PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bottle label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphatrim® IS Injectable Solution

Trimethoprim 40 mg and Sulfadiazine 200 mg

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains: Trimethoprim 40 mg, Sulfadiazine 200 mg, Chlorocresol 1 mg and Sodium Formaldehyde Sulphoxylate 1 mg.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Horses, cattle, pigs, dogs and cats.

6. INDICATION(S)

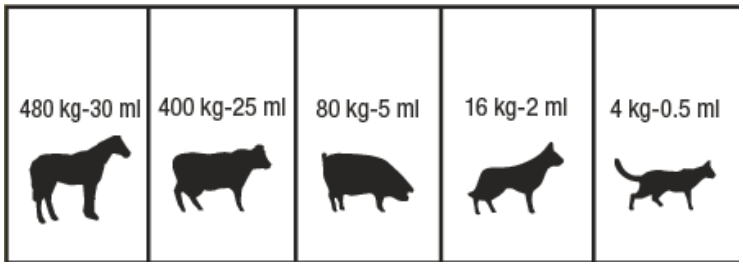
To be used in the treatment of acute, subacute and chronic bacterial infections in horses, cattle, pigs, dogs and cats.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In cattle and pigs administer by intramuscular or slow intravenous injection at a rate of 1 ml/16 kg bodyweight once, but in severe infections it may be repeated daily until 2 days after symptoms resolve up to a maximum of 5 days.

In horses administer at a rate of 1 ml/16 kg by slow intravenous injection only.

In dogs and cats administer at a rate of 1 ml/8 kg by subcutaneous injection only.



8. WITHDRAWAL PERIOD

Cattle (meat) – 12 days

(milk) – 48 hours

Pigs (meat) – 20 days

This product should not be used in horses intended for human consumption.

The horse must have been declared as not intended for human consumption in accordance with the UK's Horse Passport Legislation.

9. SPECIAL WARNING(S), IF NECESSARY

Injections should not be given by routes other than those recommended. Not to be administered intraperitoneally.

Operator warning: Care must be taken to avoid accidental self-injection. Avoid direct contact with skin and eyes. In the event of accidental spillage, wash affected area with copious amounts of water. Seek medical advice if irritation persists. Wash hands after use.

For use, disposal advice and warnings, see leaflet first.

10. EXPIRY DATE

Exp.:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Do not freeze. Protect from light.

Crystallization of the product at low temperatures can be reversed by gently warming.

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

Once broached use by:

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4048

17. MANUFACTURER’S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR:

Duphatrim® IS Injectable Solution

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Batch release site not stated

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphatrim® IS Injectable Solution

Trimethoprim 40 mg and Sulfadiazine 200 mg solution for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Duphatrim IS (Injectable Solution) is a clear yellow aqueous solution of trimethoprim and sulfadiazine for parenteral administration. Each ml contains the following active ingredients:

Trimethoprim	40 mg
Sulfadiazine	200 mg
Chlorocresol (as preservative)	1 mg
Sodium Formaldehyde Sulphoxylate	1 mg

4. INDICATION(S)

Duphatrim IS is a broad-spectrum antibacterial indicated in the treatment of a wide range of Gram-positive and Gram-negative organisms.

The two active ingredients, trimethoprim and sulfadiazine, sequentially block bacterial and protozoal synthesis of folinic acid, thus greatly potentiating the activity obtained when either ingredient is used alone.

In vitro antibacterial activity of Duphatrim IS is extensive, including *Actinobacillus* spp, *Actinomyces* spp, *Bordetella* spp, *Brucella* spp, *Corynebacterium* spp, *E.coli*, *Haemophilus* spp, *Klebsiella* spp, *Pasteurella* spp, *Pneumococcus* spp, *Proteus* spp, *Salmonella* spp, *Staphylococcus* spp (including penicillin-sensitive and penicillin-resistant), *Streptococcus* spp.

