PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tribrissen 48% Suspension for Injection

Sulfadiazine and Trimethoprim Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 1 ml contains:

Trimethoprim 80 mg, Sulfadiazine 400 mg, Sodium metabisulphate 1 mg

3. PHARMACEUTICAL FORM

Suspension for Injection

4. PACKAGE SIZE

10 x 100 ml

5. TARGET SPECIES

Cattle, pigs and horses.

6. INDICATION(S)

An injectable broad spectrum antibacterial for the treatment of cattle, pigs and horses.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dose: 1 - 1.5 ml per 32 kg bodyweight.

For intramuscular injection only.

Read package leaflet before use.

Agitate gently before withdrawing each dose, avoiding excess frothing.

Do not administer by either the intravenous or intraperitoneal route.

8. WITHDRAWAL PERIOD

Withdrawal periods:

Cattle Meat: 34 days

Milk: 6.5 days (=156 hours)

Pigs Meat: 28 days

Not to be used in horses intended for human consumption.

For additional information on withdrawal periods see package leaflet.

9. SPECIAL WARNING(S), IF NECESSARY

Sulphonamides may occasionally cause severe allergic reaction.

Read package leaflet before use.

10. EXPIRY DATE

EXP end of:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

Protect from light.

Do not freeze.

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

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-V

To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder

Intervet UK Ltd.

Walton Manor, Walton

Milton Keynes, MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4593

17. MANUFACTURER'S BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON THE THE IMMEDIATE PACKAGE

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tribrissen 48% Suspension for Injection

Sulfadiazine and Trimethoprim Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 1 ml contains:

Trimethoprim 80 mg, Sulfadiazine 400 mg, Sodium metabisulphate 1 mg

3. PHARMACEUTICAL FORM

Suspension for Injection

4. PACKAGE SIZE

50 ml

100 ml

5. TARGET SPECIES

Cattle, pigs and horses.

6. INDICATION(S)

An injectable broad spectrum antibacterial for the treatment of cattle, pigs and horses.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dose: 1 - 1.5 ml per 32 kg bodyweight.

For intramuscular injection only.

Read package leaflet before use.

Agitate gently before withdrawing each dose, avoiding excess frothing.

Do not administer by either the intravenous or intraperitoneal route.

8. WITHDRAWAL PERIOD

Withdrawal periods:

Cattle Meat: 34 days

Milk: 6.5 days (=156 hours)

Pigs Meat: 28 days

Not to be used in horses intended for human consumption.

For additional information on withdrawal periods see package leaflet.

9. SPECIAL WARNING(S), IF NECESSARY

Sulphonamides may occasionally cause severe allergic reactions.

Read package leaflet before use.

10. EXPIRY DATE

EXP end of:

Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

Protect from light.

Do not freeze.

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

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-V

To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder

Intervet UK Ltd.

Walton Manor, Walton

Milton Keynes, MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4593

17. MANUFACTURER'S BATCH NUMBER

Batch:

PACKAGE LEAFLET FOR:

Tribrissen 48% Suspension for Injection

Sulfadiazine and Trimethoprim Injection

FOR ANIMAL TREATMENT ONLY

IMPORTANT: Read before use

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

MA holder:

Intervet UK Ltd.

Walton Manor

Walton

Milton Keynes, MK7 7AJ

Manufacturer responsible for batch release not stated on current mock-up.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tribrissen 48% Suspension for Injection

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

Presentation

The undisturbed product is a cream-coloured amorphous sediment in a clear, pale yellow to brown solution. On agitation, a cream-to-brown-coloured aqueous suspension for injection is formed.

