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Termőföldtől az asztalig

National Food Chain Safety Office
Directorate of Veterinary Medicinal
Products



Hungary-1107 Budapest, Szállás u. 8.
Tel: 06-1/433-0330 Fax: 06-1/262-2839
www.nebih.gov.hu

Reference number: 02.2/5373-2/2016

Administrator: Annamária Mosolygóné dr. Telepó

Enclosures: Assessment Report,
package leaflet, labelling

Subject: Renewal of CV247 tablets and
capsules

Address: Mr. Roger Wood
CV Pharma Limited, High Leybourne,
Hascombe, Surrey GU8 4AD, United
Kingdom

CV Pharma Limited
High Leybourne / United Kingdom

In reference to the request of CV Pharma Limited (High Leybourne, Hascombe, Surrey GU8 4AD, United Kingdom) based on my sphere of authority in first degree proceedings on food chain safety, I issue the following

CERTIFICATION.

I renew the certification of registration of veterinary paramedical product **CV247 tablets and capsules.**

JUSTIFICATION

The National Food Chain Safety Office as registration authority renew the certification of the veterinary paramedical product CV247 tablets and capsules with registration number **253/1/2011 MgSzH ÁTI.**

The administrative fee is 20.000 (twenty-thousand) Hungarian Forints and it was paid by the applicant on 27th of September 2016.

The National Food Chain Safety Office certifies that the product called **CV247 tablets and capsules** satisfies the requirements of other veterinary medicinal products on the basis of regulation Art. 114/L.-114/Q. of Decree No. 128/2009. (X.6.) MARD (hereinafter referred to as D.).

2.

CV247 tablets and capsules as other veterinary medicinal products can be distributed freely on the basis of Art. 114/N. of the D.

The certification of registration of the veterinary paramedicinal product is valid for an unlimited time.

The approved label and product information attached to this certificate are according to the Art. 114/O. of the D.

Budapest, 10 October, 2016



Dr. Gábor Kulcsár
Director

Copies to:

1. Mr. Roger Wood (CV Pharma Limited, High Leybourne, Hascombe, Surrey GU 8 4AD)
2. Irattár

CV247 tablets and capsules

ASSESSMENT REPORT

Introduction

On 11 August 2016 CV Pharma Limited (High Leybourne, Hascombe, Surrey GU 8 4AD) submitted an application for renewal of the certification of registration of the veterinary paramedicinal product **CV247 tablets and capsules**. The applicant submitted distribution data, an assessment statement regarding the risk/benefit ratio of the product and other required documentations. The product information and the labelling remained unchanged.

Distribution data

Since the product was placed on the market in Hungary 3634 boxes have been sold. Reports about adverse events or lack of efficacy between October 2011 and August 2016 were not disclosed to the distributor. As the risk/benefit ratio of the use of the product has not changed it is not necessary to amend the product information.

The product information and the labelling are attached for approval.

Experties

I support the renewal of the certification of the product called CV247 tablets and capsules for CV Pharma Limited (High Leybourne, Hascombe, Surrey GU 8 4AD).

Justification

Based on the submitted documentations the risk/benefit ratio of the product complies with the regulation Decree 128/2009. (X. 6.) MARD. The renewal of the registration certificate can be recommended.

ENGLISH LABELLING OF THE BILINGUAL CARTON BOX

1. NAME OF THE PRODUCT

CV247 tablets and capsules

Adjuvant, immunostimulant, antioxidant and roburant mainly for dogs with cancer.



2. COMPOSITION

1 capsule contains:

Vitamin-C: 200 mg
Manganese gluconate: 10 mg
Copper gluconate: 10 mg

1 tablet contains:

Sodium salicylate 175 mg

3.-4. TARGET SPECIES, USE and DOSAGE

For dogs to be administered by mouth or in food or drink 1 capsule and 1 tablet daily for 10 Kg bodyweight. Maximum dose above 40 Kg BW: 4 capsules and 4 tablets daily.

Bodyweight	dose	frequency per day
5 kg	the contents of half capsule and half tablet	once
10 kg	one capsule and one tablet	once
20 kg	two capsules and two tablets	twice
30 kg	one kapszula and one tablet	3 times
40 kg and above	two capsules and two tablets	twice

For the administration of the product read the enclosed Instructions for Use.

5. WARNING:

Keep out of sight and reach of children!

6. EXPIRY DATE

Date of manuf.:

Expiry date:

7. STORAGE:

To be stored under 30 C in a dry area!

8. PRESENTATION

30 capsules and 30 tablets in blister packs within a shared carton

9. FOR ANIMAL TREATMENT ONLY!

FOR ANIMAL TREATMENT ONLY!

10. NAME AND ADDRESS OF DISTRIBUTOR AND MANUFACTURER

Distributor: Ad Astra-Ivy Medical Hungary Kft. (1016 Budapest, Naphegy tér 2. I.em.07.)
www.ivymedical.com

Manufacturer: Medreich PLC, 9, Royal Parade, Kew Gardens, Surrey TW9 3QD, U.K

11. BATCH NUMBER

Batch number:

12. REGISTRATION NUMBER

Reg. number: 253/1/2011 MgSzH ÁTI

13. HOLDER OF THE DOCUMENTATION

Holder of the documentation: CVPharma LTD, High Leybourne, Hascombe, Surrey GU8 4AD



DESCRIPTION AND USE OF CV247

INFORMATION FOR THE USER

Read all of this leaflet carefully because it contains important information for you. Keep this Leaflet. You may want to read this again. If you have any further questions after you have read it, ask your Vet.