Duphatrim IS is indicated for use in horses, cattle, pigs, dogs and cats, for the treatment of acute, subacute and chronic bacterial infections sensitive to trimethoprim/sulfadiazine therapy such as:

Bacterial infections of the respiratory tract, including rhinitis, pneumonia, bronchitis and in bacterial infections secondary to viral disease such as viral pneumonia or mycoplasma infections.

Urogenital tract infections, including cystitis, vaginitis, urethritis, nephritis and metritis.

Alimentary tract infections, including neonatal diarrhoea and salmonellosis.

Other infections, such as foul-in-the-foot, severe mastitis, bacterial agalactia of sows, infections of the eye, ear or mouth.

5. CONTRAINDICATIONS

Injections should not be given by routes other than those recommended. Not to be administered intraperitoneally.

Do not administer to animals with known sulphonamide sensitivity, severe liver parenchymal damage, or blood dyscrasias. As with all trimethoprim/sulphonamide formulations the possibility of potential damage to the kidney, liver or haemapoeitic system should be considered.

Do not administer to horses exhibiting drug-induced cardiac arrhythmias. Such arrhythmias may be associated with the administration of certain anaesthetic and sedative agents. The intravenous route is contra-indicated in the case of concurrent or previous administration of central nervous system depressants (e.g. anaesthetics, neuroleptics).

6. ADVERSE REACTIONS

The possibility of anaphylaxis should be considered and the intravenous route in the horse should only be used if therapeutically justified.

7. TARGET SPECIES

Horses, cattle, pigs, dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For cattle and pigs the dose is 1 ml per 16 kg (35 lb) bodyweight daily by intramuscular or slow intravenous injection (equivalent to 15 mg of combined active ingredients per kg bodyweight) once, but in severe infections it may be repeated daily until 2 days after symptoms resolve up to a maximum of 5 days. Duphatrim IS may be administered by intravenous injection when rapid blood levels of sulfadiazine and trimethoprim are required.

For horses the dose is 1 ml per 16 kg bodyweight daily, by slow intravenous injection only.

For dogs and cats the dose is 1ml per 8 kg bodyweight daily, by subcutaneous injection only (equivalent to 30 mg of combined active ingredients per kg bodyweight). The recommended site in dogs is the loose skin at the base of the neck.

A single injection may be sufficient in uncomplicated conditions, but in severe infections the dose may be repeated for up to a maximum of 5 consecutive days, or until 2 days after the symptoms resolve.

The suggested dosage rates are:

Horse	480 kg	30 ml
Cattle	400 kg	25 ml
Pig	80 kg	5 ml
Dog	16 kg	2 ml
Cat	4 kg	0.5 ml

9. ADVICE ON CORRECT ADMINISTRATION

Intravenous injections should be at body temperature and administered slowly over as long a period as is reasonably practical in order to avoid possible anaphylactic shock. If intolerance develops, immediately interrupt the injection and initiate shock treatment.

10. WITHDRAWAL PERIOD(S)

Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken from cows only after 48 hours from the last treatment.

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 12 days from the last treatment. Pigs may be slaughtered for human consumption only after 20 days from the last treatment.

Not to be used in horses intended for human consumption.

The horse must have been declared as not intended for human consumption in accordance with the UK’s Horse Passport Legislation.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC. Do not freeze.

Crystallization of the product at low temperatures can be reversed by gentle warming.

Protect from light.

Keep out of the reach and sight of children.

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

12. SPECIAL WARNING(S)

Adequate drinking water should be available during the therapeutic effect of the product.

Operator Warning: Care must be taken to avoid accidental self-injection.

Avoid direct contact with skin and eyes. In the event of accidental spillage, wash affected area with copious amounts of water, seek medical advice if irritation persists.

Wash hands after use.

For animal treatment only

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

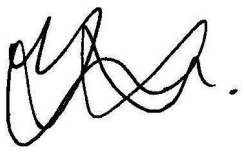
15. OTHER INFORMATION

Multidose vials of 100 ml.

POM-V

To be supplied only on veterinary prescription.

Vm 42058/4048



Approved: 26 August 2020