

## Public assessment summary report

<b>Name of the Finished Pharmaceutical Product</b>	Delstrigo™ 100 mg/300 mg/245 mg film-coated tablets
<b>Manufacturer of the Finished Product</b>	MSD International GmbH Ballydine, Kilsheelan, Clonmel, Country Tipperary Ireland
<b>License holder</b>	MSD (Pty) Ltd 117 16th Road Halfway House, 1685 South Africa
<b>Active Pharmaceutical Ingredient (API)</b>	Doravirine, lamivudine, and tenofovir disoproxil fumarate

### 1. Introduction

Based on review of quality, safety and efficacy data through the Abbreviated approval procedure, the authority granted a marketing authorization for Delstrigo™ 100 mg/300 mg/245 mg film-coated tablets. Each film-coated tablet contains 100 mg of doravirine, 300 mg of lamivudine, and 300 mg of tenofovir disoproxil fumarate equivalent to 245 mg of tenofovir disoproxil.

Delstrigo is indicated for the treatment of adults infected with HIV 1 without past or present evidence of resistance to the NNRTI class, lamivudine, or tenofovir. Therapy should be initiated by a physician experienced in the management of HIV infection

### 2. Assessment of quality

GMP compliance of the API manufacture was demonstrated by document review. The necessary waiver for cGMP of the finished pharmaceutical product has been carried out. Marketing authorization was granted by the stringent regulatory authority (SRA) and appropriate verification of marketing authorization was performed.

#### **Stability testing:**

It is confirmed that the finished product stability studies were conducted in the container closure system proposed for the marketing of the product in accordance with the current medicine registration guideline of Ethiopia. The packaged product was stored at the long term condition of 30°C/75% RH and at the accelerated condition of 40°C/75%RH. The batches were packaged in 100 cc HDPE bottle with 6 g desiccant. The packaging components used are the same as those for proposed commercial package for the marketed product. Based on the data presented, an initial shelf life of 24 months for doravirine/lamivudine/ tenofovir disoproxil fumarate tablets was proposed.

### 3. Conclusion

Based on assessment of administrative and technical document, it is considered that the benefit-risk profile of Delstrigo™ 100 mg/300 mg/245 mg film-coated tablets manufactured by MSD



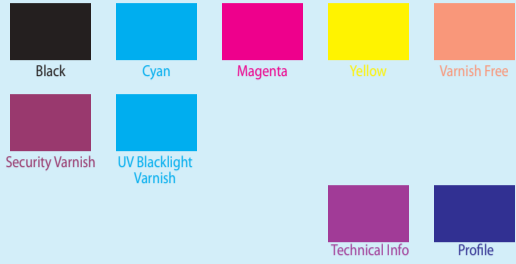
March 2023

International GmbH Ballydine, Kilsheelan, Clonmel, County Tipperary Ireland are acceptable for the following indications: for the treatment of adults infected with HIV 1 without past or present evidence of resistance to the NNRTI class, lamivudine, or tenofovir.

Bar prints 100mm @ 100%

# MSD ARTWORK

Item No.: N/A  
 CMO Item No.: (EXM) N/A  
 Revision Date & No.: N/A  
 Plant Code: N/A  
 Schawk Job No.: 402572008-0020  
 ACFID: High  
 HAN\_ 618209



SGK is a Matthews International Corporation

**Pr Proprietary**  
 100% 50% 95% 5%  
**Mock-Up Design Workflows:**  
 Placeholders ("X") where  
 component number will be  
 placed upon approval.

POM Rx Only

## Delstrigo™

**100 mg/300 mg/245 mg**

**film-coated tablets/  
 comprimidos revestidos por película**  
 doravirine/lamivudine/tenofovir disoproxil  
 doravirina/lamivudina/tenofovir disoproxil  
 30 film-coated tablets/  
 comprimidos revestidos por película

MFG:  
 LOT/LOTE:  
 EXP./VAL.:

For Position Only

Each film-coated tablet contains 100 mg of doravirine, 300 mg of lamivudine and 245 mg of tenofovir disoproxil. Contains lactose. Oral use Keep out of the sight and reach of children. Store at or below 30 °C. Keep the bottle tightly closed in order to protect from moisture.

