

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Econor 1% premix for medicated feed for pigs

**2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES**

Valnemulin 10.0 mg/g

**3. PHARMACEUTICAL FORM**

Premix for medicated feed

**4. PACKAGE SIZE**

1 kg  
2.5 kg  
25 kg

**5. TARGET SPECIES**

Pigs

**6. INDICATION(S)**

The treatment and prevention of swine dysentery.  
The treatment of clinical signs of porcine proliferative enteropathy (ileitis).  
The prevention of clinical signs of porcine colonic spirochaetosis (colitis) when the disease has been diagnosed in the herd.

**7. METHOD AND ROUTE OF ADMINISTRATION**

In-feed use

**Mixing Instructions:**

Read the package insert before use

**8. WITHDRAWAL PERIOD**

Withdrawal period: 1 day

## **9. SPECIAL WARNINGS:**

Do not administer the product to pigs receiving ionophores.

Whilst studies in rats and mice have not produced any evidence of teratogenic effect, the safety during pregnancy and lactation has not been established in pigs.

When mixing the product and handling the final feed containing the product, direct contact with the skin and mucous membranes should be avoided. In case of accidental ingestion, seek medical advice immediately and show the product label. People with known hypersensitivity to valnemulin should administer the product with caution.

Adverse drug reactions have occurred following the use of Econor. Extreme care should therefore be taken in the use of Econor in pigs of Scandinavian origin especially of the Danish and Swedish Landrace breeds, and their crossbreeds thereof.

See package insert for further information.

## **10. EXPIRY DATE**

*{month/year}*

## **11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C.

Store the product in the original container within the outer carton and protected from light and moisture. < *Polyethylene bag packed in cardboard carton* >

Store product in the original container. < *aluminium lined plastic bag* >

Part-used containers should be tightly closed following dispensing.

### Shelf life:

Shelf-life when incorporated into meal feed and protected from light and moisture: 3 months.

Shelf-life when incorporated into pelleted feed and protected from light and moisture: 3 weeks

## **12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS , IF ANY**

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

## **13. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

## **14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”**

Keep out of the reach and sight of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE IN THE EEA, IF DIFFERENT**

**Marketing Authorisation holder:**

Novartis Animal Health Austria GmbH  
Biochemiestraße 10  
A-6250 Kundl  
Austria

**Manufacturer:**

Novartis Santé Animale S.A.  
Usine de Huningue  
26, rue de la Chapelle  
BP 224  
68332 Huningue cedex  
France

**16. NUMBER IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS**

EU/2/98/010/001 (1 kg, polyethylene bag packed in cardboard carton)  
EU/2/98/010/002 (2.5 kg, polyethylene bag packed in cardboard carton)  
EU/2/98/010/003 (25 kg, polyethylene bag packed in cardboard carton)  
EU/2/98/010/004 (1 kg, aluminium lined plastic bag)  
EU/2/98/010/005 (2.5 kg, aluminium lined plastic bag)  
EU/2/98/010/006 (25 kg, aluminium lined plastic bag)

**17. MANUFACTURER'S BATCH NUMBER**

*[leave blank]*

**18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

Veterinary medicinal product subject to prescription.  
Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Econor 10% premix for medicated feed for pigs

**2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES**

Valnemulin 100 mg/g

**3. PHARMACEUTICAL FORM**

Premix for medicated feed

**4. PACKAGE SIZE**

1 kg  
25 kg

**5. TARGET SPECIES**

Pigs

**6. INDICATION(S)**

The treatment and prevention of swine dysentery.

The treatment of clinical signs of porcine proliferative enteropathy (ileitis).

The prevention of clinical signs of porcine colonic spirochaetosis (colitis) when the disease has been diagnosed in the herd.

Treatment and prevention of swine enzootic pneumonia. At the recommended dosage of 10 – 12 mg/kg bodyweight, lung lesions and weight loss are reduced, but infection with *Mycoplasma hyopneumoniae* is not eliminated.

**7. METHOD AND ROUTE OF ADMINISTRATION**

In-feed use

**Mixing Instructions:**

Read the package insert before use

**8. WITHDRAWAL PERIOD**

Withdrawal period: 1 day



## **9. SPECIAL WARNING(S):**

Do not administer the product to pigs receiving ionophores.

Whilst studies in rats and mice have not produced any evidence of teratogenic effect, the safety during pregnancy and lactation has not been established in pigs.

When mixing the product and handling the final feed containing the product, direct contact with the skin and mucous membranes should be avoided. In case of accidental ingestion, seek medical advice immediately and show the product label. People with known hypersensitivity to valnemulin should administer the product with caution.

Adverse drug reactions have occurred following the use of Econor. Extreme care should therefore be taken in the use of Econor in pigs of Scandinavian origin especially of the Danish and Swedish Landrace breeds, and their crossbreeds thereof.

See package insert for further information.

## **10. EXPIRY DATE**

*{month/year}*

## **11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C.

Store the product in the original container within the outer carton and protected from light and moisture. < Polyethylene bag packed in cardboard carton >

Store product in the original container. < Aluminium lined plastic bag >

Part-used containers should be tightly closed following dispensing.

### Shelf life:

Shelf-life when incorporated into meal feed and protected from light and moisture: 3 months.

Shelf-life when incorporated into pelleted feed and protected from light and moisture: 3 weeks

## **12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS , IF ANY**

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

## **13. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

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

Keep out of the reach and sight of children.

