



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by
Starpharma Pty Ltd

I, **Michael Shum**, as a delegate of the Secretary to the Department of Health and Aged Care, on receipt of an application from Starpharma Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representations described in paragraph **(A)**, for use in advertising the products identified in paragraph **(B)** to consumers.

(A) Restricted representations to the effect of:

1. *"Fleurstat BVgel for prevention of recurrent bacterial vaginosis and its symptoms, including abnormal vaginal odour and discharge, helping to maintain normal vaginal flora balance."*
2. *"Fleurstat BVgel prevents recurrent BV by forming a physical barrier that blocks the attachment of BV-causing bacteria to the vaginal lining."*
3. *"You can use Fleurstat BVgel when you don't have symptoms to help prevent recurrent BV and its symptoms, including abnormal vaginal odour and discharge, helping to maintain normal vaginal flora balance."*

together, (the **Representations**).

The following advisory statement, *"Use of Fleurstat BVgel beyond 16 weeks is not recommended without medical supervision"*, must be included in the Instructions for Use (IFU) and consumer advertising, except the product packaging, if any one of, or any combination of, the **Representations** are used in the IFU or consumer advertising.

In addition, advisory statements to the effect of the following **must appear**, when any one of, or any combination of, the **Representations** are used, irrespective of the type of advertisement:

- I. *"Recurrent BV is typically 3 or more episodes in a 12-month period."*
- II. *"See a doctor before using Fleurstat BVgel for the prevention of recurrent BV."*
- III. *"You can use Fleurstat BVgel when you don't have symptoms to help prevent recurrent BV and its symptoms."*

Advisory statement III, specifying that *"You can use Fleurstat BVgel when you don't have symptoms to help prevent recurrent BV and its symptoms"*, is not required if the **Representation**, *"You can use Fleurstat BVgel when you don't have symptoms to help*

prevent recurrent BV and its symptoms, including abnormal vaginal odour and discharge, helping to maintain normal vaginal flora balance” is used.

(B) Starpharma Pty Ltd - Fleurstat- VivaGel - Vaginal flora gel (ARTG 295465)

Dated this 16th day of December 2022

Signed electronically

Michael Shum

Delegate of the Secretary to the Department of Health and Aged Care

Advertising and Compliance Education and Policy Section

Regulatory Compliance Branch