

## EU approves new ileitis, colitis claims for Econor® medicated premix for swine

BASEL, Switzerland, 13 May 2004 — The European Commission has approved two new swine enteric disease claims for Econor® (valnemulin) medicated premix, the next-generation pleuromutilin antimicrobial developed specifically for use in food animals.

The expanded label permits using Econor for treating ileitis (*Lawsonia intracellularis*) and preventing spirochaetal colitis (*Brachyspira pilosicoli*) in growing and finishing pigs. The product was already approved for preventing and treating swine dysentery (*Brachyspira hyodysenteriae*), in addition to enzootic pneumonia (*Mycoplasma hyopneumoniae*)

“In many major pig-producing countries, ileitis is believed to be a problem in 90 percent of the herds,” says Lucas Heinis, International Brand Manager for Econor, Novartis Animal Health Inc., the company that developed and markets the product. “The prevalence of colitis, on the other hand, is greatly underestimated because it is difficult to diagnose. Colitis can therefore remain undetected, and research shows it can quietly result in production losses of more than 10 percent.”

In several studies, Econor demonstrated superior efficacy against ileitis, colitis and swine dysentery, compared to tylosin and lincomycin. In the pig production units this resulted in improved weight gains and feed conversion rates, and ultimately in a higher profitability.

The effect of Econor does not end with the treatment period, however. Studies show that the high level of efficacy of Econor actually helps to delay re-establishment of enteric diseases after the medication has been discontinued, which in turn has a positive effect on performance.

For example, in a study with a naturally occurring ileitis challenge, a single treatment of Econor for 21 days post-weaning effectively controlled ileitis during and beyond the medication period while significantly reducing clinical signs of the disease. Pigs treated with Econor also demonstrated statistically better feed conversion and average daily gain during the post-medication period.

“With some premix products, continuous medication is required and there is a pronounced drop-off once it is discontinued,” says Ulrich Klein, a Technical Services Veterinarian with Novartis Animal Health. “In contrast, treatment with Econor controls enteric diseases effectively during and post medication.”

Econor is unique in that it was developed specifically for use in food animals. “This is a tremendous benefit in light of the voiced concern for cross-resistance and transfer of resistant bacteria to humans. It therefore helps to pork producers reach their ultimate goal — delivering a healthy, high quality product to consumers,” Heinis says.

For more information about Econor, go to [www.Econor.com](http://www.Econor.com) or contact Novartis Animal Health Inc., Basel, Switzerland:

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Novartis Animal Health researches, develops and commercialises leading animal treatments that meet the needs of pet owners, farmers and veterinarians. Headquartered in Basel, Switzerland and present in almost 40 countries, Novartis Animal Health employs approximately 2200 associates worldwide and achieved sales of USD 682 million in 2003. For more information, please consult [www.ah.novartis.com](http://www.ah.novartis.com).

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2003, the Group's businesses achieved sales of USD 24.9 billion and a net income of USD 5.0 billion. The Group invested approximately US 3.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 78,500 people and operate in over 140 countries around the world. For further information, please consult <http://www.novartis.com>.

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**Note to Editors:** Please see sidebar next page.

## **Econor Product Information**

Econor is a semi-synthetic antimicrobial that interferes with bacterial protein synthesis at the ribosomal level. Its active ingredient, valnemulin, is a next-generation pleuromutilin antimicrobial, which inhibits the creation of peptide chains by preventing the addition of amino acids needed for protein production. Without these basic building blocks, the target organisms are unable to grow and reproduce.

Econor is available in 50%, 10% and 1% formulations for optimum flexibility. The product is rapidly absorbed, reaching peak systemic levels in 1 to 4 hours. Econor's 1-day withdrawal period also allows pig farmers to be flexible with pig flow and marketing.

Novartis Animal Health recommends using Econor at 3-4 mg/kg bodyweight per day for 14-28 days for treating ileitis and 7-28 days for treating swine dysentery. In prevention programs for spirochaetal colitis and swine dysentery, Econor should be administered at 1.0-1.5 mg/kg for 7-28 days.

## **EMEA Renewed Econor License**

The European Agency for the Evaluation of Medicinal Products (EMA) recently renewed the marketing authorization for Econor for 5 years.

"The Committee concluded that the quality, safety and efficacy of the product continued to be appropriately demonstrated..." the agency said in a statement following its meeting, January 2004. "From the beginning, Econor has met the high standards established by the European Commission, which is now reconfirmed" says Lucas Heinis, International Brand Manager for Econor.

Introduced to Europe in 1999, Econor became the first antimicrobial feed premix for swine to be approved through the centralized registration procedure established by the European Commission. The commission then reviews centrally licensed products after five years for quality, safety and efficacy.

Unlike tylosin, timlicosin and lincomycin, pleuromutilins such as Econor are not used in human medicine and are not associated with resistance in organisms significant to public health. Furthermore, pleuromutilins do not share patterns of cross-resistance with human-use antimicrobials.