

PACKAGE INSERTS

PACKAGE INSERT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Econor 1% premix for medicated feed for pigs

2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES

Econor 1% premix contains valnemulin in the form of valnemulin hydrochloride.

Valnemulin hydrochloride	10.65 mg/g
equivalent to valnemulin base	10.0 mg/g

List of excipients:

Hypromellose and talc
Colloidal anhydrous silica
Isopropyl myristate
Lactose

3. 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

4. TARGET SPECIES

Pigs

5. 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.

6. DOSAGE, METHOD AND ROUTE OF ADMINISTRATION

In-feed use

The uptake of medicated feed depends on the clinical condition of the animal. In order to obtain the correct dosage the concentration of Econor has to be adjusted. Inclusion levels may also need to be increased in older pigs or pigs on restricted feed to achieve target dosage.

Indication	Dosage (mg active substance/kg)	Application period of medicated feed as the sole daily ration	Application in feed
<u>Treatment of</u> <ul style="list-style-type: none"> ▪ Swine Dysentery 	3-4 mg/kg bodyweight/day	Minimum of 7 days and up to 4 weeks or until signs of disease disappear	Incorporation of 75 mg active substance per kg feed with: Econor 1% - 7.5 g/kg feed

This dose level is effective in the treatment of clinical disease, but higher dosages or longer duration of treatment may be necessary for complete elimination of infection. It is important to institute medication as early as possible in an outbreak of swine dysentery. If there is no response to treatment within 5 days, the diagnosis should be re-established.

Indication	Dosage (mg active substance/kg)	Application period of medicated feed as the sole daily ration	Application in feed
<u>Treatment of clinical signs</u> <ul style="list-style-type: none"> ▪ Porcine Proliferative Enteropathy (ileitis) 	3-4 mg/kg bodyweight/day	2 weeks or until signs of disease disappear	Incorporation of 75 mg active substance per kg feed with: Econor 1% - 7.5 g/kg feed

This dose level is effective under normal situation in the treatment of clinical signs of disease, but higher dosages or longer duration of treatment may be necessary for complete elimination of infection. It is important to institute medication as early as possible in an outbreak of porcine proliferative enteropathy. If there is no response to treatment within 5 days, the diagnosis should be re-established. For severely affected animals which fail to respond to treatment within 3-5 days, parenteral treatment should be considered.

Indication	Dosage (mg active substance/kg)	Application period of medicated feed as the sole daily ration	Application in feed
<u>Prevention of</u> <ul style="list-style-type: none"> ▪ Swine Dysentery ▪ Clinical signs of Porcine Colonic Spirochaetosis (colitis) 	1.0 – 1.5 mg/kg bodyweight/day	minimum of 7 days and up to 4 weeks 4 weeks	Incorporation of 25 mg active substance per kg feed with: Econor 1% - 2.5 g/kg feed

Long term preventative use of valnemulin should be avoided by improving management practice and thorough cleansing and disinfection. Consideration should be given to the eradication of infection from the farm.

7. ADVICE ON CORRECT ADMINISTRATION:

Mixing Instructions:

$\text{mg Econor 1\% premix/kg feed} = \text{Dosage required (mg/kg)} \times 100 \times \text{bodyweight (kg)/Daily feed intake (kg)}$

The product has been shown to be stable to the pelleting process at temperatures of 75°C. Aggressive pelleting conditions such as temperatures in excess of 80°C, and the use of abrasive substances for pre-mixture should be avoided.

To achieve good mixture and homogeneity of incorporation, especially when product is incorporated at a rate less than 5 kg/tonne feed, the use of a pre-mixture is recommended. The required quantity of product is thoroughly mixed with a feed ingredient of similar physical nature (e.g. wheat middlings) in the proportion: 1 part Econor 1% premix to 10 parts feed ingredient.

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

8. CONTRAINDICATIONS:

Do not administer the product to pigs receiving ionophores.
Valnemulin should not be administered to rabbits because of its toxicity in this species.

9. UNDESIRABLE EFFECTS:

Medication of pigs with Econor has led to the occurrence of adverse reactions in the European Union. Of the cases reported in 1999-2000, the majority occurred in Denmark and Sweden (one case each in Finland and Ireland). In these countries, the incidence ranged from 0.03 to 1.76% of all pigs treated.

