Complaint to TGA - Fleurstat - VivaGel® - Vaginal flora gel

Acknowledgement: This complaint is based upon an investigation of this product conducted by Monash University BMS3052 students in Semester 2, 2019.

The product: Fleurstat - VivaGel® - Vaginal flora gel (ARTG: 295465)

Classified as: Medical Device Included Class IIa; GMDN 47601 Vaginal flora gel

Intended purpose: Contains Astodrimer sodium in the form of a gel applied by the user into the vagina once daily for seven days, for topical treatment and rapid relief of bacterial vaginosis.

Sponsor: Starpharma Pty Ltd

Advertiser, distributer and domain name registrant: Aspen Pharmacare Australia Pty Ltd

The promotion (documentation appended)

- https://www.fleurstat.com.au/
- Starpharma on Channel Nine News (April 22, 2019)
- Poster advertised in a Glen Waverley Shopping Centre female bathroom on 30/8/19
- https://www.youtube.com/watch?v=Re1Ek4uJUgc
- https://www.chemistwarehouse.com.au/buy/92690/fleurstat-bv-gel-45g
- http://www.davidjonespharmacy.com.au/fleurstat-bv-gel-45g
- https://www.kersbrookpharmacy.com/?attachment_id=2690
- https://ccpharmacy.com.au/index.php/hikashop-menu-for-categories-listing/product/fleurstat-bv-gel-45g/related_product-36377
- Etc.

The claims (documentation appended):

1. "Fleurstat BVgel is a new, **clinically proven** non-antibiotic treatment (for **the treatment of bacterial vaginosis** (BV))".
2. "Fleurstat BVgel works to treat BV by **disrupting the attachment of BV-causing bacteria** to the vaginal wall. **The gel forms a physical barrier**".
3. "Pharmacy only **medicine**"

The concerns:

1. Clinically proven.

Only three Phase 1 trials have been published in peer reviewed journals O'Loughlin et al (2010),[1] McGowan, et al (2011)[2] and Cohen et al (2011),[3] which focused on safety and tolerability.

Phase 2 & 3 trial results have yet to be published in peer reviewed journals, despite being lauded in press releases.[4] While there is additional information registered on ClinicalTrials.gov this is not an acceptable form of publication for analysis, nor a platform for peer review.[5]

The FDA has requested confirmatory data prior to the approval of VivaGel® BV in the USA.[6]

I argue that this limited clinical data does not fulfil the TGA Evidence Guidelines for "clinically proven"; a breach of s. 9(a) & 9(b) of the Code. In addition, this claim is not present in the ARTG Public Summary, a breach of s.9(d) of the Code. This also represents a breach of s.15(3)(a) & (b) of the Code.

[1] https://journals.lww.com/stdjournal/fulltext/2010/02000/Safety,_Tolerability,_and_Pharmacokinetics_of.7.aspx
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3103767/
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3024437/
[4] https://starpharma.com/assets/asxannouncements/130403_VivaGel_Study_Demonstrate.pdf
[5] https://clinicaltrials.gov/ct2/results?cond=&term=SPL7013&cntry=&state=&city=&dist=
[6] https://starpharma.com/news/406

2. **Promotion of a restricted representation (bacterial vaginosis)**

   On 23 May 2018, Leanne McCauley, Delegate of the Secretary to the Department of Health, approved an application from **Starpharma Pty Ltd** under section 42DF of the *Therapeutic Goods Act 1989* for the use of restricted representations (including the treatment of bacterial vaginosis) by Starpharma Pty Ltd.[7] **The approval was only valid until 1 May 2019**.

   This approval has now lapsed; also, it was given to Starpharma, the advertiser is now Aspen Pharmacare Australia.

   In short, this product is currently being advertised by many outlets for a restricted representation without apparent approval; a breach of section 42DD of the Act.

3. Treats BV by **disrupting the attachment of BV-causing bacteria** to the vaginal lining. **The gel forms a physical barrier**.

   This is not in accord with the Public Summary information which states the intended purpose as, "helping to normalise vaginal pH and **suppress the bacteria that cause BV**".

   Indeed, the product has been described as a microbicide; it also shows potent antiviral activity against HIV-1 and HSV-2.[8]

   Another breach of s.9(d) of the Code.

4. Pharmacy only **medicine**

   This product is included on the ARTG as a medical device Class IIa. **Thus, its promotion as a "medicine" is a breach of s.9(d) of the Code.**

   Which raises the question of what is a medicine and what is a device?

   The TGA Medicine Boundary Products guideline provides an extensive list of medicine boundary products.[9] Under the category of "External use without added active substance", "barrier protectants which claim prevention of transmission of infectious disease" are classified as medical devices.

