

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARDBOARD BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hymatil 300 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: Tilmicosin 300 mg

3. PACKAGE SIZE

50 ml
100 ml
250 ml
6 x 50 ml
6 x 100 ml
6 x 250 ml
10 x 50 ml
10 x 100 ml
10 x 250 ml
12 x 50 ml
12 x 100 ml
12 x 250 ml

4. TARGET SPECIES

Cattle and sheep.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use only.

7. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:

Meat and offal: 70 days.

Milk: 36 days.

Sheep:

Meat and offal: 42 days.

Milk: 18 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.
Once opened, use by: ...

9. SPECIAL STORAGE PRECAUTIONS

Store below 25°C.
Keep the vial in the outer carton in order to protect from light.
Do not freeze.

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

“INJECTION OF TILMICOSIN IN HUMANS CAN BE FATAL – EXERCISE EXTREME CAUTION TO AVOID ACCIDENTAL SELF- INJECTION AND FOLLOW THE ADMINISTRATION INSTRUCTIONS PRECISELY.” Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Industrial Veterinaria, SA

14. MARKETING AUTHORISATION NUMBERS

Vm 36547/4000

15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {LABEL VIAL OF 50 ml}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hymatil

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Tilmicosin 300 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.

Once opened, use by: ...

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {NATURE/TYPE}
{LABEL VIAL OF 100 ml and 250 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hymatil 300 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: Tilmicosin 300 mg

3. TARGET SPECIES

Cattle and sheep.

4. ROUTES OF ADMINISTRATION

Subcutaneous use only.

"INJECTION OF TILMICOSIN IN HUMANS CAN BE FATAL – EXERCISE EXTREME CAUTION TO AVOID ACCIDENTAL SELF- INJECTION AND FOLLOW THE ADMINISTRATION INSTRUCTIONS PRECISELY."

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle:

Meat and offal: 70 days.

Milk: 36 days.

Sheep:

Meat and offal: 42 days.

Milk: 18 days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.

Once opened use by:...

7. SPECIAL STORAGE PRECAUTIONS

Store below 25°C.

Keep the vial in the outer carton in order to protect from light.

Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Industrial Veterinaria, SA

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Hymatil 300 mg/ml solution for injection for cattle and sheep

2. Composition

Each ml contains:

Active substance:

Tilmicosin 300 mg

Excipients:

Propylene glycol 250 mg

Clear, yellowish to brown-yellowish solution.

3. Target species

Cattle and sheep.

4. Indications for use

Cattle:

Treatment of bovine respiratory disease associated with *Mannheimia haemolytica* and *Pasteurella multocida*.

Treatment of interdigital necrobacillosis.

Sheep:

Treatment of respiratory tract infections caused by *Mannheimia haemolytica* and *Pasteurella multocida*.

Treatment of foot rot in sheep caused by *Dichelobacter nodosus* and *Fusobacterium necrophorum*.

Treatment of acute ovine mastitis caused by *Staphylococcus aureus* and *Mycoplasma agalactiae*.

5. Contraindications

Do not use intravenously.

Do not use intramuscularly.

Do not use in lambs weighing less than 15 kg.

Do not use in primates.

Do not use in pigs.

Do not use in horses and donkeys.

Do not use in goats.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:

Sheep

The clinical trials did not demonstrate a bacteriological cure in sheep with acute mastitis caused by *Staphylococcus aureus* and *Mycoplasma agalactiae*.

Do not administer to lambs weighing less than 15 kg since there is a risk of overdose toxicity.

Accurate weighing of lambs is important to avoid overdose. The use of a 2 ml or smaller syringe will facilitate accurate dosing.

Special precautions for safe use in the target species:

Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.

To avoid self-injection do not use automatic injection equipment.

Wherever possible, the use of the veterinary medicinal product should be based on susceptibility testing.

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

Operator Safety Warnings:

INJECTION OF TILMICOSIN IN HUMANS CAN BE FATAL – EXERCISE EXTREME CAUTION TO AVOID ACCIDENTAL SELF-INJECTION AND FOLLOW THE ADMINISTRATION INSTRUCTIONS AND THE GUIDANCE BELOW, PRECISELY

- This veterinary medicinal product should only be administered by a veterinary surgeon.
- Never carry a syringe loaded with Hymatil with the needle attached. The needle should be connected to the syringe only when filling the syringe or administering the injection. Keep the syringe and needle separate at all other times.
- Do not use automatic injection equipment.
- Ensure that animals are properly restrained, including those in the vicinity.
- Do not work alone when using Hymatil.
- In case of self-injection SEEK IMMEDIATE MEDICAL ATTENTION and take the vial or the package leaflet with you. Apply a cold pack (not ice directly) to the injection site.

Additional operator safety warnings:

- Avoid contact with skin and eyes. Rinse any splashes from skin or eyes immediately with water.
- May cause sensitisation by skin contact. Wash hands after use.

NOTE TO THE PHYSICIAN
INJECTION OF TILMICOSIN IN HUMANS HAS BEEN ASSOCIATED WITH FATALITIES.

The cardiovascular system is the target of toxicity, and this toxicity may be due to calcium channel blockade. Administration of intravenous calcium chloride should only be considered if there is positive confirmation of exposure to tilmicosin.

In dog studies, tilmicosin induced a negative inotropic effect with consequent tachycardia, and a reduction in systemic arterial blood pressure and arterial pulse pressure.

