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# Repackaging Dabigatran Etexilate into Compliance Aids

An ageing population leads to an increasing incidence of multimorbidity and polypharmacy, which can result in complex dosing regimens. Compliance aids, such as Medico Paks® and unit-dose sachets, are widely used to help manage these regimens, reduce missed doses, and improve adherence. However, due to stability concerns, not all medicines can be safely included in compliance aids.

Dabigatran etexilate is a direct thrombin inhibitor typically dosed twice daily for prophylaxis of stroke in atrial fibrillation and treatment of venous thromboembolism. Pradaxa® is the funded brand of dabigatran etexilate in Aotearoa. These capsules contain multi-layered pellets of dabigatran etexilate with a tartaric acid core to aid dissolution and absorption. The formulation is moisture-sensitive, and the manufacturer advises keeping the capsules in the original packaging until immediately before use. However, many patients who are prescribed dabigatran etexilate will benefit from using compliance aids, and it is therefore important to consider the available evidence surrounding its suitability for repackaging.

Four studies have investigated the stability of dabigatran etexilate in Pradaxa® capsules repackaged into compliance aids:

- A 2024 study conducted in Aotearoa by Noori *et al* evaluated capsules stored in compliance aids for 16 weeks under 'real-world' conditions: room temperature (22°C, 50% Relative Humidity (RH); bedroom (21°C, 63% RH); and refrigerated. Capsules stored in Medico Paks® or unit-dose sachets remained stable for up to 8 weeks under all conditions.
- A 2024 Australian study by Allahham *et al* assessed the stability of repackaged capsules under climate-controlled conditions (25°C/60% RH and 30°C/65% RH) for 4 weeks. Capsules repackaged in Webster Packs® at 25°C were stable for 4 weeks; however, those stored at 30°C/65% RH showed significant degradation.
- Wang *et al* demonstrated that capsules retained 98% of their original content when repackaged in unit-dose packs stored at 25°C for 120 days. This study did not explicitly account for environmental humidity.
- Robertson *et al* examined the stability of capsules in compliance aids under high temperature and humidity conditions (30°C/75% RH) and found significant degradation after 28 days, with drug content falling to 72% of its initial level.

Overall, these studies support repackaging of dabigatran etexilate under typical conditions in Aotearoa, in patients for whom the benefits of compliance aids are likely to outweigh the risks.

*Dabigatran etexilate repackaged into Medico Paks® (or similar compliance aids) or unit-dose sachets is likely to be stable for up to 8 weeks when stored at or below 25°C.*

*Store compliance aids in a cool, dry place away from direct sunlight and moisture.*

*In high-temperature or humid environments (e.g. tropical climates), limit storage duration to 14 days, or consider storing in the fridge if a longer shelf-life is required (maximum 8 weeks).*

## References

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2. Allahham A, Nooney VB, Jones A, Weigl BJ, Sridhar J, Farah L, et al. Stability of dabigatran etexilate (Pradaxa) capsules in dose administration aids. J Pharm Pract Res. 2024 https://onlinelibrary.wiley.com/doi/abs/10.1002/jppr.1963
3. Robertson SG, Glass BD. Stability of repackaged dabigatran etexilate capsules in dose administration aids. Eur J Hosp Pharm Sci Pract. 2018 Oct;25(e2):e93–7.
4. Wang EH, Bolt JL, Décarie D, Semchuk W, Ensom MH. Stability of dabigatran etexilate in manufacturer's blister pack, unit-dose packaging, and community pharmacy blister pack. Can J Hosp Pharm. 2015;68(1):16.

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