Each 1.0ml contains:

Trimethoprim	80mg
Sulfadiazine	400mg
Sodium metabisulphate	1mg

4. INDICATION(S)

Uses

Principal action: The two active ingredients produce a sequential double blockade of bacterial synthesis of folinic acid, giving a level of activity many times greater than that obtained from either drug alone. The *in vitro* activity covers most common Gram-positive and Gram-negative bacteria including: *Actinobacillus* spp., *Actinomyces bovis, Bordetella* spp., *Corynebacterium and Arcanobacterium* spp., *Escherichia coli, Fusobacterium necrophorum, Haemophilus* spp., *Klebsiella* spp., *Listeria monocytogenes, Nocardia* spp., *Pasteurella* and *Mannhemia* spp., *Proteus* spp., *Salmonella* spp., *Staphylococcus* spp. and *Streptococcus* spp.

Indications: The injection may be used in the treatment of a wide range of diseases and conditions of bacterial origin in cattle, pigs, horses:

Respiratory infections of bacterial origin.

Urogenital tract infections.

Alimentary tract infections.

Other infections, such as foul-in-the-foot, severe mastitis, bacterial agalactia of sows, and infections of the eye, ear or mouth. It may also be used for antibacterial medication in surgical cases where infection is likely to be present, e.g. compound fractures where there is established peritonitis.

5. CONTRAINDICATIONS

See section 12.

6. ADVERSE REACTIONS

See section 12.

7. TARGET SPECIES

Cattle, pigs and horses.

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

Dosage and Administration

Dose: For cattle, pigs and horses the dose is 1ml per 32kg (70lb) bodyweight daily, i.e. equivalent to 15mg active ingredients/kg bodyweight. In cases of severe infection the dose may be increased to 1.5ml per 32kg (70lb) daily i.e. equivalent to 22.5mg active ingredients/kg bodyweight. A single injection may be sufficient in uncomplicated conditions such as wounds and post-operative infections, but in all severe or complicated infections the dose should be repeated daily for up to five days, or until two days after the symptoms resolve, up to a maximum of five consecutive days.

Administration: Agitate gently before withdrawing each dose, avoiding excessive frothing.

By intramuscular injection. It is recommended that in cattle and horses not more than 20ml, and in pigs not more than 10ml, be injected at any one site.

9. ADVICE ON CORRECT ADMINISTRATION

See section 8.

10. WITHDRAWAL PERIOD(S)

The following is included in the "Contraindications, warnings, etc" section of the mock-up

Withdrawal periods:

Not to be used in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under the national horse passport legislation.

Animals must not be slaughtered for human consumption during treatment. Pigs may only be slaughtered for human consumption after 28 days from the last treatment. Cattle may be slaughtered for human consumption only after 34 days from the last treatment.

Milk for human consumption must not be taken during treatment.

Milk for human consumption may be taken from animals only after 6.5 days (156 hours) from the last treatment.

11. SPECIAL STORAGE PRECAUTIONS

Pharmaceutical Precautions

Do not store above 25°C.

Protect from light.

Do not freeze.

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

When the container is broached (opened) for the first time, the date on which any product remaining in the container should be discarded should be calculated. A statement of the in-use shelf-life of the product is given on this package leaflet. This discard date should be written on the space provided on the label.

12. SPECIAL WARNING(S)

Contra-indications, Warnings, etc.

User Warnings:

Care should be taken to avoid accidental injection and contact with the skin.

Wash hands after use.

Sulphonamides may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to sulphonamides may lead to cross reactions with other antibiotics.

Allergic reactions to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitive to sulphonamides.

2. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning.

Interactions

Concurrent administration with sedatives or anaesthetics is contra-indicated in horses due to risk of cardiac arrhythmia.

Warnings: Do not administer by the intravenous or intraperitoneal route, as on rare occasions death has rapidly followed injection, especially by the intravenous route.

Very occasionally there may be a temporary local irritating swelling at the site of the injection.

Keep out of reach and sight of children.

For animal treatment only.

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

Disposal

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

Date of text preparation: February 2012

15. OTHER INFORMATION

Legal category

POM-V
To be supplied only on veterinary prescription

Package quantities: Amber glass bottle of 100ml

MA number: Vm 01708/4593

Distributor in Northern Ireland:

Intervet Ireland Ltd.

Magna Drive, Magna Business Park

Citywest Road

Dublin 24

Approved: 07/08/2017