

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Container and box for sachets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cubarmix Equi 400 mg/g + 80 mg/g oral powder

2. STATEMENT OF ACTIVE SUBSTANCES

Sulfadiazine: 400 mg/g

Trimethoprim 80 mg/g

3. PACKAGE SIZE

500 g

800 g

15 x 12.5 g; 100 x 12.5 g

5 x 37.5 g; 10 x 37.5 g; 100 x 37.5 g

5 x 50 g; 10 x 50 g; 100 x 50 g

4. TARGET SPECIES

Horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In feed use.

7. WITHDRAWAL PERIODS

Withdrawal period:

Meat and offal: 6 months.

Not authorised for use in animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months. (Container)

Once opened use by ...

Once opened use immediately. (sachet)

Shelf life after mixing into the feed: use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package in order to protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.

14. MARKETING AUTHORISATION NUMBERS

UK(NI) Vm 28365/3006

UK(GB) Vm 28365/5009

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
Sachets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cubarmix Equi 400 mg/g + 80 mg/g oral powder

2. STATEMENT OF ACTIVE SUBSTANCES

Sulfadiazine: 400 mg/g
Trimethoprim 80 mg/g

3. TARGET SPECIES

Horses.

4. ROUTES OF ADMINISTRATION

In feed use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 6 months.
Not authorised for use in animals producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately.

Shelf life after mixing into the feed: use immediately.

7. SPECIAL STORAGE PRECAUTIONS

Store in the original package in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each gram contains:

Active substances:

Sulfadiazine: 400 mg

Trimethoprim 80 mg

White to cream coloured powder.

3. Target species

Horses.

4. Indications for use

Treatment of infections caused by micro-organisms susceptible to the combination of sulfadiazine and trimethoprim, such as infections of the upper respiratory tract and wound infections.

5. Contraindications

Do not use in cases of hypersensitivity to the active substances (or any other sulfonamide) or to any of the excipients. Do not use in horses with severe liver parenchymal damage or kidney damage. Do not use in horses with blood dyscrasias or cardiac arrhythmias.

6. Special warnings

Special warnings:

In case of infections involving purulent conditions, trimethoprim-sulfonamides combinations are not recommended due to a diminished efficacy under such conditions.

Cross-resistance has been shown between sulfadiazine and other sulfonamides. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to combinations of trimethoprim with other sulfonamides because its effectiveness may be reduced.

Special precautions for safe use in the target species:

The use in horses under 1 year old should be avoided.

Throughout the treatment, animals should have free access to drinking water to avoid possible crystalluria.

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

This veterinary medicinal product may cause hypersensitivity reactions following inhalation, ingestion or skin contact. Hypersensitivity to sulfonamides may lead to cross reactions with other antibiotics. Allergic reactions to sulfonamides may occasionally be serious. People with known hypersensitivity to sulfadiazine (or other sulfonamides) or trimethoprim should avoid contact with the veterinary medicinal product.

The veterinary medicinal product may be harmful in case of accidental ingestion including hand-to-mouth contact, inhalation or accidental contact with unprotected skin and eyes. This veterinary medicinal product may cause irritation to skin, eyes and respiratory system.

Care should be taken not to inhale any dust and contact with skin and eyes should be avoided. Take care to avoid accidental ingestion, especially by children.

Personal protective equipment consisting of rubber gloves, goggles and a dust mask (disposable half-mask respirator conforming to EN149 or a non-disposable respirator EN140 with a filter EN143) should be worn when mixing or handling the veterinary medicinal product. Do not smoke, eat or drink while handling the veterinary medicinal product. The veterinary medicinal product should be stored at a safe place out of the reach and site of children.

In case of skin or eyes contact, rinse immediately with plenty of water. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the physician this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy or lactation in mares.

Laboratory studies in rats and rabbits have shown evidence of teratogenic effects at dosages that were above the therapeutic dosages.

Do not use during pregnancy.

When administered to lactating females, small amounts of trimethoprim and sulfadiazine are present in the maternal milk.

The use is not recommended during lactation.

Interactions with other medicinal products and other forms of interaction:

Potentiated sulfonamides used in conjunction with alpha2-adrenoceptor agonists like detomidine are known to be able to cause fatal arrhythmias in the horse.

Do not administer concurrently with para-aminobenzoic acid (PABA).

Local anaesthetics from the group of para-aminobenzoic acid esters (procaine, benzocaine, tetracaine) can locally inhibit the effect of sulfonamides.

Overdose:

In case of an overdose loose faeces or diarrhoea may be observed. This is generally self-limiting, but treatment should be discontinued and if needed symptoms can be treated symptomatically e.g. fluid therapy in case of dehydration.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Horses:

Common (1 to 10 animals / 100 animals treated):	Digestive tract disorder (e.g. loose stool, diarrhoea, colitis) ¹
Undetermined frequency (cannot be estimated from the available data)	Hypersensitivity reaction (e.g. urticaria) Inappetence Hepatic disorder Renal disorder, renal tubular disorder ² Haematologic effects (e.g. anaemia, thrombocytopenia, or leucopenia) Haematuria, crystalluria

¹ Treatment should be discontinued and symptomatic treatment initiated, if needed.

