

## **ANNEX I**

### **SUMMARY OF PRODUCT CHARACTERISTICS**

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

VetZink, 1000 mg/g, premix for medicated feeding stuff, for pigs.

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

### **Active substance:**

Zinc oxide 1000 mg/g.

## **3. PHARMACEUTICAL FORM**

Premix for medicated feeding stuff.

## **4. CLINICAL PARTICULARS**

### **4.1 Target species**

Weaned pigs up to 10 weeks of age.

### **4.2 Indications for use, specifying the target species**

Prevention of diarrhoea in weaned pigs.

### **4.3 Contraindications**

None.

### **4.4 Special warnings for each target species**

None.

### **4.5 Special precautions for use**

#### Special precautions for use in animals

The product should be used as a temporary aid, in conjunction with the implementation of relevant measures to prevent post-weaning diarrhoea. Official, national treatment policies should be taken into account when the veterinary medicinal product is used

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

Airways/ingestion:

- As with any powder, this product can cause irritation of the airways
- Avoid inhalation
- Avoid dust formation. Avoid dust formation when mixing the feed. Using a mask respirator is not necessary in case of sufficient ventilation or when using a self-contained system. In case of exposure to large quantities of dust, the dust mask P2 must be used
- In case of accidental inhalation, provide fresh air and contact a doctor in case of discomfort. In case of accidental ingestion, rinse the mouth with water and drink plenty of water. Seek medical advice in case of discomfort.

Eyes:

- As with any powder this product can cause irritation to the eyes
- Avoid contact with eyes
- Wear eye protection
- In case of accidental eye contact, rinse thoroughly with plenty of water. Then remove any/possible contact lenses and continue rinsing. Seek medical advice in case of discomfort.

Skin:

- As with any powder, this product can cause irritation of the skin
- Avoid contact with skin
- Wear work clothes and protective gloves (of leather, rubber, or cotton). Wash hands after use.
- In case of accidental skin contact, wash with soap and water.

Other precautions regarding impact on the environment

Zinc is very toxic to aquatic organisms, but can affect growth, survival and reproduction in both aquatic and terrestrial plants and animals. Zinc is persistent in soils and may accumulate in sediments. Toxicity will depend on environmental conditions and habitat types. The risk to the environment can be reduced by adhering to the following measures.

When spreading manure from treated animals, the maximum total zinc load as defined in the national or local regulations has to be strictly respected. Undiluted manure from treated piglets should not be applied to land. Dilution with manure of untreated animals or sows is required so that the total amount of treated piglet manure is as low as possible and is never exceeding 40%, the ratio when manure of weaned piglets and sows is stored together. The product should not be used on farms where mixing of manure from treated animals with manure of non-treated animals is not possible.

The bioavailability of zinc, and therefore the environmental risk, varies between soil types. Manure from treated piglets should not be spread on vulnerable soil types, which have been identified as freely draining, acidic ( $\text{pH} \leq 6$ ), sandy soils.

Manure containing zinc should not be spread on the same area of land in successive years to avoid accumulation of zinc which may cause adverse effects in the environment.

When spreading manure from treated animals, the minimum distance to surface water as defined in the national or local regulations has to be strictly respected, and at least a minimum buffer zone of 3 m applied, because the manure contains zinc which may cause adverse effects in the aquatic environment.

#### **4.6 Adverse reactions (frequency and seriousness)**

New studies have shown that in swine herds positive for MRSA (methicillin-resistant Staphylococci), the use of zinc oxide for weaners may increase the prevalence of the resistant bacteria among the weaners.

#### **4.7 Use during pregnancy, lactation or lay**

Not applicable.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

None known.

#### **4.9 Amounts to be administered and administration route**

For incorporation into dry feed at a mill approved by the [name of the local authority].

2500 mg zinc per kg feed equivalent to 3000 mg zinc oxide per kg feed for up to a maximum of 14 days.

The feed consumption during the two weeks after weaning is approximately 6-7 kg/pig. The amount of medicated feed prescribed should not exceed 10 kg/pig.

For oral administration only.

