File downloaded on 2026-11-08
Source URL: https://medicines.health.europa.eu/veterinary/en/600000047122

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 subject to veterinary prescription

---

Authorisation status:

Valid

Authorised in:

Denmark

Package description:

Immediate packageImmediate 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

Immediate packageImmediate 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 packageImmediate 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 20 syringes

Immediate packageImmediate 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 14 syringes

Immediate packageImmediate 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 10 syringes
Immediate packageImmediate 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 packageImmediate 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:
21/05/2021

Manufacturing sites for batch release:
Chanelle Pharmaceuticals Manufacturing Limited

Responsible authority:
Danish Medicines Agency

Authorisation number:
65219

Date of authorisation status change:
21/05/2021

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

English (PDF)
Published on: 20/07/2025
Updated on: 13/03/2026
Download

Combined File of all Documents