

23 February 2022

s 9(2)(a)

By email: s 9(2)(a)  
Ref: H202200581

Dear s 9(2)(a)

### Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 25 January 2022 for information regarding Truvada:

*I wish to request the following information regarding the medicine Truvada tablet (Tenofovir disoproxil fumarate 300mg, Emtricitabine 200mg):*

- Please provide a copy of the most recent primary and secondary labelling (including pack insert and tertiary labelling if applicable) approved by Medsafe in a CMN or notified in a SACN.*
- If there has been no CMN or SACN approved since the original NMA, please provide the labelling which was approved in the NMA.*

Copies of the currently approved labels for Truvada are attached to this letter as Document 1.

I trust this information fulfils your request.

Under section 28(3) of the Act you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: [info@ombudsman.parliament.nz](mailto:info@ombudsman.parliament.nz) or by calling 0800 802 602.

Yours sincerely



Chris James  
**Group Manager**  
**Medsafe**

100% size


Each tablet contains 300 mg tenofovir disoproxil fumarate and 200 mg of emtricitabine.

Store below 25°C.  
Oral use.  
Use as directed by your Doctor.  
Contains lactose.


Manufactured for:  
Gilead Sciences Pty Ltd  
Level 6, 417 St Kilda Road  
Melbourne, Victoria 3004  
Australia

**PRESCRIPTION ONLY MEDICINE**  
KEEP OUT OF REACH OF CHILDREN

**Truvada®**  
**tenofovir disoproxil**  
**fumarate 300 mg /**  
**emtricitabine 200 mg**  
**30 tablets**

AUST R 107072  GILEAD

Lot: **610261XX**  
EXP:

|   |                                |                             |                                |
|---|--------------------------------|-----------------------------|--------------------------------|
|  <b>GILEAD</b> | <b>PRODUCT</b><br>Truvada      | <b>LABEL TYPE</b><br>Label  | <b>COUNTRY</b><br>Australia NZ |
|   | <b>PART NUMBER</b><br>610261XX | <b>REVISION</b><br>02       | <b>DATE</b><br>17 Jul 2020     |
| <b>COLOURS USED</b><br>4  | <b>BLACK</b>                   | PANTONE COOL GRAY 11 (100%) | <b>PANTONE 1235</b>            |
|   | <b>PANTONE 193</b>             | PANTONE COOL GRAY 11 (50%)  |                                |
| <b>FOR REFERENCE ONLY</b>   | <b>DIELINE</b>                 | <b>VARNISH FREE</b>         |                                |

For further information please contact the **Labelling Operations Group** at Gilead Sciences Ireland UC, IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland.



|                           |                                |                             |   |
|---------------------------|--------------------------------|-----------------------------|---|
|                           | <b>PRODUCT</b><br>Truvada      | <b>LABEL TYPE</b><br>Carton | <b>COUNTRY</b><br>Australia NZ Made in Canada |
|                           | <b>PART NUMBER</b><br>010230XX | <b>REVISION</b><br>03       | <b>DATE</b><br>17 Jul 2020                    |
| <b>COLOURS USED</b><br>4  | <b>BLACK</b>                   | <b>PANTONE 193</b>          | <b>PANTONE 1235</b>                           |
|                           | PANTONE COOL GRAY 11 (100%)    | PANTONE COOL GRAY 11 (10%)  |   |
| <b>FOR REFERENCE ONLY</b> | <b>DIELINE</b>                 | <b>VARNISH FREE</b>         |   |



PRESCRIPTION ONLY MEDICINE  
KEEP OUT OF REACH OF CHILDREN

**Truvada<sup>®</sup>**  
tenofovir disoproxil  
fumarate 300 mg /  
emtricitabine 200 mg  
30 tablets

AUST R 107072



PRESCRIPTION ONLY MEDICINE  
KEEP OUT OF REACH OF CHILDREN

**Truvada<sup>®</sup>**  
tenofovir disoproxil  
fumarate 300 mg /  
emtricitabine 200 mg  
30 tablets

AUST R 107072



**Truvada<sup>®</sup>**  
tenofovir disoproxil  
fumarate 300 mg /  
emtricitabine 200 mg  
30 tablets

H2

**Truvada<sup>®</sup> Tablets**  
30 Tablets

Each tablet contains 300 mg of  
tenofovir disoproxil fumarate  
and 200 mg of emtricitabine.

Store below 25°C.

Oral use.

Use as directed by your Doctor.

Contains lactose, refer to the Consumer  
Medicine Information about other  
ingredient(s) present in this medicine.

Manufactured for:  
Gilead Sciences Pty Ltd  
Level 6, 417 St Kilda Road  
Melbourne, Victoria 3004  
Australia

Made in Ireland



Lot: 010261XX  
EXP:



|                           |                                |                             |  |
|---------------------------|--------------------------------|-----------------------------|--|
|                           | <b>PRODUCT</b><br>Truvada      | <b>LABEL TYPE</b><br>Carton | <b>COUNTRY</b><br>Australia NZ Made in Ireland |
|                           | <b>PART NUMBER</b><br>010261XX | <b>REVISION</b><br>03       | <b>DATE</b><br>17 Jul 2020                     |
| <b>COLOURS USED</b><br>4  | <b>BLACK</b>                   | <b>PANTONE 193</b>          | <b>PANTONE 1235</b>                            |
|                           | PANTONE COOL GRAY 11 (100%)    | PANTONE COOL GRAY 11 (10%)  |  |
| <b>FOR REFERENCE ONLY</b> | <b>DIELINE</b>                 | <b>VARNISH FREE</b>         |  |



|                           |                                |                             |  |
|---------------------------|--------------------------------|-----------------------------|--|
|                           | <b>PRODUCT</b><br>Truvada      | <b>LABEL TYPE</b><br>Carton | <b>COUNTRY</b><br>Australia NZ Made in Germany |
|                           | <b>PART NUMBER</b><br>010240XX | <b>REVISION</b><br>03       | <b>DATE</b><br>17 Jul 2020                     |
| <b>COLOURS USED</b><br>4  | <b>BLACK</b>                   | <b>PANTONE 193</b>          | <b>PANTONE 1235</b>                            |
|                           | PANTONE COOL GRAY 11 (100%)    | PANTONE COOL GRAY 11 (10%)  |  |
| <b>FOR REFERENCE ONLY</b> | <b>DIELINE</b>                 | <b>VARNISH FREE</b>         |  |