When the product is mixed into the feed, the amount of zinc already present in the feed, either as naturally occurring zinc or added for nutritional purposes, should be taken into consideration. Without prescription the maximum amount of zinc content in feed is 150 mg/kg. Taking the actual amount of zinc in the feed into consideration a quantity of the product should be added so that the total amount of zinc does not exceed 2500 mg zinc per kg feed (this equals 2.8-3 kg of the product mixed into 1000 kg of feed depending on the zinc already presented in the feed).

To ensure adequate distribution of the product in the final feed it is recommended to premix the product with a suitable quantity of feed ingredients before blending into the final feed. The final feed should be fed as the only feed for up to maximum 14 days.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

Hepatic toxicity (lipid accumulation in hepatocytes) was demonstrated in weaned pigs provided with use of the recommended dose for 4 weeks.

#### **4.11 Withdrawal period(s)**

Piglets (slaughter): 0 days.

## **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Anti-diarrhoeals, intestinal anti-inflammatory/anti-infective agents  
ATCvet code: QA07XA91.

### **5.1 Pharmacodynamic properties**

Zinc is an essential trace element which is crucial for growth processes. The mechanism of action of zinc oxide in the treatment and control of diarrhoea in pigs has not been established. It has been shown to have a favourable effect on the gut microflora by stabilizing intestinal microflora. Furthermore it is known that  $Zn^{2+}$  interferes with the binding of E. coli to the enterocytes.

### **5.2 Pharmacokinetic particulars**

#### *Absorption*

Zinc oxide is relatively poorly absorbed and at therapeutic levels blood levels only increased 2-fold.

#### *Distribution*

Therapeutic levels of zinc oxide increase zinc levels in the liver and kidneys in pigs approximately 3-5-fold and 2-fold, respectively. No increases in muscle levels were observed.

#### *Biotransformation*

Since therapeutic levels of zinc are poorly absorbed, it is believed that most is excreted unchanged in the faeces.

#### *Elimination*

The majority of zinc from zinc oxide is excreted without absorption. Levels of zinc in liver and kidneys return to normal within 7 days following withdrawal.

### **5.3 Environmental properties**

Zinc is very toxic to aquatic organisms and is persistent in soils and sediments.

Zinc may accumulate in soil following continual application of manure from treated animals; with acidic sandy soils being most vulnerable.

The bioavailability of zinc, and therefore the environmental risk, varies between soil types and environmental conditions (e.g. dissolved organic carbon, calcium and pH).

Zinc oxide is mainly excreted in the faeces, only a small proportion is excreted in the urine. The substance is not biotransformed and enters the environment in the form of slurry and manure. The impact on the total environmental zinc burden has been assessed and is not expected to be unacceptable when the product is used as prescribed.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

None.

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.  
Shelf life after incorporation into meal or pelleted feed: 3 months.

#### **6.4. Special precautions for storage**

- Store in a dry place.
- This veterinary medicinal product does not require any special temperature storage conditions.

#### **6.5 Nature and composition of immediate packaging**

Paper sack (three-ply paper sack. The outer ply is coated with PE).

Pack sizes: 10 kg and 25 kg.

Not all pack sizes may be marketed.

#### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used containers.

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

### **7. MARKETING AUTHORISATION HOLDER**

Vepidan Aps  
Østerbrogade 23  
DK-9670 Løgstør  
Denmark

### **8. MARKETING AUTHORISATION NUMBER(S)**

To be completed nationally.

### **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

{DD/MM/YYYY}

### **10 DATE OF REVISION OF THE TEXT**

{MM/YYYY}

## **LABELLING**



**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

Paper sack (three-ply paper sack. The outer ply is coated with PE).

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

VetZink, 1000 mg/g, premix for medicated feeding stuff.

Zinc oxide.

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

Zinc oxide 1000 mg/g.

**3. PHARMACEUTICAL FORM**

Premix for medicated feeding stuff.

**4. PACKAGE SIZE**

10 kg

25 kg

**5. TARGET SPECIES**

Weaned pigs up to 10 weeks of age.

**6. INDICATION(S)**

*[Indication to be included **only** for medicinal products **not** subject to medical prescription.]*

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

For incorporation into dry feed at a mill approved by the [name of the local authority].

2500 mg zinc per kg feed equivalent to 3000 mg zinc oxide per kg feed for up to a maximum of 14 days.

The feed consumption during the two weeks after weaning is approximately 6-7 kg/pig. The amount of medicated feed prescribed should not exceed 10 kg/pig.

