Cubarmix Equi 400 mg/g and 80 mg/g oral powder for horses

Authorised

- Sulfadiazine
- Trimethoprim

Product identification

Medicine name:
Cubarmix Equi 400 mg/g and 80 mg/g oral powder for horses

Active substance:
Sulfadiazine

Trimethoprim

Target species:
Horse

Route of administration:
Oral use

Product details

Active substance and strength:
Sulfadiazine
400.00 milligram(s) / 1.00 gram(s)

Trimethoprim

80.00 milligram(s) / 1.00 gram(s)

Pharmaceutical form:
Oral powder

Withdrawal period by route of administration:
Oral use:

- **Horse**
  - Meat and offal. 6 month

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01EW10

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Ireland

Package description:
White cylindrical polypropylene container, covered with a low density polyethylene lid containing 500g of oral powder.
White cylindrical polypropylene container, covered with a low density polyethylene lid containing 800g of oral powder.
Heat-sealed, white coloured, 4-layer sachet containing 12.5 g of oral powder. 15 sachets per pack.
Heat-sealed, white coloured, 4-layer sachet containing 12.5 g of oral powder. 100 sachets per pack
Heat-sealed, white coloured, 4-layer sachet containing 37.5 g of oral powder. 5 sachets per pack
Heat-sealed, white coloured, 4-layer sachet containing 37.5 g of oral powder. 10 sachets per pack
Heat-sealed, white coloured, 4-layer sachet containing 37.5 g of oral powder. 100 sachets per pack

Heat-sealed, white coloured, 4-layer sachet containing 50 g of oral powder. 5 sachets per pack
Heat-sealed, white coloured, 4-layer sachet containing 50 g of oral powder. 10 sachets per pack
Heat-sealed, white coloured, 4-layer sachet containing 50 g of oral powder. 100 sachets per pack

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Hybrid application – change in strength (Article 19(1)(a) of Regulation (EU) 2019/6)

Marketing authorisation holder:
Dopharma Research B.V.

Marketing authorisation date:
23/01/2026

Manufacturing sites for batch release:
Dopharma B.V.
Dopharma France

Responsible authority:
Health Products Regulatory Authority

Authorisation number:
VPA10791/024/001

Date of authorisation status change:
23/01/2026

Reference member state:
Ireland

Procedure number:
IE/V/0673/001

Concerned member states:
Austria Belgium Denmark France Germany Hungary Italy Netherlands Poland Romania Spain Sweden United Kingdom (Northern Ireland)

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

Documents

Combined File of all Documents

Summary of Product Characteristics

ie-puar-mr-iev0673001-cubarmix-equi-400-mgg-and-80-mgg-oral-powder-for-h-en.pdf