

## **BioMedica's Probiotic** **Stability Statement**

Probiotics are more sensitive to moisture than to temperature. Our packaging has been designed to minimise water activity in our probiotic products, however, long term therapeutic potential is generally maximised by storing in refrigerated conditions.

Many of the probiotic strains used in our refrigerated probiotics tolerate ambient temperatures quite effectively, showing little viable cell loss when kept for 24 months (2 years) at 23-25°C. Indeed, this stability data was a significant factor in the choice of these particular strains for the products; all BioMedica products are formulated in the knowledge that they will be shipped around Australia (from Sydney to the tropical far north and Western Australia), and internationally (including Singapore and the UK), and will need to maintain efficacy after having been exposed to variable conditions for a number of weeks.

TriFlora and SB Pro have been formulated to not require refrigeration at all, and can be unrefrigerated for their entire shelf life. Ideally they should be kept at or below 25°C for long term storage, to maintain optimal viability throughout their shelf life.

Where appropriate, overage has been intentionally included in our probiotic products at levels to ensure survival during transit and throughout the products' shelf life. This is a particular consideration in products such as Femex Forte and TriGenex, which have been formulated based on clinically researched strains, and where temperature tolerance was not a factor in strain selection.

Stability testing on our products is performed to full compliance with Australian TGA guidelines. Stability samples are shipped interstate for testing, unrefrigerated, using the same shipping methods and packaging used to transport products to our customers. Stability results are therefore reflective of the state in which our products are delivered to our customers.

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