DO NOT GIVE ADRENALIN OR BETA-ADRENERGIC ANTAGONISTS SUCH AS PROPRANOLOL.

In pigs, tilmicosin-induced lethality is potentiated by adrenalin.

In dogs, treatment with intravenous calcium chloride showed a positive effect on the left ventricular inotropic state and some improvements in vascular blood pressure and tachycardia.

Pre-clinical data and an isolated clinical report suggest that calcium chloride infusion may help to reverse tilmicosin induced changes in blood pressure and heart rate in humans.

Administration of dobutamine should also be considered due to its positive inotropic effects although it does not influence tachycardia.

As tilmicosin persists in tissues for several days, the cardiovascular system should be closely monitored and supportive treatment provided.

Physicians treating patients exposed to this compound are advised to discuss clinical management with the National Poisons Information Service on: (indicate here the telephone number of the centre).

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Interactions between macrolides and ionophores could be observed in some species.

Overdose:

In cattle subcutaneous injections of 10, 30 and 50 mg/kg body weight, repeated three times with a 72 hours interval, did not cause death. As expected, oedema developed at the site of injection. The only lesion observed

at autopsy was a necrosis of the myocardium in the group treated with 50 mg/kg body weight.

Doses of 150 mg/kg body weight, administered subcutaneously with an interval of 72 hours caused death. Oedema at the site of injection was observed and at autopsy a light necrosis of the myocardium was the only lesion determined. Other symptoms observed were: difficulty in moving, reduced appetite and tachycardia.

In sheep single injections (approximately 30 mg/kg body weight) may cause a slight increase of the rate of respiration. Higher doses (150 mg/kg body weight) caused ataxia, lethargy and the inability to raise the head.

Deaths occurred after one single intravenous injection of 5 mg/kg body weight in cattle and 7.5 mg/kg body weight in sheep.

Special restrictions for use and special conditions for use:

For administration only by a veterinarian.

Major incompatibilities:

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

7. Adverse events

Cattle and sheep:

Rare (1 to 10 animals / 10,000 animals treated):	Recumbency Incoordination, convulsion
Undetermined frequency (cannot be estimated from the available data)	Injection site swelling ¹ Death ²

¹Soft and diffuse. Disappears within five to eight days.

²Deaths of cattle have been observed following a single intravenous dose of 5 mg/kg body weight, and following the subcutaneous injection of doses of 150 mg/kg body weight at 72 hour intervals. Sheep have died following a single intravenous injection of 7.5 mg/kg body weight.

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

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

Subcutaneous use only.

Use 10 mg tilmicosin per kg body weight (corresponding to 1 ml veterinary medicinal product per 30 kg body weight).

To ensure a correct dosage, body weight should be determined as accurately as possible.

Cattle:

Method of administration:

Withdraw the required dose from the vial and remove the syringe from the needle, leaving the needle in the vial. When a group of animals has to be treated, leave the needle in the vial to remove the subsequent doses. Restrain the animal and insert separate needle subcutaneously at the injection site, preferably in a skinfold over the rib cage behind the shoulder. Attach the syringe to the needle and inject into the base of the skinfold. Do not inject more than 20 ml per injection site.

Sheep:

Method of administration:

The use of a 2 ml syringe or smaller improves accurate dosing.

Withdraw the required dose from the vial and remove the syringe from the needle, leaving the needle in the vial. Restrain the sheep whilst leaning over the animal and insert a separate needle subcutaneously into the injection site, which should be in a skinfold over the rib cage behind the shoulder. Attach the syringe to the needle and inject into the base of the skin fold. Do not inject more than 2 ml per injection site.

9. Advice on correct administration

If no improvement is noted within 48 hours, the diagnosis should be confirmed.

Avoid introduction of contamination into vial during use. Do not use Hymatil if you notice any foreign particulate matter and/or abnormal physical appearance.

10. Withdrawal periods

Cattle:

Meat and offal: 70 days.

Milk: 36 days.

If the veterinary medicinal product is administered to cows during the dry period or to pregnant dairy heifers, milk should not be used for human consumption until 36 days after calving.

Sheep:

Meat and offal: 42 days.

Milk: 18 days.

If the veterinary medicinal product is administered to ewes during the dry period or to pregnant ewes, milk should not be used for human consumption until 18 days after lambing.

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 25°C.

Keep the vial in the outer carton in order to protect from light.

Do not freeze.

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: 28 days.

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

Vm 36547/4000

Package sizes:

Cardboard box containing 1 vial of 50 ml

Cardboard box containing 1 vial of 100 ml

Cardboard box containing 1 vial of 250 ml

Cardboard box containing 6, 10 or 12 vials of 50 ml

Cardboard box containing 6, 10 or 12 vials of 100 ml

Cardboard box containing 6, 10 or 12 vials of 250 ml

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:

Industrial Veterinaria, S.A.
Calle Esmeralda, 19
E-08950 Esplugues de Llobregat
Spain

Manufacturer responsible for batch release:

Industrial Veterinaria, S.A.
Esmeralda 19
08950 Esplugues de Llobregat (Barcelona) Spain

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell Germany

Local representatives and contact details to report suspected adverse reactions:

FORTE Healthcare Limited
Block 3, Unit 9
CityNorth Business Campus
Stamullen, Co. Meath. K32 D990
Republic of Ireland
IE: +353 1 841 7666
UK: +44 1292 800013

17. Other information

POM-V

 Veterinary medicinal product subject to prescription

Gavin Hall
Approved: 23 January 2025