tablet daily for the next seven days.	The dosage of ALYACEN 1/35, for the initial cycle of therapy, is one "active" tablet administered daily from the 1st through the 21st day of the menstrual cycle, counting the first day of menstrual flow as "Day 1" followed by one light green "reminder" tablet daily for 7 days. Tablets are taken without interruption for 28 days.

	The next and all subsequent courses of BREVINOR-1® 28 Day will begin on the day after the last package was completed, even if withdrawal bleeding is still in progress.	After 28 tablets have been taken, a new course is started the next day.
Blister Strip	 Start day in green area to corresponding day and follow arrows.	 Start day at Week 1 to corresponding day and follow weekly arrows.
Color of Active Tablet	White Tablet 	Peach Tablet 
Color of Inactive Tablet	Orange Tablet 	Light Green Tablet 
Pack Size	BREVINOR-1® 28 Day is available in calendar packs consisting of three strips of tablets (3 months' supply).	Carton containing 3 blister cards of 28 tablets
Storage	Keep your BREVINOR-1® 28 Daytablets in a dry place, at a temperature below 25°C.	Store at 20°C to 25°C.
Potential Allergens	· Lactose · Sunset yellow	· Lactose · Sunset yellow (FD&C Yellow)

While a package insert is included with ALYACEN 1/35 we recommend referring to the Product Information available on the Medsafe website for dosing and administration information instead: https://www.medsafe.govt.nz/Medicines/infoSearch.asp

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 **ALYACEN 1/35 (Norethindrone Tablets and Ethinyl Estradiol, USP 1 mg/0.035 mg)** should be reported

by healthcare professionals and patients to MEDSAFE at
https://www.medsafe.govt.nz/safety/report-a-problem.asp#Medicine

Alternatively, this information can be reported to ORSPEC Pharma on (+61) 24 339 4239 or email at safety@orspecpharma.com .

Please forward this information to relevant staff members in your organisation.

For further information, please contact ORSPEC Pharma on (+61) 24 339 4239 or email regulatory@orspecpharma.com or newzealand@orspecpharma.com

Yours sincerely,

Michelle Pruis
Regulatory and Quality Pharmacist
ORSPEC Pharma Management Limited