tiamulin

Denagard

I NOVARTIS NUMAL HEALTH

The right choice

- Proven efficacy and activity against key poultry mycoplasmas *M. gallisepticum*, *M. synoviae* and *M. meleagridis*
- Remains active against potentially resistant isolates to other antimicrobials, such as tylosin, oxytetracycline and enrofloxacin¹
- Shows *in-vitro* activity against a number of other key poultry pathogens
- Compatible with chlortetracycline to control complicated Mycoplasma infections (CCRD)³
- Convenient dosage form for water medication
- Zero withdrawal period for eggs

Data Sheet Denagard® 12.5% Oral Solution

Contra-indications and warnings etc

Birds must not be slaughtered for human consumption during treatment. Chickens may be slaughtered for human consumption after 2 days from the last treatment and turkeys 5 days from the last ment. There is a nil withdrawal period required for eggs.

Birds should not receive products containing monensin, narasin or salinomycin during or for at least seven days before or after treatment with tiamulin. Severe growth depression or death may result. Concomitant use of tiamulin and the ionophore anticoccidial maduramicin may lead to a mild to moderate growth depression in chickens. The situation is transient and recovery normally occurs within 3-5 days following withdrawal of tiamulin treatment. This does not seem to occur with the ionophores lasalocid or semduramicin. In order to avoid interactions between tiamulin and the incompatible ionophore monensin, narasin and salinomycin, the feed mill supplying the birds feed should be notified that tiamulin will be used and that these products should not be included in the feed or contaminate the feed. The feed should be tested for the ionophores prior to use if there is any suspicion that contamination of the feed might occur. If an interaction does occur, stop tiamulin water medication immediately and replace with fresh water. Remove contaminated feed as soon as possible and replace with feed not containing the ionophores

Do not use in animals hypersensitive to the active ingredient

For use in the drinking water of chickens and turkeys only. Monitor water intake at frequent intervals during medication. Fresh solutions of tiamulin-medicated drinking water should be made up each day. Water

Reference

- 1. Burch and Valks (2002) Proceedings of the XII International Congress of the World Veterinary Poultry Association, Cairo, Egypt. p 322
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- 3. Burch & Stipkovits (1994) Proceedings 6th EAVPT Congress, Edinburgh, UK. p 202
- 4. Mazurkiewicz and others (1986) Proceedings of the VII European Poultry Conference, Paris, France. vol 2 pp 1162-1166 5. Stipkovits et al (1977) Poultry Science 56, 4, pp 1209-1215
- 6. Hannan et al (1997) Antimicrobial Agents and Chemotherapy 41, 9, pp 2037-2040
- 7. Takahata et al (1992) 19th World Poultry Congress, Amsterdam, Holland.
- 8. Aitken et al (1992) Research Report to Sandoz data on file
- 9. Drews et al (1975) Antimicrobial Agents and Chemotherapy 7, 5, pp 507-516
- 10. Takahashi et al (1990) Journal Japanese Veterinary Medical Association 43, pp 187-191
- 11. Vera-Lizarazo et al (2006) American Journal of Veterinary Research 67, 4, pp 663-668
- 12. Devriese et al (2001) Avian Pathology 30, pp 197-200
- 13. Jones (2006) Research Report to Novartis data on file
- 14. Yamamoto et al (2001) Journal of Veterinary Medicine Series B, 48, 2, pp 115-126
- 15. Stipkovits & Burch (1997) Proceedings 10th World Veterinary Poultry Association Congress, Budapest, Hungary. p 81

The right choice - see the difference Denagard makes to your poultry... and your profits.

For further information contact your veterinary surgeon or Pig & Poultry Division, Novartis Animal Health UK Ltd, New Cambridge House, Litlington, Near Royston, Hertfordshire SG8 OSS Tel: 01763 850500

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intake may be depressed during the administration of tiamulin to birds. It appears to be concentration dependent with 0.025% (250ppm)

tiamulin reducing intake by approximately 15%. It does not appear to

have any adverse effect on overall performance of the birds or efficacy of the product. If there is no response to treatment within 5 days the

Tiamulin may be used in laying and breeding birds as it has been

shown to have no adverse effects on egg production, fertility and

wearing impermeable rubber gloves and safety glasses. In case of

Do not store above 25°C. Fresh medicated water must be prepared

every 24 hours. Watering equipment should be thoroughly cleaned prior

to addition of Denagard® 12.5% Oral Solution. Disposal: Dispose of any unused product and empty containers in accordance with guidance

should be washed off immediately. Wash hands after use

When mixing, direct contact with skin and eyes should be avoided by

accidental eye contact, irrigate the eyes thoroughly with clean running water immediately. Seek medical advice if irritation persists.

Contaminated clothing should be removed and any splashes on the skin

diagnosis should be re-established.

hatchability in chickens and turkeys.

FOR ANIMAL TREATMENT ONLY.

Pharmaceutical precautions

KEEP OUT OF THE REACH OF CHILDREN.

from your local waste regulation authority.