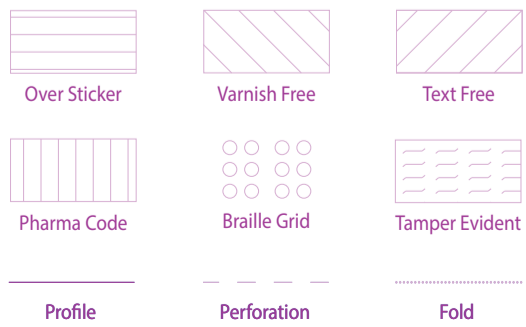
Cada comprimido revestido por película contém 100 mg de doravirina, 300 mg de lamivudina e 245 mg de tenofovir disoproxil. Contém lactose. Via oral Manter fora do alcance e da vista das crianças. Conservar a ou abaixo 30 °C. Manter o frasco bem fechado para proteger da humidade.

MSD (Pty) Ltd

XXXXXXXXXX-1-1/5007

# MSD PROFILE

Profile: LA136x49\_HAN  
 Profile Revision: 8  
 Profile Revision Date: 180918  
 Dimensions (mm): 136x49



Bar prints 100mm @ 100%

**MSD ARTWORK**

Item No.: N/A  
 CMG Item No.: (EXM) N/A  
 Revision Date & No.: N/A  
 Plant Code: N/A  
 Schawk Job No.: 402572027-0020  
 ACFID: High  
 HAN\_618204

Black Cyan Magenta Yellow Varnish Free  
 Security Varnish UV Blacklight Varnish  
 Microtext Technical Info Profile

**SGK** Proprietary  
 Mock-Up Design Workflows:  
 Placeholders ("X") where  
 component number will be  
 placed upon approval.

SGK is a Matthews International Corporation

XXXXXXXXXX  
 X-X  
 5007

**Delstrigo™**  
 100 mg/300 mg /245 mg

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 100 mg/300 mg /245 mg

**Delstrigo™**  
 100 mg/300 mg /245 mg

Each film-coated tablet contains 100 mg of doravirine; 300 mg of lamivudine and 245 mg of tenofovir disoproxil. Contains lactose. Read the package leaflet before use. Oral use. Swallow whole. Keep out of the sight and reach of children. Store at or below 30 °C. Keep the bottle tightly closed in order to protect from moisture.

Cada comprimido revestido por película contém 100 mg de doravirina; 300 mg de lamivudina e 245 mg de tenofovir disoproxil. Contém lactose. Consultar o folheto informativo antes de utilizar. Via oral. Engolir inteiro. Manter fora da vista e do alcance das crianças. Conservar a ou abaixo 30 °C. Manter o frasco bem fechado para proteger da humidade.

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 100 mg/300 mg /245 mg

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MARKETING AUTHORISATION NUMBER(S)  
 NÚMERO(S) DA AUTORIZAÇÃO DE INTRODUÇÃO  
 NO MERCADO

ETHIOPIA	
KENYA	
MALAWI	
NIGERIA (NAFDAC REG. NO.)	
TANZANIA	
UGANDA	
ZAMBIA	
ZIMBABWE	

Medicinal product subject to medical prescription.  
 Medicamento sujeito a receita médica.

Marketing Authorization Holder/Titular da  
 Autorização de Introdução no Mercado:  
 MSD (Pty) Ltd, 117 16<sup>th</sup> Road, Halfway House,  
 1685, South Africa/África do Sul

Manufacturer/Fabricante:  
 MSD International GmbH, Ballydine,  
 Kilsheelan, Clonmel, Co. Tipperary,  
 Ireland/Irlanda

30 film-coated tablets/  
 comprimidos revestidos  
 por película

For Position Only

**MSD PROFILE**

Profile: HAN\_CRTN\_893  
 Profile Revision: 2  
 Profile Revision Date: 170620  
 Dimensions (mm): 60x60x112

Over Sticker Varnish Free Text Free  
 Pharma Code Braille Grid Tamper Evident  
 Profile Perforation Fold