On affected farms, one third of the pigs treated were affected, with a mortality of 1%. Affected pigs are pyrexia, exhibit inappetence, and in severe cases become incoordinated, ataxic and may become recumbent. A percentage of such pigs may also suffer oedema or erythema (posterior in distribution), and palpebral oedema. The reaction has been studied in controlled trials in susceptible animals. Mortality was less than 1% but might be increased as a result of secondary infections.

In the case of an adverse reaction, immediate withdrawal of medication is recommended. Severely affected pigs should be removed to clean dry pens and given symptomatic treatment, including treatment for concurrent disease.

An epidemiological survey has indicated that there is likely to be an association between the susceptibility to adverse reactions and the Danish and Swedish Landrace breeds, and their crossbreeds thereof, especially younger pigs.

Valnemulin is well-accepted in feed, but administered at concentrations above 200 mg/kg feed may result in transient reduction in food consumption associated with unpalatability during the first few days of feeding.

If you notice any other side effects, please inform your veterinary surgeon.

10. WITHDRAWAL PERIOD

1 day

11. SPECIAL STORAGE CONDITIONS

Keep out of the reach and sight of children.

Do not store above 25°C.

For aluminium-lined bags, store product in the original container.

For polyethylene bags, store the product in the original container within the outer carton and protected from light and moisture.

Part-used containers should be tightly closed following dispensing.

Shelf life:

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

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 WARNINGS:

Valnemulin has been shown to interact with ionophores such as monensin, salinomycin and narasin and may result in signs indistinguishable from an ionophore toxicosis. Animals should not receive products containing monensin, salinomycin or narasin, during or at least 5 days before or after treatment with valnemulin. Severe growth depression, ataxia, paralysis or death may result.

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. Their occurrence may be principally restricted to the Scandinavian countries and appears to be mainly associated with breed mixes that include Danish and/or Swedish Landrace. 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.

13. 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.

14. OTHER INFORMATION

Valnemulin is an antibiotic belonging to the pleuromutilin group, which act by the inhibition of the initiation of protein synthesis at the level of the bacterial ribosome.

15. DATE ON WHICH THE TEXT WAS LAST REVISED

March 2004

PACKAGE INSERT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Econor 10% premix for medicated feed for pigs

2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES

Econor 10% premix contains valnemulin in the form of valnemulin hydrochloride.

Valnemulin hydrochloride	106.5 mg/g
equivalent to valnemulin base	100 mg/g

List of excipients:

Hypromellose and talc
Colloidal anhydrous silica
Isopropyl myristate
Lactose

3. 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

4. TARGET SPECIES

Pigs

5. 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.

6. DOSAGE, METHOD AND ROUTE(S) OF ADMINISTRATION

In-feed use

The uptake of medicated feed depends on the clinical condition of the animal. In order to obtain the correct dosage the concentration of Econor has to be adjusted. Inclusion levels may also need to be increased in older pigs or pigs on restricted feed to achieve target dosage.

Indication	Dosage (mg active substance/kg)	Application period of medicated feed as the sole daily ration	Application in feed
<u>Treatment of</u> <ul style="list-style-type: none"> ▪ Swine Dysentery 	3-4 mg/kg bodyweight/day	Minimum of 7 days and up to 4 weeks or until signs of disease disappear	Incorporation of 75 mg active substance per kg feed with: Econor 10% - 750 mg/kg feed

This dose level is effective in the treatment of clinical disease, but higher dosages or longer duration of treatment may be necessary for complete elimination of infection. It is important to institute medication as early as possible in an outbreak of swine dysentery. If there is no response to treatment within 5 days, the diagnosis should be re-established.

Indication	Dosage (mg active substance/kg)	Application period of medicated feed as the sole daily ration	Application in feed
<u>Treatment of clinical signs</u> <ul style="list-style-type: none"> ▪ Porcine Proliferative Enteropathy (ileitis) 	3-4 mg/kg bodyweight/day	2 weeks or until signs of disease disappear	Incorporation of 75 mg active substance per kg feed with: Econor 10% - 750 mg/kg feed

This dose level is effective under normal situation in the treatment of clinical signs of disease, but higher dosages or longer duration of treatment may be necessary for complete elimination of infection. It is important to institute medication as early as possible in an outbreak of porcine proliferative enteropathy. If there is no response to treatment within 5 days, the diagnosis should be re-established. For severely affected animals which fail to respond to treatment within 3-5 days, parenteral treatment should be considered.

