

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETo-ZINON 60 Concentrate for Dip Emulsion A.U.V.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Diazinon

600 g / litre

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for dip emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep.

4.2 Indications for use, specifying the target species

The product (stable emulsion in water) has an ectoparasitic activity in sheep against mites (*Sarcoptes scabiei var. ovis*, *Chorioptes bovis*), lice (*Bovicola ovis*), sheep ked (*Melophagus ovinus*) and myiasis (*Lucilia sericata*, *Wolffarthia magnifica*) for prevention and therapy. During the treatment of the animal the ovine husbandry and equipment are to be treated as well.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance. Do not treat ill, weak, exhausted or thirsty animals. Do not use the product on lambs less than three weeks old. Animals less than four weeks old can be treated only with the thorough assessment of the risk/benefit. Not permitted for use in lactating sheep producing milk for human consumption. Do not use in cats, birds, poultry, fish and honey bees.

4.4 Special warnings for each target species

Contact of the product with the skin and the eyes should be avoided. Swallowing or inhalation of the product should be avoided.

4.5 Special precautions for use

The concentrate is extremely flammable. Poisonous! Before using read the product leaflet of precautions thoroughly! Poisonous to cats, birds, bees, fish and other animals living in the freshwater and the sea. Not to be used on rainy days because the effectiveness of the treatment is lower.

Special precautions for use in animals

It should be prevented that the sheep drink or inhale from the dip emulsion. Before dipping drinking water should be given to the animals.

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

Contact of the product with the skin and the eyes should be avoided. Swallowing or inhalation of the product should be avoided. During the treatment with the emulsion water resistant overalls, protecting apron, protecting cap, protecting mask, rubber boots and rubber gloves must be worn. During spraying

protecting overalls, protecting gloves, protecting cap, rubber boot and a respiration protecting mask with a combined filter must be worn. After handling the product wash your hands, face and hair. The dirty clothes are to be taken off immediately and washed. The tools used during the treatment are to be washed. If suspicion of poisoning or illness arises, the activity is to be ceased and a doctor should be seen. Do not eat, drink or smoke when handling the product. In case the product contacts skin, it is to be washed immediately with soap and water. In case the product contacts the eyes, rinse immediately abundantly with water for at least 15 minutes, and seek medical advice. In case of accidental ingestion, emptying of the stomach is necessary, a doctor is to be seen immediately, showing the package leaflet or the label to the physician. The hospital observation of the patient is necessary for more than 12 hours even in case of a symptomless period. An antidote is atropine; in case of serious poisoning give haemoperfusion and cholinesterase deactivator (Pralidoxim). Until the appearance of signs of atropinisation give several ampoules of atropine. Atropinisation must be continued until the end of an increased bronchus secretion. In case of tachycardia and mydriasis increasing the dose of atropine is not contraindicated. Monitoring the cholinesterase activity in the serum and the red blood cells is necessary. Because of the prolonged absorption of atropine the treatment can only be finished slowly and only when the activity of cholinesterase has reached at least half of the lower limit of the normal value. In case of poisoning giving morphine, theophylline, aminophylline, phenothiazins, furosemide and muscle relaxants is contraindicated.

4.6 Adverse reactions (frequency and seriousness)

Poisoning of the organophosphate type may occur. Symptoms: salivation, perspiration, tremor, hyperventilation, hyperaesthesia, vomiting, mydriasis and unconsciousness.

4.7 Use during pregnancy, lactation or lay

The use is not recommended during the pregnancy. Do not use in sheep producing milk for human consumption.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use with other organophosphate and carbamate type products. Microsomal enzyme inductors increase the toxicity of diazinon in the liver.

4.9 Amounts to be administered and administration route

For external use only. To dip the sheeps the emulsion is to be used containing 250 mg diazinon/litre as initial concentration; 425 ml of VETo-ZINON 60 Concentrate for Dip Emulsion must be diluted with 1000 litres of tap water. The dip emulsion is to be prepared before use, and should be diluted with tap water. During the preparation of the dip emulsion it is to be mixed continuously to achieve homogeneity. The dip emulsion is to be supplemented according to shrinkage; if 10% has run out, the emulsion is to be supplemented with 750 mg diazinon/litre concentrated solution which can be prepared by 1250 ml VETo-ZINON 60 Concentrate for Dip Emulsion diluted with 1000 litres of water. The group treatment is to be arranged in an outdoor basin, in dry weather and in the morning period. Animals held together must be treated at the same time. Sheep are to be dipped into the dip emulsion for 30 to 60 seconds, for one second the head of the sheep is to be dipped as well, being careful that the animals do not drink or inhale of it. Animals can be treated individually in an outdoor vat or in a well-ventilated room. The dipping is to be done at an unutilized field not producing cereal. The frequency of the treatment depends on the extent of the infection, the growth cycle of ectoparasites and the environmental conditions. Scabious or suspectedly scabious animals are to be treated two times at a 7 to 10 day interval. The dip emulsion is to be used up within 24 hours. Diazinon adheres to the skin, dissolves in the wool fat, so it has a longer protection against ectoparasites. The treatment of scab-infected sheep is recommended to be done between 4 to 6 weeks after trimming, because at that time the sheep has enough wool to be able to absorb 2 to 3 litres of dip emulsion, which is sufficient for a longer protection period. In case of myiasis the efficacy of the