   The TGA definition of a "medical device" includes the phrase, "that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means".[10]

   The TGA definition of a "medicine" is "therapeutic goods (other than biologicals) that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human".[11]

   The ingredient, Astodrimer sodium is listed as a Schedule 3 (Pharmacy only) medicine.[12] It clearly fits the above TGA definition of a medicine.

   This product would appear to have been misclassified by the sponsor &/or the TGA resulting in several regulatory anomalies and Code breaches.

Screen shots taken 26 September 2019 follow

[7] https://www.tga.gov.au/advert-exempt/advertising-exemption-starpharma-pty-ltd-vivagelr-vaginal-gel-fleurstattm-bv-gel
[8] https://www.burnet.edu.au/system/publication/file/84/pone.0024095.pdf
[9] https://www.tga.gov.au/sites/default/files/devices-guidelines-35-150323.pdf
https://www.tga.gov.au/sites/default/files/devices-guidelines-35-150323.pdf
[10] https://www.tga.gov.au/what-medical-device
[11] https://www.tga.gov.au/acronyms-glossary#summary-m
[12] https://www.legislation.gov.au/Details/F2019L00685

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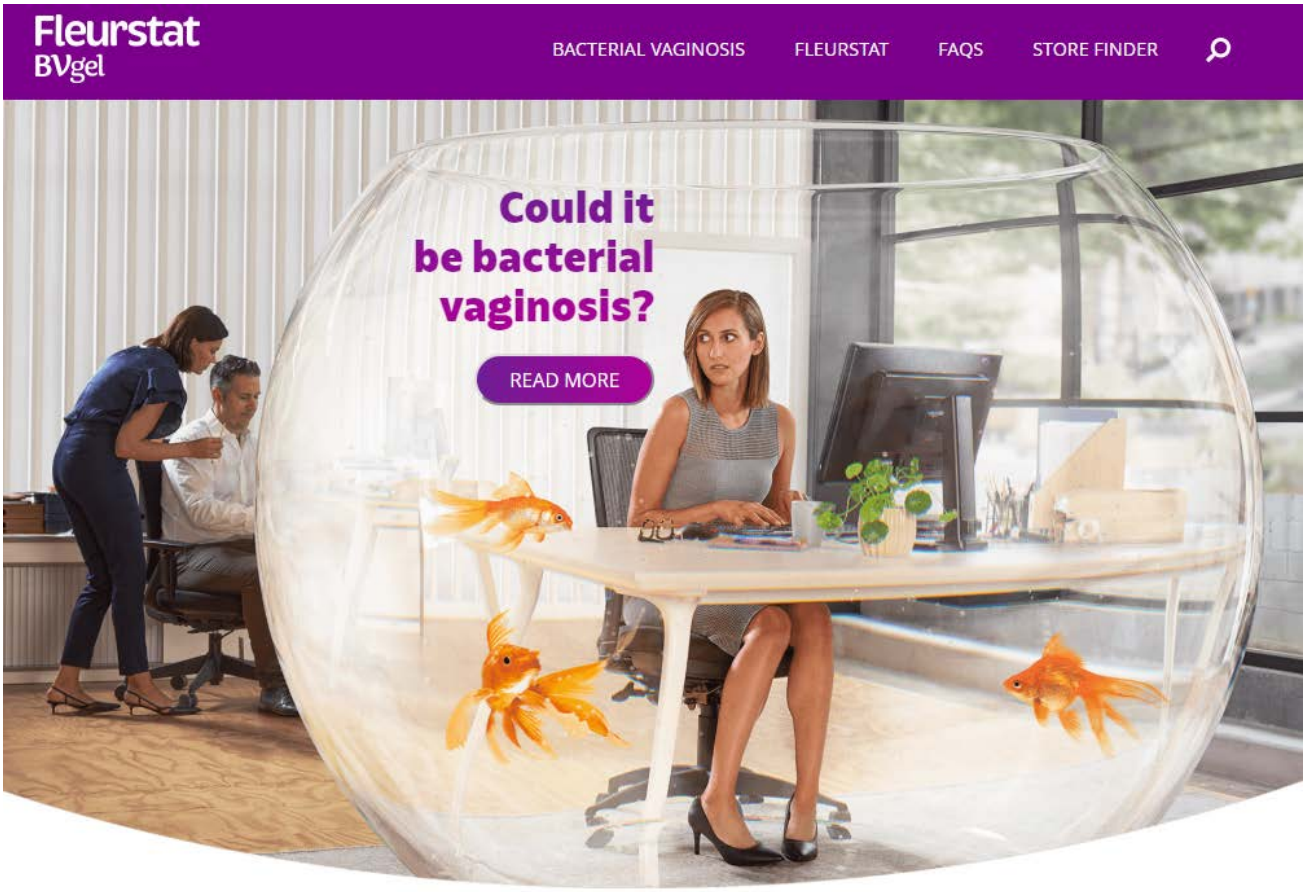

How does Fleurstat BVgel treat bacterial vaginosis?