Indication	Dosage (mg active substance/kg)	Application period of medicated feed as the sole daily ration	Application in feed
<u>Prevention of</u> <ul style="list-style-type: none"> ▪ Swine Dysentery ▪ Clinical signs of Porcine Colonic Spirochaetosis (colitis) 	1.0 – 1.5 mg/kg bodyweight/day	minimum of 7 days and up to 4 weeks 4 weeks	Incorporation of 25 mg active substance per kg feed with: Econor 10% - 250 mg/kg feed

Long term preventative use of valnemulin should be avoided by improving management practice and thorough cleansing and disinfection. Consideration should be given to the eradication of infection from the farm.

Indication	Dosage (mg active substance/kg)	Application period of medicated feed as the sole daily ration	Application in feed
<u>Treatment & Prevention of</u> <ul style="list-style-type: none"> ▪ Swine Enzootic Pneumonia 	10 – 12 mg/kg bodyweight/day	Up to 3 weeks	Incorporation of 200 mg active substance per kg feed with : Econor 10% - 2 g/kg feed

Secondary infection by organisms such as *Pasteurella multocida* and *Actinobacillus pleuropneumoniae* may complicate enzootic pneumonia and require specific medication.

7. ADVICE ON CORRECT ADMINISTRATION:

Mixing Instructions:

mg Econor 10% premix/kg feed = Dosage required (mg/kg) x 10 x bodyweight (kg)/Daily feed intake (kg)

The product has been shown to be stable to the pelleting process at temperatures of 75°C. Aggressive pelleting conditions such as temperatures in excess of 80°C, and the use of abrasive substances for pre-mixture should be avoided.

To achieve good mixture and homogeneity of incorporation, the use of a pre-mixture is recommended. The required quantity of product is thoroughly mixed with a feed ingredient of similar physical nature (e.g. wheat middlings) in the proportion: 1 part Econor 10% premix to 10 parts feed ingredient.

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

8. CONTRAINDICATIONS:

Do not administer the product to pigs receiving ionophores.
Valnemulin should not be administered to rabbits because of its toxicity in this species.

9. UNDESIRABLE EFFECTS:

Medication of pigs with Econor has led to the occurrence of adverse reactions in the European Union. Of the cases reported in 1999-2000, the majority occurred in Denmark and Sweden (one case each in Finland and Ireland). In these countries, the incidence ranged from 0.03 to 1.76% of all pigs treated. On affected farms, one third of the pigs treated were affected, with a mortality of 1%. Affected pigs are pyrexic, exhibit inappetence, and in severe cases become incoordinated, ataxic and may become recumbent. A percentage of such pigs may also suffer oedema or erythema (posterior in distribution), and palpebral oedema. The reaction has been studied in controlled trials in susceptible animals. Mortality was less than 1% but might be increased as a result of secondary infections.

In the case of an adverse reaction, immediate withdrawal of medication is recommended. Severely affected pigs should be removed to clean dry pens and given symptomatic treatment, including treatment for concurrent disease.

An epidemiological survey has indicated that there is likely to be an association between the susceptibility to adverse reactions and the Danish and Swedish Landrace breeds, and their crossbreeds thereof, especially younger pigs.

Valnemulin is well-accepted in feed, but administered at concentrations above 200 mg/kg feed may result in transient reduction in food consumption associated with unpalatability during the first few days of feeding.

If you notice any other side effects, please inform your veterinary surgeon.

10. WITHDRAWAL PERIOD

1 day

11. SPECIAL STORAGE CONDITIONS

Keep out of the reach and sight of children.

Do not store above 25°C.

For aluminium-lined bags, store product in the original container.

For polyethylene bags, store the product in the original container within the outer carton and protected from light and moisture.

Part-used containers should be tightly closed following dispensing.

Shelf life:

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

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 WARNING(S):

Valnemulin has been shown to interact with ionophores such as monensin, salinomycin and narasin and may result in signs indistinguishable from an ionophore toxicosis. Animals should not receive products containing monensin, salinomycin or narasin, during or at least 5 days before or after treatment with valnemulin. Severe growth depression, ataxia, paralysis or death may result.

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. Their occurrence may be principally restricted to the Scandinavian countries and appears to be mainly associated with breed mixes that include Danish and/or Swedish Landrace. 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.

13. 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.