² tubular obstruction

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

In feed use.

The recommended dose per administration is 30 mg combined active ingredients per kg body weight, meaning 25 mg sulfadiazine and 5 mg trimethoprim per kg body weight or 62.5 mg veterinary medicinal product/kg body weight (equivalent to 12.5 g powder per 200 kg of BW) administered once daily for 5 days.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated weighing equipment is recommended.

Mix with a small quantity of feed. It is recommended that other feed be withdrawn until medicated feed has been consumed.

The veterinary medicinal product is to be administered only for the treatment of individually fed animals.

10. Withdrawal periods

Meat and offal: 6 months.

Not authorised for use in animals producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special temperature storage conditions.

Store in the original package in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging:

- Container: 3 months.
- Sachet: use immediately.

Shelf life after mixing into the feed: use immediately.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

UK(NI) Vm 28365/3006

UK(GB) Vm 28365/5009

Container: 500 g, 800 g.

Box of 15 or 100 sachets of 12.5 g.

Box of 5, 10 or 100 sachets of 37.5 g.

Box of 5, 10 or 100 sachets of 50 g.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:

Dopharma Research B.V.

Zalmweg 24

4941 VX Raamsdonksveer

The Netherlands

Tel: +31-162-582000

pharmacovigilance@dopharma.com

Manufacturer responsible for batch release:

Dopharma Research B.V.

Zalmweg 24

4941 VX Raamsdonksveer

The Netherlands

Dopharma France S.A.S.

23 Rue du Prieuré, Saint-Herblon

FR 44150 Vair-sur-Loire

17. Other information

Trimethoprim is persistent in soil.

POM-V

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet Container (500 g, 800 g) and box for sachets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Sulfadiazine: 400 mg/g

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White to cream coloured powder.

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Horses.

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Indications for use

Treatment of infections caused by micro-organisms susceptible to the combination of sulfadiazine and trimethoprim, such as infections of the upper respiratory tract and wound infections.

6. CONTRAINDICATIONS

Contraindications

Do not use in cases of hypersensitivity to the active substances (or any other sulfonamide) or to any of the excipients. Do not use in horses with severe liver parenchymal damage or kidney damage. Do not use in horses with blood dyscrasias or cardiac arrhythmias.

7. SPECIAL WARNINGS

Special warnings

Special warnings:

In case of infections involving purulent conditions, trimethoprim-sulfonamides combinations are not recommended due to a diminished efficacy under such conditions.

Cross-resistance has been shown between sulfadiazine and other sulfonamides. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to combinations of trimethoprim with other sulfonamides because its effectiveness may be reduced.

Special precautions for safe use in the target species:

The use in horses under 1 year old should be avoided.

Throughout the treatment, animals should have free access to drinking water to avoid possible crystalluria.

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

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seek medical advice and show the physician this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

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Overdose:

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In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

8. ADVERSE EVENTS

Adverse events

Horses:

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Undetermined frequency (cannot be estimated from the available data)	Hypersensitivity reaction (e.g. urticaria) Inappetence Hepatic disorder

	Renal disorder, renal tubular disorder ² Haematologic effects (e.g. anaemia, thrombocytopenia, or leucopenia) Haematuria, crystalluria
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¹ Treatment should be discontinued and symptomatic treatment initiated, if needed.

² tubular obstruction

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

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9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

In feed use.

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10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

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Mix with a small quantity of feed. It is recommended that other feed be withdrawn until medicated feed has been consumed.

The veterinary medicinal product is to be administered only for the treatment of individually fed animals.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal: 6 months.

Not authorised for use in animals producing milk for human consumption.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

UK(NI) Vm 28365/3006

UK(GB) Vm 28365/5009

Pack sizes

Container: 500 g, 800 g.

Box of 15 or 100 sachets of 12.5 g.

Box of 5, 10 or 100 sachets of 37.5 g or 50 g.

Not all pack sizes may be marketed.

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17. CONTACT DETAILS

Contact details

Marketing authorisation holder and contact details to report suspected adverse events:

Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer
The Netherlands Tel: +31-162-582000
pharmacovigilance@dopharma.com

Manufacturer responsible for batch release:

Dopharma B.V.
Zalmweg 24
NL 4941 VX Raamsdonksveer

Dopharma France S.A.S.
23 Rue du Prieuré, Saint-Herblon
FR 44150 Vair-sur-Loire

18. OTHER INFORMATION

Other information

Trimethoprim is persistent in soil.

POM-V

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once opened use within 3 months (container).

Once opened use by ...

Once opened use immediately (sachet).

Shelf life after mixing into the feed: use immediately.

21. BATCH NUMBER

Lot {number}

Gavin Hall
Approved: 21 January 2026