Fleurstat BVgel is a new product for the treatment of bacterial vaginosis and relief of its symptoms. It works to treat BV by disrupting the attachment of BV-causing bacteria to the vaginal lining. It is not an antibiotic.

READ MORE

https://www.fleurstat.com.au/

Fleurstat BVgel is a new, clinically proven non-antibiotic treatment.

https://www.fleurstat.com.au/fleurstat/

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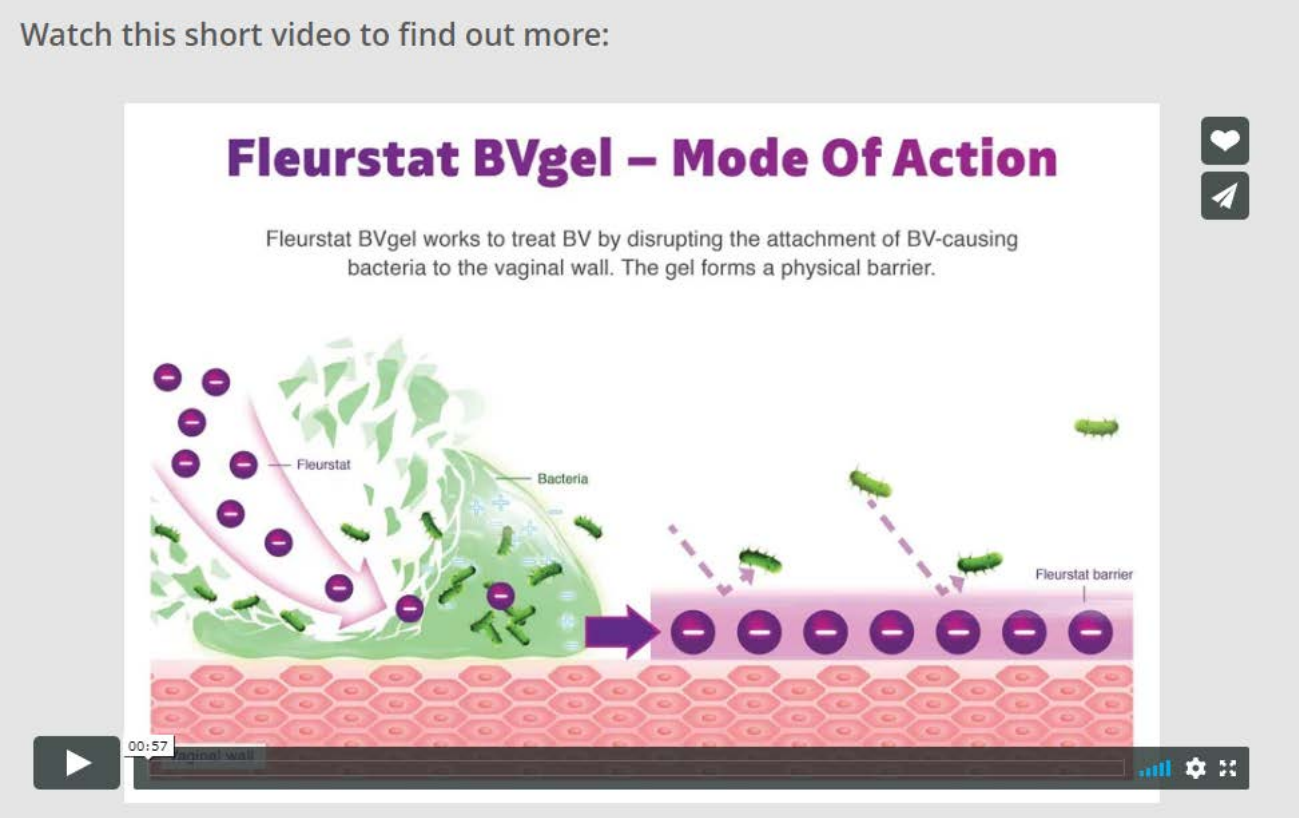

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Starpharma on Channel Nine News (April 22, 2019) https://www.youtube.com/watch?v=-RrAmqJyz20