14. OTHER INFORMATION

Valnemulin is an antibiotic belonging to the pleuromutilin group, which act by the inhibition of the initiation of protein synthesis at the level of the bacterial ribosome.

15. DATE ON WHICH THE TEXT WAS LAST REVISED

March 2004

PACKAGE INSERT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Econor 50% premix for medicated feed for pigs

2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES

Econor 50% premix contains valnemulin in the form of valnemulin hydrochloride.

Valnemulin hydrochloride	532.5 mg/g
equivalent to valnemulin base	500 mg/g

List of excipients:

Hypromellose and talc

3. 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:

Sandoz GmbH
Schaffnau Plant
A-6336 Langkampfen
Austria

4. TARGET SPECIES

Pigs

5. 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.

6. DOSAGE, METHOD AND ROUTE(S) OF ADMINISTRATION

In-feed use.

The uptake of medicated feed depends on the clinical condition of the animal. In order to obtain the correct dosage the concentration of Econor has to be adjusted. Inclusion levels may also need to be increased in older pigs or pigs on restricted feed to achieve target dosage.

Indication	Dosage (mg active substance/kg)	Application period of medicated feed as the sole daily ration	Application in feed
<u>Treatment of</u> <ul style="list-style-type: none"> ▪ Swine Dysentery 	3-4 mg/kg bodyweight/day	Minimum of 7 days and up to 4 weeks or until signs of disease disappear	Incorporation of 75 mg active substance per kg feed with: Econor 50% - 150 mg/ kg feed

This dose level is effective in the treatment of clinical disease, but higher dosages or longer duration of treatment may be necessary for complete elimination of infection. It is important to institute medication as early as possible in an outbreak of swine dysentery. If there is no response to treatment within 5 days, the diagnosis should be re-established.

Indication	Dosage (mg active substance/kg)	Application period of medicated feed as the sole daily ration	Application in feed
<u>Treatment of clinical signs</u> <ul style="list-style-type: none"> ▪ Porcine Proliferative Enteropathy (ileitis) 	3-4 mg/kg bodyweight/day	2 weeks or until signs of disease disappear	Incorporation of 75 mg active substance per kg feed with: Econor 50% - 150 mg/ kg feed

This dose level is effective under normal situation in the treatment of clinical signs of disease, but higher dosages or longer duration of treatment may be necessary for complete elimination of infection. It is important to institute medication as early as possible in an outbreak of porcine proliferative enteropathy. If there is no response to treatment within 5 days, the diagnosis should be re-established. For severely affected animals which fail to respond to treatment within 3-5 days, parenteral treatment should be considered.

Indication	Dosage (mg active substance/kg)	Application period of medicated feed as the sole daily ration	Application in feed
<u>Prevention of</u> <ul style="list-style-type: none"> ▪ Swine Dysentery ▪ Clinical signs of Porcine Colonic Spirochaetosis (colitis) 	1.0 – 1.5 mg/kg bodyweight/day	minimum of 7 days and up to 4 weeks 4 weeks	Incorporation of 25 mg active substance per kg feed with: Econor 50% - 50 mg/ kg feed

Long term preventative use of valnemulin should be avoided by improving management practice and thorough cleansing and disinfection. Consideration should be given to the eradication of infection from the farm.

Indication	Dosage (mg active substance/kg)	Application period of medicated feed as the sole daily ration	Application in feed
<u>Treatment & Prevention of</u> <ul style="list-style-type: none"> ▪ Swine Enzootic Pneumonia 	10 – 12 mg/kg bodyweight/day	Up to 3 weeks	Incorporation of 200 mg active substance per kg feed with : Econor 50% - 400 mg/kg feed

Secondary infection by organisms such as *Pasteurella multocida* and *Actinobacillus pleuropneumoniae* may complicate enzootic pneumonia and require specific medication.

7. ADVICE ON CORRECT ADMINISTRATION:

Mixing Instructions:

mg Econor 50% premix/kg feed = Dosage required (mg/kg) x 2 x bodyweight (kg)/Daily feed intake (kg)

The product has been shown to be stable to the pelleting process at temperatures of 75°C. Aggressive pelleting conditions such as temperatures in excess of 80°C, and the use of abrasive substances for pre-mixture should be avoided.

