B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Equibactin vet. 250 mg/g + 50 mg/g oral powder for horses

2. Composition

Each gram contains:
Active substances:
Sulfadiazine 250 mg
Trimethoprim 50 mg

White to off-white powder.

3. Target species

Horses.

4. Indications for use

For the treatment of infections in horses caused by micro-organisms susceptible to the combination of trimethoprim and sulfadiazine, such as infections of the upper respiratory tract, the urogenital system and wound infections.

5. Contraindications

Do not use in horses with severe liver or kidney disease.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use in cases of resistance to trimethoprim and sulphonamides.

6. Special warnings

Special precautions for safe use in the target species:
Throughout the treatment, animals should have free access to drinking water to avoid possible crystalluria.
In the treatment of new-born animals and animals with liver damage, caution should be exercised.
Renal impairment may cause accumulation, increasing the risk of side effects in long term treatment.
Use the veterinary medicinal product cautiously in horses with blood dyscrasias.
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 bacteria 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 Use of the product deviating from the instructions given in this leaflet may increase the prevalence of bacteria resistant to the veterinary medicinal product and may decrease the effectiveness of treatment with other antimicrobials or classes of antimicrobials due to the potential for cross-resistance.
In case of infections involving purulent conditions, trimethoprim-sulphonamides combinations are not recommended due to a diminished efficacy under such conditions.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product contains sulfadiazine, a sulphonamide which can cause hypersensitivity reactions following skin contact, inhalation or accidental ingestion. Hypersensitivity to sulphonamides may lead to cross reactions with other antibiotics. Allergic reactions to sulphonamides may occasionally be serious.
Contact with the veterinary medicinal product should be avoided. This is especially important for people with known hypersensitivity to sulphonamides.
Avoid inhalation of dust. Wear either a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator conforming to European Standard EN140 with filter EN143 when handling this veterinary medicinal product.
Avoid contact with skin. Rubber gloves should be worn when handling this veterinary medicinal product. In the case of contact with skin, wash with soap and water.
If symptoms develop following exposure such as a skin rash or difficulty with breathing and irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands thoroughly after use.

Pregnancy and lactation:
The safety of the veterinary medicinal product during pregnancy and lactation has not been assessed in the target species
Laboratory studies in rats and mice have shown evidence of teratogenic effects at dosages that are above therapeutic dosages.
The use is not recommended during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Potentiated sulphonamides used in conjunction with alpha2-adrenoceptor agonists like detomidine are known to be able to cause fatal arrhythmias in the horse.

Overdose:
In case of an overdose loose faeces or diarrhoea may be observed. This is generally self-limiting, but if needed 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

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hypersensitivity reaction (e.g. urticaria (hives)) Inappetence Digestive tract disorder (e.g. loose stool, diarrhoea, colitis (inflammation of the lining of the colon) Hepatic disorder (liver disorder) Haematological disorder (e.g. anaemia (reduction of red blood cells), thrombocytopenia (low amount of platelets), leucopenia (low level of white blood cells))
Undetermined frequency (cannot be estimated from the available data)	Renal disorder (kidney disorder), Urinary tract obstruction[a] Haematuria (blood in the urine), Crystalluria (crystals in the urine)

[a] 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 its local representative> using the contact details at the end of this leaflet, or via your national reporting system:

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

In-feed use.

The recommended dose is 30 mg of the active substances together (i.e. 25 mg sulfadiazine and 5 mg trimethoprim) per kg body weight. equivalent to 10 g powder per 100 kg, once or twice daily for 5 days.
Frequency of dosing is decided on basis of the susceptibility of the pathogens involved and location of the infection.
The veterinary medicinal product is to be administered only for the treatment of individually fed animals or a small group of animals where the intake by individual animals can be affectively controlled.

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 for the administration of the calculated
amount of the veterinary medicinal product is recommended when using the jars or parts of the sachets.
The powder can be mixed in a handful of feed immediately prior to dosing. The active ingredients in the powder have a bitter taste. Adding molasses or other sweetener to the feed can facilitate administration of the veterinary medicinal product. The remaining feed should be withheld until half an hour after the horse has eaten the feed with the medicine.
Should a horse continue to reject the medicated feed, treatment should be continued with another pharmaceutical form with the same actives.

10. Withdrawal periods

Meat and offal: 20 days
Milk: 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.
Keep the sachets and jars tightly closed after first opening in order to protect from moisture.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label after Exp. The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packaging (jars): 3 months
Shelf-life after first opening the immediate packaging (sachets): 24 hours if stored dry and re-closed with clip (after folding the edge of the opened sachet).
Shelf life after incorporation into meal: use immediately

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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

Cardboard box with one jar of 105 g, 210 g, 420 g or 840 g oral powder.
Cardboard box with 10, 20 or 28 sachets of 5 g, 15 g, 30 g or 60 g oral powder.
Cardboard box with 10 sachets of 100 g oral powder.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

30 October 2025

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

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

Manufacturer responsible for batch release:
LelyPharma B.V.
Zuiveringweg 42
8243 PZ Lelystad
The Netherlands

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information