



Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Variation under section 42DH of conditions of approval for use of restricted representations
by Starpharma Pty Ltd

I, Leanne McCauley, Delegate of the Secretary to the Department of Health, vary the conditions imposed on the use of the restricted representations approved for use on 16 March 2018 in the consumer advertising of the product VivaGel® Vaginal Gel (Fleurstat™ BV Gel) (ARTG No. 295465)¹.

The varied conditions are:

The following must appear whenever any one of, or any combination of, the restricted representations is used:

1. Warning statements² to the effect of:
 - *See a doctor if you are pregnant or diabetic.*
 - *See a doctor if not better after (Insert number of days as per approved Product Information) days*
 - *If symptoms recur within two weeks of completing the course, consult a doctor.*
 - *Do not use for more than 7 days unless a doctor has told you to.*
 - *See your healthcare provider if you consider that you may be at risk of a Sexually Transmitted Infection (STI).*
 - *See a doctor if you plan to become pregnant, or are breastfeeding or plan to breastfeed*

must appear whenever any one of, or any combination of, the restricted representations is used, irrespective of the type of advertisement.

2. A statement to the following effect:
 - BV is associated with a characteristic 'fishy' vaginal odour and an abnormal greyish-white, thin vaginal discharge. Other common vaginal infections may be associated with intense itching or painful urination, and

¹ See the original approval at <https://www.tga.gov.au/advert-exempt/advertising-exemption-starpharma-pty-ltd-vivagelr-vaginal-gel-fleurstattm-bv-gel>

² These warning statements, or words to a similar effect, are also mandated on the labelling as a result of the inclusion of astodrimer sodium in the [Poisons Standard](#).

clumpy or frothy discharge. If you are unsure you have BV, or suspect you have a vaginal infection other than BV, please see your healthcare provider.

must appear in the Instructions for Use (IFU) whenever any one of, or any combination of, the restricted representations is used in the IFU.

These conditions are in substitution for the conditions originally imposed, namely³:

1. A statement to the effect:

See your healthcare provider if:

- *you consider that you may be at risk of an STI;*
- *your symptoms persist or recur, or your condition worsens, as these symptoms may be indicative another infection, including an STI;*
- *you are pregnant or plan to become pregnant, or you are breastfeeding or plan to breastfeed; you should seek advice of your healthcare provider before using Fleurstat™ BVgel.*

must appear whenever any one of, or any combination of, the restricted representations is used, irrespective of the type of advertisement.

2. A statement to the following effect:

- BV is associated with a characteristic 'fishy' vaginal odour and an abnormal greyish-white, thin vaginal discharge. Other common vaginal infections may be associated with intense itching or painful urination, and clumpy or frothy discharge. If you are unsure you have BV, or suspect you have a vaginal infection other than BV, please see your healthcare provider.

must appear whenever any one of, or any combination of, the restricted representations is used in the IFU and the product carton.

3. This approval is valid only until 1 May 2019.

4. Use of the representations is permitted on condition that the Device is available only from a pharmacy or other suitable healthcare provider.

Dated this 23rd Day of April 2019

Signed and authorised by

Leanne McCauley
Delegate of the Secretary to the Department of Health; and
Advertising Education and Assurance Section
Regulatory Education and Compliance Branch

³ See the original approval at <https://www.tga.gov.au/advert-exempt/advertising-exemption-starpharma-pty-ltd-vivagelr-vaginal-gel-fleurstattm-bv-gel>