For oral administration only.

When the product is mixed into the feed, the amount of zinc already present in the feed, either as naturally occurring zinc or added for nutritional purposes, should be taken into consideration.. Without prescription the maximum amount of zinc content in feed is 150 mg/kg. Taking the actual amount of zinc in the feed into consideration a quantity of the product should be added so that the total amount of zinc does not exceed 2500 mg zinc per kg feed (this equals 2.8-3 kg of the product mixed into 1000 kg of feed depending on the zinc already presented in the feed).

To ensure adequate distribution of the product in the final feed it is recommended to premix the product with a suitable quantity of feed ingredients before blending into the final feed. The final feed should be fed as the only feed for up to maximum 14 days.

## **8. WITHDRAWAL PERIOD**

Withdrawal period:

Piglets (slaughter): 0 days.

## **9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

Airways/ingestion:

- As with any powder, this product can cause irritation of the airways
- Avoid inhalation
- Avoid dust formation. Avoid dust formation when mixing the feed. Using a mask respirator is not necessary in case of sufficient ventilation or when using a self-contained system. In case of exposure to large quantities of dust, the dust mask P2 must be used
- In case of accidental inhalation, provide fresh air and contact a doctor in case of discomfort. In case of accidental ingestion, rinse the mouth with water and drink plenty of water. Seek medical advice in case of discomfort.

Eyes:

- As with any powder this product can cause irritation to the eyes
- Avoid contact with eyes
- Wear eye protection
- In case of accidental eye contact, rinse thoroughly with plenty of water. Then remove any contact lenses and continue rinsing. Seek medical advice in case of discomfort.

Skin:

- As with any powder, this product can cause irritation of the skin
- Avoid contact with skin
- Wear work clothes and protective gloves (of leather, rubber, or cotton). Wash hands after use.
- In case of accidental skin contact, wash with soap and water.

Hepatic toxicity (lipid accumulation in hepatocytes) was demonstrated in weaned pigs provided with use of the recommended dose for 4 weeks.

## **10. EXPIRY DATE**

EXP

<b>11. SPECIAL STORAGE CONDITIONS</b>
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- Store in a dry place
- This veterinary medicinal product does not require any special temperature storage conditions.

<b>12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY</b>
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Dispose of waste material in accordance with local requirements.

<b>13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE</b>
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For animal treatment only. <To be supplied only on veterinary prescription.>

<b>14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”</b>
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Keep out of the sight and reach of children.

<b>15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER</b>
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Vepidan Aps  
Østerbrogade 23  
DK-9670 Løgstør  
Denmark

<b>16. MARKETING AUTHORISATION NUMBER(S)</b>
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<b>17. MANUFACTURER'S BATCH NUMBER</b>
----------------------------------------

Batch

## **B. PACKAGE LEAFLET**

## **PACKAGE LEAFLET FOR:**

VetZink, 1000 mg/g, premix for medicated feeding stuff, for pigs

### **1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder and manufacturer responsible for batch release:

Vepidan ApS  
Østerbrogade 23  
DK-9670 Løgstør  
Denmark

### **2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

VetZink, 1000 mg/g, premix for medicated feeding stuff, for pigs.

Zinc oxide.

### **3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

Zinc oxide 1000mg/mg.

### **4. INDICATION(S)**

Prevention of diarrhoea in weaned pigs.

### **5. CONTRAINDICATIONS**

None.

### **6. ADVERSE REACTIONS**

New studies have shown that in swine herds positive MRSA (methicillin-resistant Staphylococci), the use of zinc oxide for weaners may increase the prevalence of the resistant bacteria among the weaners.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

### **7. TARGET SPECIES**

Weaned pigs up to 10 weeks of age.

### **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

For incorporation into dry feed at a mill approved by the [insert name of the local authority].

2500 mg zinc per kg feed equivalent to 3000 mg zinc oxide per kg feed for up to a maximum of 14 days.

The feed consumption during the two weeks after weaning is approximately 6-7 kg/pig. The amount of medicated feed prescribed should not exceed 10 kg/pig.

For oral administration only.