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A-6250 Kundl  
Austria

**Manufacturer:**

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Usine de Huningue  
26, rue de la Chapelle  
BP 224  
68332 Huningue cedex  
France

**16. NUMBER IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS**

EU/2/98/010/015 (1 kg, Polyethylene bag packed in cardboard carton)  
EU/2/98/010/016 (25 kg, Polyethylene bag packed in cardboard carton)  
EU/2/98/010/017 (1 kg, Aluminium lined plastic bag)  
EU/2/98/010/018 (25 kg, Aluminium lined plastic bag)

**17. MANUFACTURER'S BATCH NUMBER**

*[leave blank]*

**18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

Veterinary medicinal product subject to prescription.  
Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Econor 50% premix for medicated feed for pigs

**2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES**

Valnemulin                      500 mg/g

**3. PHARMACEUTICAL FORM**

Premix for medicated feed

**4. PACKAGE SIZE**

1 kg  
25 kg

**5. TARGET SPECIES**

Pigs

**6. INDICATION(S)**

The treatment and prevention of swine dysentery.

The treatment of clinical signs of porcine proliferative enteropathy (ileitis).

The prevention of clinical signs of porcine colonic spirochaetosis (colitis) when the disease has been diagnosed in the herd.

Treatment and prevention of swine enzootic pneumonia. At the recommended dosage of 10 - 12 mg/kg bodyweight lung lesions and weight loss are reduced, but infection with *Mycoplasma hyopneumoniae* is not eliminated.

**7. METHOD AND ROUTE OF ADMINISTRATION**

In-feed use.

**Mixing Instructions:**

Read the package insert before use

**8. WITHDRAWAL PERIOD**

Withdrawal period: 1 day

## **9. SPECIAL WARNING(S):**

Do not administer the product to pigs receiving ionophores.

Whilst studies in rats and mice have not produced any evidence of teratogenic effect, the safety during pregnancy and lactation has not been established in pigs.

When mixing the product and handling the final feed containing the product, direct contact with the skin and mucous membranes should be avoided. In case of accidental ingestion, seek medical advice immediately and show the product label. People with known hypersensitivity to valnemulin should administer the product with caution.

Adverse drug reactions have occurred following the use of Econor. Extreme care should therefore be taken in the use of Econor in pigs of Scandinavian origin especially of the Danish and Swedish Landrace breeds, and their crossbreeds thereof.

See package insert for further information.

## **10. EXPIRY DATE**

*{month/year}*

## **11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C.

Store the product in the original container within the outer carton and protected from light and moisture. <Polyethylene bag packed in cardboard carton>

Store product in the original container. <Aluminium lined plastic bags>

Part-used containers should be tightly closed following dispensing.

### Shelf life:

Shelf-life when incorporated into meal feed and protected from light and moisture: 3 months.

Shelf-life when incorporated into pelleted feed and protected from light and moisture: 3 weeks

## **12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS , IF ANY**

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Novartis Animal Health Austria GmbH  
Biochemiestraße 10  
A-6250 Kundl  
Austria

**Manufacturer:**

Sandoz GmbH  
Schaftenau Plant  
A-6336 Langkampfen  
Austria

**16. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS**

EU/2/98/010/019 (1 kg, Polyethylene bag packed in cardboard carton)  
EU/2/98/010/020 (25 kg, Polyethylene bag packed in cardboard carton)  
EU/2/98/010/021 (1 kg, Aluminium lined plastic bags)  
EU/2/98/010/022 (25 kg, Aluminium lined plastic bag)

**17. MANUFACTURER'S BATCH NUMBER**

*[leave blank]*

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Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Econor 0.5% premix for medicated feed for pigs

**2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES**

Valnemulin                      5 mg/g

**3. PHARMACEUTICAL FORM**

Premix for medicated feed

**4. PACKAGE SIZE**

5 kg  
25 kg

**5. TARGET SPECIES**

Pigs

**6. INDICATION(S)**

For the treatment and prevention of swine dysentery.  
The treatment of clinical signs of porcine proliferative enteropathy (ileitis).  
The prevention of clinical signs of porcine colonic spirochaetosis (colitis) when the disease has been diagnosed in the herd.

**7. METHOD AND ROUTE OF ADMINISTRATION**

In-feed use

**Mixing Instructions:**

Read the package insert before use

**8. WITHDRAWAL PERIOD**

Withdrawal period: 1 day

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Adverse drug reactions have occurred following the use of Econor. Extreme care should therefore be taken in the use of Econor in pigs of Scandinavian origin especially of the Danish and Swedish Landrace breeds, and their crossbreeds thereof.

See package insert for further information.

## **10. EXPIRY DATE**

*{month/year}*

## **11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C.

Store product in the original container.

Part-used containers should be tightly closed following dispensing.

### Shelf life:

Shelf-life when incorporated into meal feed and protected from light and moisture: 3 months.

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**Manufacturer:**

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Usine de Huningue  
26, rue de la Chapelle  
BP 224  
68332 Huningue cedex  
France

**16. NUMBER IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS**

EU/2/98/010/023 (5kg)  
EU/2/98/010/024 (25 kg)

**17. MANUFACTURER'S BATCH NUMBER**

*[leave blank]*

**18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

Veterinary medicinal product subject to prescription.  
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