To achieve good mixture and homogeneity of incorporation, the use of a pre-mixture is required. The required quantity of product is thoroughly mixed with a feed ingredient of similar physical nature (e.g. wheat middlings) in the proportion: 1 part Econor 50% premix to 20 parts feed ingredient.

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

8. CONTRAINDICATIONS:

Do not administer the product to pigs receiving ionophores.
Valnemulin should not be administered to rabbits because of its toxicity in this species.

9. UNDESIRABLE EFFECTS:

Medication of pigs with Econor has led to the occurrence of adverse reactions in the European Union. Of the cases reported in 1999-2000, the majority occurred in Denmark and Sweden (one case each in Finland and Ireland). In these countries, the incidence ranged from 0.03 to 1.76% of all pigs treated. On affected farms, one third of the pigs treated were affected, with a mortality of 1%. Affected pigs are pyrexia, exhibit inappetence, and in severe cases become incoordinated, ataxic and may become recumbent. A percentage of such pigs may also suffer oedema or erythema (posterior in distribution), and palpebral oedema. The reaction has been studied in controlled trials in susceptible animals. Mortality was less than 1% but might be increased as a result of secondary infections.

In the case of an adverse reaction, immediate withdrawal of medication is recommended. Severely affected pigs should be removed to clean dry pens and given symptomatic treatment, including treatment for concurrent disease.

An epidemiological survey has indicated that there is likely to be an association between the susceptibility to adverse reactions and the Danish and Swedish Landrace breeds, and their crossbreeds thereof, especially younger pigs.

Valnemulin is well-accepted in feed, but administered at concentrations above 200 mg/kg feed may result in transient reduction in food consumption associated with unpalatability during the first few days of feeding.

If you notice any other side effects, please inform your veterinary surgeon.

10. WITHDRAWAL PERIOD

1 day

11. SPECIAL STORAGE CONDITIONS

Keep out of the reach and sight of children.

Do not store above 25°C.

For aluminium-lined bags, store product in the original container.

For polyethylene bags, store the product in the original container within the outer carton and protected from light and moisture.

Part-used containers should be tightly closed following dispensing.

Shelf life:

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

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 WARNING(S)

Valnemulin has been shown to interact with ionophores such as monensin, salinomycin and narasin and may result in signs indistinguishable from an ionophore toxicosis. Animals should not receive products containing monensin, salinomycin or narasin, during or at least 5 days before or after treatment with valnemulin. Severe growth depression, ataxia, paralysis or death may result.

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. Their occurrence may be principally restricted to the Scandinavian countries and appears to be mainly associated with breed mixes that include Danish and/or Swedish Landrace. 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.

13. 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.

14. OTHER INFORMATION

Valnemulin is an antibiotic belonging to the pleuromutilin group, which acts by the inhibition of the initiation of protein synthesis at the level of the bacterial ribosome.

15. DATE ON WHICH THE TEXT WAS LAST REVISED

March 2004

PACKAGE INSERT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Econor 0.5% premix for medicated feed for pigs

2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES

Econor 0.5% premix contains valnemulin in the form of valnemulin hydrochloride.

Valnemulin hydrochloride	5.325 mg/g
equivalent to valnemulin base	5 mg/g

List of excipients:

Hypromellose and talc
Colloidal anhydrous silica
Isopropyl myristate
Lactose

3. 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

4. TARGET SPECIES

Pigs

5. 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.

6. DOSAGE, METHOD AND ROUTE(S) OF ADMINISTRATION

In-feed use

The uptake of medicated feed depends on the clinical condition of the animal. In order to obtain the correct dosage the concentration of Econor has to be adjusted. Inclusion levels may also need to be increased in older pigs or pigs on restricted feed to achieve target dosage.

Indication	Dosage (mg active substance/kg)	Application period of medicated feed as the sole daily ration	Application in feed
<u>Treatment of</u> <ul style="list-style-type: none"> ▪ Swine Dysentery 	3-4 mg/kg bodyweight/day	Minimum of 7 days and up to 4 weeks or until signs of disease disappear	Incorporation of 75 mg active substance per kg feed with: Econor 0.5% - 15 g/kg feed

This dose level is effective in the treatment of clinical disease, but higher dosages or longer duration of treatment may be necessary for complete elimination of infection. It is important to institute medication as early as possible in an outbreak of swine dysentery. If there is no response to treatment within 5 days, the diagnosis should be re-established.

