

Gastazole 370 mg/g oral paste for horses

Authorised

- Omeprazole

Product identification

Medicine name:

Gastazole 370 mg/g oral paste for horses

Active substance:

Omeprazole

Target species:

Horse

Route of administration:

Oral use

Product details

Active substance and strength:

Omeprazole

370.00 milligram(s) / 1.00 gram(s)

Pharmaceutical form:

Oral paste

Withdrawal period by route of administration:**Oral use:**

-

Horse

- Meat and offal. 1 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QA02BC01

Legal status of supply:

Veterinary medicinal product not subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Italy

Package description:

Immediate packaging: Opaque white pre-filled oral syringe containing 7.57g of paste composed of Barrel: HDPE & LLDPE Barrel Cap: LLDPE+HDPE Plunger: Polypropylene Ring: Polypropylene Plastic Seal: LDPE Package sizes Carton box of 72 syringes

Immediate packaging: Opaque white pre-filled oral syringe containing 7.57g of paste composed of Barrel: HDPE & LLDPE Barrel Cap: LLDPE+HDPE Plunger: Polypropylene Ring: Polypropylene Plastic Seal: LDPE Package sizes Carton box of 56 syringes

Immediate packaging: Opaque white pre-filled oral syringe containing 7.57g of paste composed of Barrel: HDPE & LLDPE Barrel Cap: LLDPE+HDPE Plunger: Polypropylene Ring: Polypropylene Plastic Seal: LDPE Package sizes Carton box of 20 syringes

Immediate packaging: Opaque white pre-filled oral syringe containing 7.57g of paste composed of Barrel: HDPE & LLDPE Barrel Cap: LLDPE+HDPE Plunger: Polypropylene Ring: Polypropylene Plastic Seal: LDPE Package sizes Carton box of 14 syringes

Immediate packaging: Opaque white pre-filled oral syringe containing 7.57g of paste composed of Barrel: HDPE & LLDPE Barrel Cap:

LLDPE+HDPEPlunger: PolypropyleneRing: PolypropylenePlastic Seal: LDPEPackage sizesCarton box of 10 syringes

Immediate packaging: Opaque white pre-filled oral syringe containing 7.57g of paste composed of Barrel: HDPE & LLDPEBarrel Cap:

LLDPE+HDPEPlunger: PolypropyleneRing: PolypropylenePlastic Seal: LDPEPackage sizesCarton box of 7 syringes

Immediate packaging: Opaque white pre-filled oral syringe containing 7.57g of paste composed of Barrel: HDPE & LLDPEBarrel Cap:

LLDPE+HDPEPlunger: PolypropyleneRing: PolypropylenePlastic Seal: LDPEPackage sizesCarton box of 1 syringe

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:

Chanelle Pharmaceuticals Manufacturing Limited

Marketing authorisation date:

23/01/2023

Manufacturing sites for batch release:

Chanelle Pharmaceuticals Manufacturing Limited

Responsible authority:

Ministry Of Health

Authorisation number:

105581

Date of authorisation status change:

23/01/2023

Reference member state:

Ireland

Procedure number:

IE/V/0658/001

Concerned member states:

Austria Belgium Czechia Denmark Finland France Germany Greece
Hungary Italy Netherlands Norway Poland Portugal Romania Spain Sweden

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Documents

Combined File of all Documents

English (PDF)

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Summary of Product Characteristics