

Gastazole 370 mg/g oral paste for horses

Authorised

- Omeprazole

Product identification

Medicine name:

Gastazole 370 mg/g oral paste for horses

Gastazole 370 mg/g στοματική πάστα για άλογα

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 subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Greece

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 1 syringe

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 7 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 10 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 20 syringes
Immediate packagelImmediate 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 56 syringes
Immediate packagelImmediate 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 72 syringes

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:

2/10/2022

Manufacturing sites for batch release:

Chanelle Pharmaceuticals Manufacturing Limited

Responsible authority:

National Organization For Medicines

Authorisation number:

101858/03-10-2022/K-0247501

Date of authorisation status change:

2/10/2022

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

To consult adverse reactions on veterinary medicinal products please go to
www.adrreports.eu/vet

Documents

Summary of Product Characteristics

Combined File of all Documents