ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pruban 0.1 % cream for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s)

Resocortol butyrate 1 mg/g

3. PHARMACEUTICAL FORM

White to off-white cream

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use

Treatment of acute localised moist dermatitis.

4.3 Contra-indications

Do not use in dogs with extensive lesions.
Do not use in dogs with infected lesions of bacterial, viral, fungal or parasitic origin or with ulcerated lesions.
Do not use in animals suffering from Cushing's syndrome.
Do not use in puppies under 6 months of age.

4.4 Special warnings for each target species

Since glucocorticosteroids can slow growth, use in young, growing animals should be well controlled and large lesions should not be treated.

4.5 Special precaution(s) for use

Special precautions for use in animals

Lesions should be monitored closely for signs of infection. In case of diabetes mellitus, the potential systemic effects of the product may influence glycaemia.

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

This product belongs to the class of dermocorticoids. The therapeutic use of these substances in humans has been recognised to induce local side effects such as skin thinning, skin weakness, delayed healing process and secondary infections.
Avoid contact with the product. Wear disposable gloves when applying the product. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

On rare occasions hyperaemia of the treated area has been observed.

4.7 Use during pregnancy and lactation

Do not use in dogs for breeding nor in lactating or pregnant bitches.

4.8 Interaction with other veterinary medicinal products and other forms of interaction

Do not apply other topical preparations concomitantly to the same lesions.

4.9 Amounts to be administered and administration route

During initial treatment apply the cream twice daily. Apply a 1 cm strip (0.2 g) of cream per 10 cm^2 of lesion. Treat for 7 to 14 days. The treatment period should not exceed 14 days. Clean the affected areas and clip the hair covering the lesions before application. Wearing disposable gloves, apply the cream gently to the lesion. It is recommended that the animal be distracted for several minutes following treatment to prevent licking (oral absorption of the cream is not harmful to the dog, but removal of the cream by licking directly after treatment might decrease efficacy).

The dog should be re-examined by the veterinarian if the lesion is not cured after 14 days of treatment.

4.10 Overdose

The maximum total surface of lesions (treated in cm^2) should not exceed 10 times the body weight (in kg). For example, the total surface area treated of a dog weighing 5 kg should not exceed 50 cm^2).

Overdosing, i.e. application rate of more than twice a day, or extension of the duration of treatment, increases the risk of glucocorticoid systemic effects particularly when administered on extensive lesions.

4.11 Withdrawal periods

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Glucocorticosteroid, ATCvet code: QD07AC**90**.

Pruban contains the active principle resocortol butyrate. Resocortol butyrate is a corticosteroid which has a high intrinsic glucocorticoid activity. Its mineralocorticoid and progestational activity is very low.
Resocortol butyrate has local and systemic glucocorticoid effects. The expression of these effects depends on the mode of application and the dosage applied. After topical application on the skin, a local anti-inflammatory effect is seen, which is accompanied by a moderate and reversible adrenal suppression at higher doses. After oral administration in dogs few systemic effects were observed.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

None known.

6.2 Shelf-life

24 months.

Shelf-life after first opening of the tube: 8 weeks.

6.3 Special precautions for storage

Do not store above 25 °C.

6.4 Nature and composition of immediate packaging

Collapsible aluminium tube containing 15 g cream, sealed with aluminium and closed with a polyethylene screw cap, packed in cardboard boxes, one tube per box.

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

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

7. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/00/024/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16.11.2000

10 DATE OF REVISION OF THE TEXT

11 PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

D. STATEMENT OF THE MRLs

A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

The Ministerie van Landbouw, Natuurbeheer en Visserij confirmed that the manufacturing site was authorised under number 324-BVEAK for pharmaceutical products.

B. CONDITIONS OF THE MARKETING AUTHORISATION INCLUDING RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

Not applicable.

D. STATEMENT OF THE MRLs

Not applicable.

ANNEX III

LABELLING AND PACKAGE INSERT

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pruban 0.1 % cream for dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Resocortol butyrate 1mg/g

3. PHARMACEUTICAL FORM

Cream

4. PACKAGE SIZE

Tube containing 15 g of cream

5. TARGET SPECIES

Dog

6. INDICATION(S)

Treatment of acute localised moist dermatitis.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cutaneous use.
Apply to the affected skin by gently applying it to the lesion.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

This product belongs to the class of dermocorticoids. The therapeutic use of these substances in humans has been recognised to induce local side effects such as skin thinning, skin weakness, delayed healing process and secondary infections.