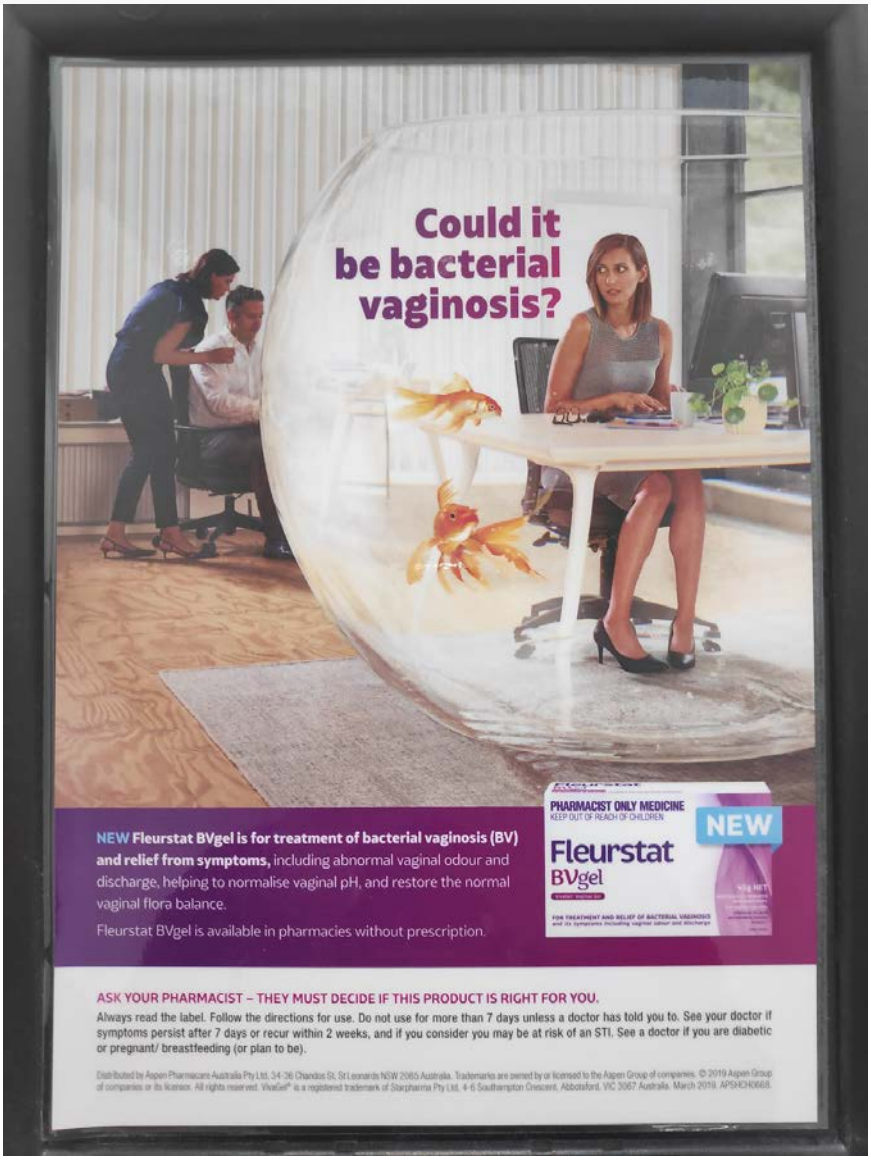

Photo of Fleurstat BV Gel advertised in a Glen Waverley Shopping Centre female bathroom on 30/8/19

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Complaint submitted by:

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26 September 2019

Australian Government

Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 295465 Starpharma Pty Ltd - Fleurstat - VivaGel - Vaginal flora gel

ARTG entry for	Medical Device Included Class IIa
Sponsor	Starpharma Pty Ltd
Postal Address	PO Box 2022, PRESTON, VIC, 3072 Australia
ARTG Start Date	24/10/2017
Product category	Medical Device Class IIa
Status	Active
Approval area	Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
Starpharma Pty Ltd	4-6 Southampton Crescent ABBOTSFORD, VIC, 3067 Australia

Products

1. Fleurstat - VivaGel - Vaginal flora gel

Product Type	Single Device Product	**Effective date**	24/10/2017

GMDN	47601 Vaginal flora gel
Intended purpose	Astodrimer sodium (Fleurstat; VivaGel®), in the form of a gel applied by the user into the vagina once daily for seven days, for topical treatment and rapid relief of bacterial vaginosis (BV), including unpleasant vaginal odour and discharge, helping to normalise vaginal pH and suppress the bacteria that cause BV. After application, the device cannot be reused.

Specific Conditions

* This medical device ARTG inclusion is limited to some medical devices of the kind. These devices of the kind are medical devices identified by the manufacturer as: Fleurstat; VivaGel®.
* Other devices of the kind must not be supplied under this ARTG entry in Australia until and unless evidence of compliance of those devices with the essential principles is provided and accepted by the TGA.
* Further the person in relation to whom the kind of device is included in the ARTG (the sponsor) must provide to the Therapeutic Goods Administration, Department of Health, on an annual basis reports similar to a kind referred to in regulation 5.11 of the Therapeutic Goods (Medical Devices) Regulations 2002.
* The reporting periods and the time for providing these reports must be consistent with the time specified in paragraph (4) of this 5.11 regulation. - If the sponsor requires a variation to the ARTG entry to include details of the medical devices that are to be imported, supplied or exported under an entry, the sponsor will need to submit a Device Change Request to the TGA.

Public Summary