PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan 200, 200 mg/ml Solution for Injection
Tylosin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Active substance:
Tylosin activity 200 mg

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

cattle and pigs.

6. INDICATION(S)

Not applicable for the outer package.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For administration by intramuscular Injection

Read the package leaflet before use

The maximum injection volume for cattle is limited to 15 ml per injection site.

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid under dosing.

8. WITHDRAWAL PERIOD(S)

Pigs:	Meat - 9 days
Cattle:	Meat - 28 days
	Milk - 108 hours.

9. SPECIAL WARNING(S), IF NECESSARY

Use different injection sites for repeat injections.

User Warnings
Wash hands after use.

Do not handle the product if you are allergic to ingredients in the product.

Accidental injection may induce irritation – read package leaflet before use. Care should be taken to avoid accidental self-injection. If accidental self-injection occurs, seek medical attention immediately.

10. EXPIRY DATE

Exp. {month/year}
Once broached, use by …….
Once broached/opened, use within 28 days Discard unused material.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

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

Any unused veterinary medicinal product or waste materials derived from such products should be disposed of in accordance with national requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only
To be supplied only on veterinary prescription.
POM-V

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Procured from within the EU and repackaged by the licence holder:
Kernfarm B.V., De Corridor 14D 3621 ZB
Breukelen, The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 43877/4004

17. MANUFACTURER'S BATCH NUMBER

Lot

PACKAGE LEAFLET FOR:

Tylan 200, 200 mg/ml Solution for Injection

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

Marketing Authorisation Holder:
Kernfarm B.V., De Corridor 14D, 3621 ZB Breukelen, The Netherlands

Manufacturer for batch release
Eli Lilly and Company Ltd., Speke Operations, Liverpool, United Kingdom.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylan 200, 200 mg/ml Solution for Injection

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

A clear yellow solution, each ml contains:

Active substance:
Tylosin activity 200 mg

Excipients:
Benzyl alcohol 40 mg

4. INDICATION(S)

Tylan 200 is indicated in all conditions associated with bacteria sensitive to tylosin which includes organisms in the following genera:

Streptococcus	Campylobacter	Chlamydia
Bacillus	Spirochaetes	
Staphylococcus	Mycoplasma	
Corynebacterium	Fusiformis	
Clostridium	Pasteurella	
Erysipelothrix		

Tylan 200 has been successfully used in respiratory and genitourinary tract infections, otitis, cellulitis and secondary bacterial conditions associated with virus disease or post operative infections.

Specific disease entities treated successfully with Tylan include swine dysentery, erysipelas and enzootic pneumonia in pigs, foul in the foot, mastitis and calf pneumonia in cattle.

5. CONTRAINDICATIONS

Tylan 200 should not be given to chickens or turkeys.
Do not administer to horses or other equines in which injection of tylosin may be fatal.

6. ADVERSE REACTIONS

Possible adverse reactions attributed to the product when used as recommended
and their frequency are: In very rare cases the following have been observed;
- swelling/inflammation at the site of injection,
- vulvular swelling in cattle,
- oedema of the rectal mucosa, partial anal protrusion (‘rosebudding’), erythema and pruritus in pigs.
- Anaphylactic shock and death.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

cattle and pigs.

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

Tylan should be given by intramuscular injection at the following dose rates:
Cattle and calves: 4 to 10 mg per kg bodyweight daily.
Pigs: 2 to 10 mg per kg bodyweight daily.

If there is no response to treatment in 3 days, diagnosis and treatment should be reassessed.

The maximum injection volume for cattle is limited to 15ml per injection site.
To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid under dosing.

9. ADVICE ON CORRECT ADMINISTRATION

For administration by the intramuscular route only.
Use different injection sites for repeat injections

10. WITHDRAWAL PERIOD(s)

Pigs: Meat - 9 days
Cattle: Meat - 28 days
Milk - 108 hours.

With cows milked twice daily, milk for human consumption may be taken only from 108 hours (i.e. at the 9th milking) after the last treatment. With other

dosing routines, the basis of the veterinary surgeons advice should be that milk may be taken for human consumption only after the same period from the last treatment (i.e. with three times a day milking, milk for human consumption may be taken only from 108 hours i.e. at the 14th milking).

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25°C.

Do not use after the expiry date which is stated on the label after “Exp.”
Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 28 days
Discard unused material.

12. SPECIAL WARNING(S)

Special warnings for each target species

None.

Special precautions for use

(i) Special precautions for use in animals
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information.
For administration by the intramuscular route only.
Use different injection sites for repeat injections.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals
Care should be taken to avoid accidental self-injection.

If accidental self-injection occurs, seek medical attention immediately.

In the event of accidental skin contact, wash thoroughly with soap and water. In case of accidental eye contact, flush the eyes with plenty of clean, running water.

Wash hands after use.

Tylosin may induce irritation. Macrolides, such as tylosin, may also cause hypersensitivity (allergy) following injection, inhalation, ingestion or contact with skin or eye. Hypersensitivity to tylosin may lead to cross reactions to other macrolides and vice versa. Allergic reactions to these substances may occasionally be serious and therefore direct contact should be avoided.

Do not handle the product if you are allergic to ingredients in the product.

If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the physician this warning. Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

(iii) Other precautions
Blemishes may occur at the site of injection and can persist for up to 21 days following administration.

Use during pregnancy, lactation or lay
No adverse effects to tylosin have been seen in fertility, multi-generation or teratology studies.

Interaction with other medicinal products and other forms of interaction
None observed.

Overdose (symptoms, emergency procedures, antidotes), if necessary
Pigs and calves: Intramuscular injection of 30 mg/kg bodyweight per day (three times maximum recommended dose) for five days produced no adverse effects.

The LD50 for subcutaneous injection of tylosin in mice is estimated to be >2500 mg/kg bodyweight.

Incompatibilities
This veterinary medicinal product must not be mixed with other veterinary medicinal products as this may cause precipitation of the active ingredient.

For Animal Treatment Only

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

Any unused veterinary medicinal product or waste materials derived from such products should be disposed of in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

……. 2016

15. OTHER INFORMATION

100 ml or 250 ml clear glass vials sealed with a white or grey chlorobutyl rubber bung with aluminium overseal. Each vial is packed into a carton.
Not all pack sizes may be marketed.

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

Adverse events should be reported to the MAPI holder. To report an adverse event, ring [UK telephone number]

Vm: 43877/4004

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Approved: 26/05/2016