See the difference in your birds... and the improvement in your profits



- Also active against Brachyspira species, which cause Avian Intestinal Spirochaetosis², and shows *in-vitro* activity against a number of other key poultry pathogens
- Compatible with chlortetracycline to control complicated Mycoplasma infections (CCRD)³
- Increased egg production⁴
- Convenient dosage form for water medication
- Zero withdrawal period for eggs



12.5%OralSol





Proven efficacy against M. gallisepticum, M. synoviae, M. meleagridis

Active against chlortetracycline and tylosin resistant strains¹



The right choice Tiamutin® will be marketed as Denagard® through 2007 due to the globalisation of the Novartis® tiamulin brand.

Denagard® tiamulin

The right choice – for *Mycoplasmal* infections in poultry

Producing healthy, productive poultry is now more challenging than ever so poultry farmers need a product they can trust, one that has proven efficacy against *M. gallisepticum*, *M. synoviae* and *M. meleagridis* and works fast, even against chlortetracycline and tylosin resistant strains¹. Denagard 12.5% Oral Solution from Novartis can help deliver maximum performance since it offers increased growth rates and FCE in broilers and turkeys*5 and increased egg production in layers⁴ together with a zero withdrawal period for eggs.

*Incompatible with the ionophore anticoccidials monesin, salinomycin and narasin.

Denagard has been proven to be highly effective against key poultry *Mycoplasmas*

Tylosin

Oxytetracycline

Enrofloxacin

Mild air saco

caused by MG (CRD)

Colisept

(CCRD)

Mycoplasma meleagridis⁷

<i>Mycoplasma gallisepticum</i> ^₅ 20 isolates				
	MIC ₅₀ (µg/ml)	MIC₉₀ (µg/ml)	Range (µg/ml)	
Denagard	0.001	0.025	0.0005-0.25	
Tylosin	0.01	2.5 ^r	0.0025-10 ^r	
Oxytetracycline	0.25	0.5	0.05-0.5	
Enrofloxacin	0.05	0.1	0.025-1.0	

Mycoplasma synoviae [®] 28 isolates					
	MIC ₅₀ (µg/ml)	MIC₉₀ (µg/ml)	Range (µg/ml)		
Denagard	0.1	0.25	0.05-0.5		
Tylosin	0.025	50 ^r	0.0025-50 ^r		
Oxytetracycline	0.1	100 ^r	0.025->100 ^r		
Enrofloxacin	0.25	0.5	0.05-0.5		

MIC = Minimum inhibitory concentration ^r = Potentially resistant isolates

Denagard also shows in-vitro activity against...

Organisms showing <i>in-vitro</i> susceptibility to Denagard						
Organism	No of isolates	MIC ₅₀ µg/ml	MIC90 µg/ml	Range µg/ml		
Brachyspira pilosicoli ²	17	<0.1	<1.0	<0.1-<1.0		
Brachyspira intermedia ²	25	<1.0	<4.0	<0.1-<4.0		
Campylobacter spp ⁸	10	0.5	2.0	0.5-4.0		
Staphylococcus aureus ⁹	9	0.039	0.078	0.0125-0.078		
Haemophilus paragallinarum ¹⁰	24	3.13	6.25	0.78-6.25		
Pasteurella multocida ¹¹	132	16	32	<2.0->32		
Ornithobacterium rhinotracheale ¹²	45	≤0.12	0.25	≤0.12-0.25		
Clostridium perfringens ¹³	20	1	8	0.25-8.0		
Erysipelothrix rhusiopathiae ¹⁴	214	3.13	6.25	0.2-6.25		

Estimated clinical breakpoints: Respiratory/Systemic infections: ≤1.0 µg/ml; Enteric infections: ≤4.0 µg/ml

Denagard is also compatible with recommended doses of chlortetracycline and combined use has been shown to enhance the activity of both medicines against CRD and mixed respiratory infections following a M. gallisepticum challenge³.

Reduces air sac lesions caused by Mycoplasma...

In an artificial infection study with *M. gallisepticum*¹⁵, Denagard at 250ppm was given in the drinking water for 3 days at the time of infection and markedly reduced the level of airsacculitis in comparison with untreated controls and birds medicated with commonly used antimicrobials.



11 isolates

0.025-3.13^r 0.025-6.25^r

0.39-100^r

0.1-3.13^r

MIC₅₀ (μg/ml) MIC₉₀ (μg/ml) Range (μg/ml)

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...and reduces the recovery of Mycoplasma and possible further challenge

The percentage of re-isolation of *M. gallisepticum* from the air sac lesions was also greatly reduced in the Denagard 250ppm group.

Denagard 12.5% Oral solution – a convenient dosage form for water medication (does not contain lactose)

The dosage for chickens and turkeys is 25 mg tiamulin/kg bodyweight or 100mls of Denagard 12.5% Oral Solution for 500 kgs of bird. Denagard should be administered continuously in the drinking water at a level of 0.025% (250ppm) for 3-5 days to chickens and 5 days to turkeys.







evel provides approximately the following dosage of tiamulin				
oird	Chickens (dose mg/kg)	Turkeys (dose mg/kg)		
	125-150	-		
	-	70		
	30-50	50		
	-	25-30		
S	30-45	-		
S	-	25		
reeder	25	-		