PRODUCT

CV247 tablets and capsules

Adjuvant, antioxidant, roborant and immune stimulant mainly for dogs



COMPOSITION OF THE PRODUCT

1 capsule contains:

Manganese gluconate: 10 mg

Copper gluconate: 10 mg

Ascorbic Acid (Vitamin C): 200 mg

1 tablet contains:

Sodium salicylate: 175 mg

TARGET SPECIES: Dog

INDICATIONS FOR USE

A substance with therapeutic effect for the improvement of the quality of life of dogs suffering from malignant tumours and conditions. It may be advantageous for the adjuvant treatment of animals treated with chemotherapy or radiotherapy. It may prevent or delay the recurrence of tumours so treated or partially or completely removed surgically. It can be advantageous for the improvement of the condition of ailing or aged animals, for epileptic or arthritic dogs and for the stimulation of recovery and healing after illness, chemotherapy or surgery.

MECHANISM OF ACTION

Manganese and copper are essential trace elements for the functioning of enzymes (such as Superoxide Dismutase, SOD) promoting the stimulation of the immune system and antioxidation processes. In malignant neoplasia these enzymes are not functioning adequately and thus cannot prevent the damages of DNA, a frequent cause of tumour formation.

Ascorbic acid (Vitamin-C) reduces the free radicals and other harmful oxidation products in the body and stimulates the immune system. It promotes the repair processes, the regeneration of connective tissue and wound healing.

Sodium salicylate supports the anti-inflammatory processes and the reduction of pain thereby improving the quality of life of sick animals. It reduces oxidation processes by suppressing oxidising enzymes (such as cyclooxygenase, COX-2) whose excessive activity enhances DNA damaging and the proliferation of tumour cells and their blood supply. It restores the correct balance between cell proliferation and natural cell-death (apoptosis).

APPLICATION AND DOSAGE

The dose is one Essential Minerals/C-vitamin capsule and one tablet of Sodium Salicylate per day for a dog of 10 Kg bodyweight, according to the following Table:

Bodyweight	CV247 daily dosage
<5Kg	half capsule and half tablet once a day
5-15 Kg	one capsule and one tablet once a day
15-25 Kg	one capsule and one tablet twice a day
25-40 Kg	one capsule and one tablet three times a day
>40 Kg	two capsules and two tablets twice a day

When the animal responds to treatment, the frequency and dose of administration may be reduced or modified on the advice of the treating veterinary surgeon who should periodically assess progress. For the prevention of tumour recurrence a lower dosage may be sufficient.

ADMINISTRATION OF THE CAPSULE AND TABLET

- a. Either if the owner is experienced enough and the dog is placid enough, put them one by one onto the base of the tongue and then hold the mouth closed by hand for a while, until the dog swallows them. For dogs with good appetite they can be offered hidden into a piece of treat..
- b. Or open the capsule and crush the tablet, pour and mix the contents into a small amount of food BEFORE feeding, while animal still hungry.
- c. Or into a small amount of favourite fluid, juice, syrup, broth etc. and offer it to drink.
- d. Or administer this solution (from c) by a 10 cc (or so) syringe or by a spoon directly into the buccal cavity. (the mouth need not even be opened).
- e. Or put into some honey or marmite etc. and spoon feed (if the dog likes these).

CONTRAINDICATIONS:

CV247 should not be used in animals who are:

- Suffering from gastrointestinal ulceration or bleeding
- Hypersensitive to any component of the formulation
- In pregnant or lactating bitches
- Young animals less than 3 months old
- Do not administer less than 7 days before surgery

SPECIAL WARNINGS, SIDE-EFFECTS

Do not exceed recommended dose

CV247 should be used with caution for the treatment of dog varieties that could be sensitive to copper due to hereditary enzyme deficiency, such as Doberman Pinschers and Bedlington Terriers.

Gastric irritation following sodium salicylate administration may occur; seek veterinary advice if irritation occurs. Because salicylic acid may enhance the effect of certain drugs, CV247 should be co-administered cautiously with anti-coagulant drugs (such as coumarins) as salicylic acid impedes the binding of these drugs to plasma proteins. It should be given with caution with NSAID's, taking into account the total daily NSAID intake.

Hands must be washed after handling CV247.

STORAGE

The preparation is to be stored at room temperature not exceeding 25°C in dry conditions.

PRESENTATION

Outer Boks: Contains 2 inner Boxes.

Boks A: 3 blister packs of 10 tablets of 175 mg Sodium Salicylate tablets

Boks B: 3 blister packs of 10 capsules of Essential Minerals and Vitamin-C

FOR ANIMAL TREATMENT ONLY

CV247 is patented by Ivy Medical Chemicals Development Limited under Patent Number: GB2374008B

CVT

KEEP OUT OF SIGHT OF CHILDREN

DISPOSAL OF UNUSED PRODUCT: According to local rules



3.

NAME OF MANUFACTURER See Boxes

NAME OF DISTRIBUTOR: CV Pharma Representative Office, 1016 Budapest, Naphegy tér 4. I/05, Hungary. website: www.ivymedical.hu

BATCH No, MANUFACTURE, EXPIRY DATES: on cartons

NUMBER OF AUTHORISATION: 253/1/2011 MgSzH ÁTI

HOLDER: CVPHARMA Ltd, High Leybourne, Hascombe, Surrey GU8 4AD