treatment increases if the treatment against the adult flies is done before the hatching of the first maggots.

Simultaneously with animal treatment the sheep pen and equipment is to be sprayed or be washed with a 2.5% VETO-ZINON 60 Concentrate for Dip Emulsion; pour 200 ml VETO-ZINON 60 Concentrate for Dip Emulsion into 5 litres of tap water. 5 l of the diluted emulsion is needed on a 100 m² surface. The disinfection of the pen should be performed by a skilled worker, spraying or washing is to be done in the empty building.

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

The organophosphate ester type poisoning may occur in case of overdose. Symptoms: salivation, perspiration, tremor, hyperventilation, hyperaesthesia, vomiting, mydriasis and unconsciousness. Diazinon is an inhibitor of cholinesterase, highly poisonous! In case the treated animals show poisoning symptoms, a veterinarian is to be seen immediately.

Antidotes: atropine; oxim preparations: Toxogonin or PAM, which can be used by a veterinarian only.

4.11 Withdrawal period

Meat and offal: 28 days

Not permitted for use in lactating sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

The diazinon, previously known as dimpylate /C₁₂H₂₁N₂O₃PS, CAS number: 333-41-5/ belongs to the group of organophosphate esters.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antiparasitic products.

ATCvet code: QP53AF03.

Diazinon has insecticide and acaricidal properties, it is used as an ectoparasitic compound in veterinary therapy, besides that as a biocide and pesticide. Diazinon acts as a cholinesterase inhibitor. Cholinesterase enzymes regulate the production/degradation of acetylcholine in mammals and arthropods. In the lack of acetylcholinesterase acetylcholine increases and causes long-lasting depolarisation on the postsynaptic membrane.

5.2 Pharmacokinetic particulars

The oxidised metabolite of diazinon is diazoxon, which is more toxic than the parent drug. The mechanism of detoxication is fast and complete in mammals, but moderate and incomplete in arthropods. Therefore, the therapy spectrum of the product is wide in arthropods, while the toxicity of the product is low in mammals.

Environmental properties

Poisonous to cats, birds, bees, fish and other animals living in the freshwater and the sea.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Emulsion AG/MS,
Emulsion AG/L,
Emulsion 3720,
Butyl hydroxitoluol,

Solvesso 100.

6.2 Incompatibilities

The product resolves in acidic or alkaline milieu.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

The dip emulsion is to be used up within 24 hours.

6.4. Special precautions for storage

The well closed product is to be stored in a dry, closed place with good ventilation.

After using keep the container tightly closed.

The product is flammable. Avoid direct sunlight and do not store below -10°C and above +25°C.

6.5 Nature and composition of immediate packaging

5 x 5 ml brown glass vials in a paper box; 1 litre and 5 litres in screw-topped closing coextruded plastic container.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed as dangerous waste materials.

Deposition of the remaining concentrate or the dip emulsion into soil and living water is prohibited.

The equipment used for the dipping is to be rinsed thoroughly and stored in an assigned place securely. The diazinon in the unused dip emulsion disintegrates within 6 to 10 days; the disintegration of the ester-binding is catalysed by acidic or alkaline. The remains of the dip solution may be disposed of by composting for 60 days; another method is adding 5 to 10 kg slacked lime to 1000 litres of the dip emulsion. The slacked lime disintegrates the diazinon within 24 to 48 hours.

7. MARKETING AUTHORISATION HOLDER

V.M.D. nv/sa

Hoge Mauw 900, B-2370 Arendonk

Belgium

8. MARKETING AUTHORISATION NUMBER(S)

3176/01/12 NÉBIH ÁTI (5 x 5 ml vials in a paper box)

3176/02/12 NÉBIH ÁTI (1 litre)

3176/03/12 NÉBIH ÁTI (5 litre)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

October 27, 2005. / June 13, 2012

10 DATE OF REVISION OF THE TEXT

August 06, 2014

PROHIBITION OF SALE, SUPPLY AND/OR USE

For animal treatment only.

To be supplied without veterinary prescription.