Avoid contact with the product. Wear disposable gloves when applying the product. Wash hands after use.

Do not use in dogs with extensive lesions. The maximum total surface of lesions (treated in cm^2) should not exceed 10 times the body weight (in kg). For example, the total surface area treated of a dog weighing 5 kg should not exceed 50 cm^2).

Do not use in dogs with infected lesions of bacterial, viral, fungal or parasitic origin or with ulcerated lesions.
Do not use in animals suffering from Cushing's syndrome.
Do not use in dogs used for breeding and in lactating or pregnant bitches.
Do not use in puppies under 6 months of age.

10. EXPIRY DATE

Month/Year
Once broached, use within 8 weeks

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF REACH AND SIGHT OF CHILDREN"

Keep out of reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

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

17. MANUFACTURER'S BATCH NUMBER

PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pruban 0.1 % cream for dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE

Resocortol butyrate 1 mg/g

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

15 g

4. ROUTE(S) OF ADMINISTRATION

Cutaneous use.

5. BATCH NUMBER

6. EXPIRY DATE

Month\Year
Once broached, use within 8 weeks

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE INSERT

PACKAGE INSERT

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

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pruban 0.1 % cream for dogs

3. STATEMENT OF THE ACTIVE SUBSTANCE

Resocortol butyrate: 1mg/g

4. INDICATION

Treatment of acute localised moist dermatitis.

5. CONTRA-INDICATIONS

Do not use in dogs with extensive lesions. The maximum total surface of lesions (treated in cm^2) should not exceed 10 times the body weight (in kg). For example, the total surface area treated of a dog weighing 5 kg should not exceed 50 cm^2).

Do not use in dogs with infected lesions of bacterial, viral, fungal or parasitic origin or with ulcerated lesions.
Do not use in animals suffering from Cushing's syndrome.
Do not use in dogs used for breeding and in lactating or pregnant bitches.
Do not use in puppies under 6 months of age.

6. ADVERSE REACTIONS

On rare occasions hyperaemia of the treated area has been observed. Lesions should be monitored closely for signs of infection. In case of diabetes mellitus, the potential systemic effects of the product may influence glycaemia.

Overdosing, i.e. application rate of more than twice a day, or extension of the duration of treatment, increases the risk of glucocorticoid systemic effects particularly when administered on extensive lesions.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

For topical administration to the skin.
Apply a 1 cm strip (0.2 g) of cream per 10 cm^2 of lesion.

9. ADVICE ON CORRECT ADMINISTRATION

During initial treatment apply the cream twice daily. Treat for 7 to 14 days. The treatment period should not exceed 14 days. Clean the affected areas and clip the hair covering the lesions before application. Wearing disposable gloves, apply the cream gently to the lesion. It is recommended that the animal be distracted for several minutes following treatment to prevent licking (oral absorption of the cream is not harmful to the dog, but removal of the cream by licking directly after treatment might decrease efficacy).

The dog should be re-examined by the veterinarian, if the lesion is not cured after 14 days of treatment.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not store above 25 °C.
Shelf life after first opening of the tube: 8 weeks

12. SPECIAL WARNINGS

After topical application on the skin, a local anti-inflammatory effect is seen, which is accompanied by a moderate and reversible adrenal suppression at higher doses. After oral administration in dogs few systemic effects were observed.

Since glucocorticosteroids can slow growth, use in young, growing animals should be well controlled and large lesions should not be treated.

This product belongs to the class of dermocorticoids. The therapeutic use of these substances in humans has been recognised to induce local side effects such as skin thinning, skin weakness, delayed healing process and secondary infections.

Avoid contact with the product. Wear disposable gloves when applying the product. Wash hands after use.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Resocortol butyrate is a corticosteroid which has a high intrinsic glucocorticoid activity. Its mineralocorticoid and progestational activity is very low. Resocortol butyrate has local and systemic glucocorticoid effects. The expression of these effects depends on the mode of application and the dosage applied.