Indication	Dosage (mg active substance/kg)	Application period of medicated feed as the sole daily ration	Application in feed
<u>Treatment of clinical signs</u> <ul style="list-style-type: none"> ▪ Porcine Proliferative Enteropathy (ileitis) 	3-4 mg/kg bodyweight/day	2 weeks or until signs of disease disappear	Incorporation of 75 mg active substance per kg feed with: Econor 0.5% - 15 g/kg feed

This dose level is effective under normal situation in the treatment of clinical signs of disease, but higher dosages or longer duration of treatment may be necessary for complete elimination of infection. It is important to institute medication as early as possible in an outbreak of porcine proliferative enteropathy. If there is no response to treatment within 5 days, the diagnosis should be re-established. For severely affected animals which fail to respond to treatment within 3-5 days, parenteral treatment should be considered.

Indication	Dosage (mg active substance/kg)	Application period of medicated feed as the sole daily ration	Application in feed
<u>Prevention of</u> <ul style="list-style-type: none"> ▪ Swine Dysentery ▪ Clinical signs of Porcine Colonic Spirochaetosis (colitis) 	1.0 – 1.5 mg/kg bodyweight/day	minimum of 7 days and up to 4 weeks 4 weeks	Incorporation of 25 mg active substance per kg feed with: Econor 0.5% - 5 g/kg feed

Long term preventative use of valnemulin should be avoided by improving management practice and thorough cleansing and disinfection. Consideration should be given to the eradication of infection from the farm.

7. ADVICE ON CORRECT ADMINISTRATION:

Mixing Instructions:

mg Econor 0.5% premix/kg feed = Dosage required (mg/kg) x 200 x bodyweight (kg) / Daily feed intake (kg)

The product has been shown to be stable to the pelleting process at temperatures of 75°C. Aggressive pelleting conditions such as temperatures in excess of 80°C, and the use of abrasive substances for pre-mixture should be avoided.

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

8. CONTRAINDICATIONS:

Do not administer the product to pigs receiving ionophores.

Valnemulin should not be administered to rabbits because of its toxicity in this species.

9. UNDESIRABLE EFFECTS:

Medication of pigs with Econor has led to the occurrence of adverse reactions in the European Union. Of the cases reported in 1999-2000, the majority occurred in Denmark and Sweden (one case each in Finland and Ireland). In these countries, the incidence ranged from 0.03 to 1.76% of all pigs treated. On affected farms, one third of the pigs treated were affected, with a mortality of 1%. Affected pigs are pyrexic, exhibit inappetence, and in severe cases become incoordinated, ataxic and may become recumbent. A percentage of such pigs may also suffer oedema or erythema (posterior in distribution), and palpebral oedema. The reaction has been studied in controlled trials in susceptible animals. Mortality was less than 1% but might be increased as a result of secondary infections.

In the case of an adverse reaction, immediate withdrawal of medication is recommended. Severely affected pigs should be removed to clean dry pens and given symptomatic treatment, including treatment for concurrent disease.

An epidemiological survey has indicated that there is likely to be an association between the susceptibility to adverse reactions and the Danish and Swedish Landrace breeds, and their crossbreeds thereof, especially younger pigs.

Valnemulin is well-accepted in feed, but administered at concentrations above 200 mg/kg feed may result in transient reduction in food consumption associated with unpalatability during the first few days of feeding.

If you notice any other side effects, please inform your veterinary surgeon.

10. WITHDRAWAL PERIOD

1 day

11. SPECIAL STORAGE CONDITIONS

Keep out of the reach and sight of children.

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 of the veterinary medicinal product as packaged for sale: 3 years

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 WARNING(S)

Valnemulin has been shown to interact with ionophores such as monensin, salinomycin and narasin and may result in signs indistinguishable from an ionophore toxicosis. Animals should not receive products containing monensin, salinomycin or narasin, during or at least 5 days before or after treatment with valnemulin. Severe growth depression, ataxia, paralysis or death may result.

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. Their occurrence may be principally restricted to the Scandinavian countries and appears to be mainly associated with breed mixes that include Danish and/or Swedish Landrace. 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.

13. 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.

14. OTHER INFORMATION

Valnemulin is an antibiotic belonging to the pleuromutilin group, which act by the inhibition of the initiation of protein synthesis at the level of the bacterial ribosome.

15. DATE ON WHICH THE TEXT WAS LAST REVISED

March 2004