

Dolutegravir

30 Tablets

Het

Tablets 50 mg

Hetora

50 mg 30 Tablets **Dolutegravir Tablets** Hetgra

Dolutegravir 50 mg Dolutegravir sodium equivalent to Each film coated tablet contains:

Neutral Code No.: HR/DRUGS/296-0SP(H)

Batch No : HDL-001

Exp Date: NOV-2020 Mfg Date: DEC-2018

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Keep out of reach of children. Colours: Titanium Dioxide and Store in original package and keep the bottle tightly closed in order to protect from moisture. Store below 25°C. Protect from light. age :- As directed by the Physician Indigo Carmine.

Tablets 50 mg Dolutegravir Hetoria 30 Tablets HEET HEALTH CARE Health Care your bealth Manufactured for : Neutral Code No.: HR/DRUGS/296-0SP(H) Het

Keep out of reach of children.

WARNING: To be sold by retail on the

prescription of specialist only.

Store in original package and keep the Store below 25°C. Protect from light. Dosage :- As directed by the Physician

Colours: Titanium Dioxide and

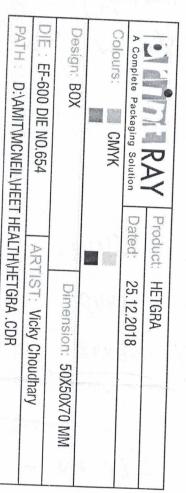
Indigo Carmine,

Dolutegravir 50 mg

Dolutegravir sodium equivalent to Each film coated tablet contains:

bottle tightly closed in order to protect

FREE AREA VARNISH



Mcneil and Argus Pharmaceuticals Limited

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<u>Items to be Manufactured</u> <u>Under Manufacturing Licence No: 296-OSP(H)</u> (For Exports only)

Sr. Name of the Product

1. Dolutegravir Tablets 50mg

Composition:

Each film coated tablet contains: Dolutegravir Sodium Equivalent to Dolutegravir 50mg

Approved colours to be used.

Storage: Store, protected from moisture at a temperature not exceeding 30° C

Importing Country: Vietnam. Quantity: 3,00,000 Tablets

Pack Size: 30 Tablets in HDPE Bottles in Printed carton with leaflet

For Moneil & Argus Pharmaceuticals Ltd.

Chairman/Managing Director

Bhai G. D. Chhibber Chairman cum Managing Director

For Mcneil & Argus Pharmaceuticals Ltd.

Authorised Signator

State Drugs Controller-cting Controlling & Licensing Authority

Food & Drugs Administration, Haryana

MCNEIL & ARGUS PHARMACEUTICALS LTD.

100 - Rampur Sarsehri Road, Ambala Cantt 133001 India

Form 39 {See Rule 150-E(F)}

The Drugs and Cosmetics Act 1940 & Rules made Thereunder

Our Ref. No. : AT/27.12.2018/T/02

Dated: 27.12.2018

Product Name: HETGRA (Dolutegravir Tablets 50mg)

Report No: AT/27.12.2018/T/02

Received Date: 26.12.2018

Batch No. HDL-001

Neutral code No: HR/DRUGS/296-OSP(H)

Sample Qty: 30 Tablets

D/M: DEC 2018

Product Name: HETGRA (Report No: AT/27.12.2018/T/02

Received Date: 26.12.2018

Product Name: HETGRA (Report No: AT/27.12.2018/T/02

Description

Sky Blue colour, round , convex film coated Tablets

Identification

Positive for Dolutegravir Sodium

Average weight

412.00mg

Uniformity of weight

Within the limit

Lt: (± 5 %)

Disintegration Time

4-5minutes

Lt: (NMT 30 Minutes)

Assay

Each Film coated tablet contains

Claim

Present

Protocol

Dolutegravir Sodium Eq. to Dolutegravir

50mg

50.04mg

IN House

In the opinion of the undersigned the submitted sample is **Standard Quality** as defined in The Drugs and Cosmetics Act 1940 & Rules made there under for reason given below

Heena Morga

Analyst For Mcneil & Argus Pharmaceuticals LDate

Authorised Signatory

27.12.2018

Chemist-in-chief