When the product is mixed into the feed, the amount of zinc already present in the feed, either as naturally occurring zinc or added for nutritional purposes, should be taken into consideration. Without prescription the maximum amount of zinc content in feed is 150 mg/kg. Taking the actual amount of zinc in the feed into consideration a quantity of the product should be added so that the total amount of zinc does not exceed 2500 mg zinc per kg feed (this equals 2.8-3 kg of the product mixed into 1000 kg of feed depending on the zinc already presented in the feed).

To ensure adequate distribution of the product in the final feed it is recommended to premix the product with a suitable quantity of feed ingredients before blending into the final feed. The final feed should be fed as the only feed for up to maximum 14 days.

## **9. ADVICE ON CORRECT ADMINISTRATION**

## **10. WITHDRAWAL PERIOD**

Piglets (slaughter): 0 days.

## **11. SPECIAL STORAGE PRECAUTIONS**

- Store in a dry place.
- This veterinary medicinal product does not require any special temperature storage conditions.
- Keep out of the sight and reach of children.

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 of the veterinary medicinal product as packaged for sale: 2 years

Shelf life after incorporation into meal or pelleted feed: 3 months.

## **12. SPECIAL WARNING(S)**

Special precautions for use in animals:

The product should be used as a temporary aid, in conjunction with the implementation of relevant measures to prevent post-weaning diarrhoea. Official, national treatment policies should be taken into account when the veterinary medicinal product is used.

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

Airways/ingestion:

- As with any powder, this product can cause irritation of the airways

- Avoid inhalation
- Avoid dust formation. Avoid dust formation when mixing the feed. Using a mask respirator is not necessary in case of sufficient ventilation or when using a self-contained system. In case of exposure to large quantities of dust, the dust mask P2 must be used
- In case of accidental inhalation, provide fresh air and contact a doctor in case of discomfort. In case of accidental ingestion, rinse the mouth with water and drink plenty of water. Seek medical advice in case of discomfort.

#### Eyes:

- As with any powder this product can cause irritation to the eyes
- Avoid contact with eyes
- Wear eye protection
- In case of accidental eye contact, rinse thoroughly with large quantities/plenty of water. Then remove any/possible contact lenses and continue rinsing. Seek medical advice in case of discomfort.

#### Skin:

- As with any powder, this product can cause irritation of the skin
- Avoid contact with skin
- Wear work clothes and protective gloves (of leather, rubber, or cotton). Wash hands after use.
- In case of accidental skin contact, wash with soap and

water. Overdose (symptoms, emergency procedures, antidotes):

Hepatic toxicity (lipid accumulation in hepatocytes) was demonstrated in weaned pigs provided with use of the recommended dose for 4 weeks.

#### Other precautions regarding impact on the environment

Zinc is very toxic to aquatic organisms, but can affect growth, survival and reproduction in both aquatic and terrestrial plants and animals. Zinc is persistent in soils and may accumulate in sediments. Toxicity will depend on environmental conditions and habitat types. The risk to the environment can be reduced by adhering to the following measures.

When spreading manure from treated animals, the maximum total zinc load as defined in the national or local regulations has to be strictly respected. Undiluted manure from treated piglets should not be applied to land. Dilution with manure of untreated animals or sows is required so that the total amount of treated piglet manure is as low as possible and is never exceeding 40 %, the ratio when manure of weaned piglets and sows is stored together. The product should not be used on farms where mixing of manure from treated animals with manure of non-treated animals is not possible.

The bioavailability of zinc, and therefore the environmental risk, varies between soil types. Manure from treated piglets should not be spread on vulnerable soil types, which have been identified as freely draining, acidic ( $\text{pH} \leq 6$ ), sandy soils.

Manure containing zinc should not be spread on the same area of land in successive years to avoid accumulation of zinc which may cause adverse effects in the environment.

When spreading manure from treated animals, the minimum distance to surface water as defined in the national or local regulations has to be strictly respected, and at least a minimum buffer zone of 3 m applied, because the manure contains zinc which may cause adverse effects in the aquatic environment.

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

**EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.** Do not contaminate surface waters or ditches with the product or used containers.

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

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

#### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

#### **15. OTHER INFORMATION**

Paper sack (three-ply paper sack. The outer ply is coated with PE).

Pack sizes: 10 kg and 25 kg.

Not all pack sizes may be marketed.