IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10277/033/001**
Case No: 7002018

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) hereby grants to:

Schering Plough Limited

Shire Park,, **Welwyn Garden City,**, **Hertfordshire AL7 1TW**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Savlon Veterinary Antiseptic Concentrate

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Savlon Veterinary Antiseptic Concentrate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances	
Chlorhexidine gluconate solution Ph. Eur. equivalent to chlorhexidine gluconate	1.56% w/v
Strong cetrimide solution 40% w/v Ph. Eur. equivalent to cetrimide	15.00% w/v
Excipients	
Benzyl Benzoate	0.14% w/v
Sunset Yellow F.C.F. E110	0.10% w/v

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Antiseptic Concentrate

A clear deep orange liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

All species except those species used for food production.

4.2 Indications for use, specifying the target species

A general antiseptic for use in veterinary practice and on the farm.

4.3 Contraindications

Not for injection.
Do not use in animals known to be hypersensitive to the active substances.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Dilute before use.

Avoid getting solutions of Concentrate into the eyes, brain, meninges or middle ear. Avoid accidental oral, rectal or intra-uterine administration. Specific antidotes to accidental ingestion of solutions containing cetrimide are mild soap and anionic surfactants.

Instruments containing cemented glass components must not be immersed in solutions of Concentrate and prolonged immersion of rubber appliances is undesirable.

Syringes and needles which have been immersed in solutions of Concentrate must be thoroughly rinsed in sterile water or saline before use.

Hypochlorite bleaches may cause brown stains to develop in fabrics which have previously been in contact with solutions containing chlorhexidine gluconate. Cork may protect certain Gram-negative organisms from the action of antiseptics. Solutions must always be stored in glass or rubber stopped bottles.

Where it is required to leave metal instruments stored in Savlon solutions for more than eight hours, sodium nitrite 0.4% (4 x 1 g tablets in 1 litre) should be added to prevent corrosion, and the solution should be changed at weekly intervals.

Special Precautions to be taken by the Person Administering the Product to Animals

If concentrate comes into contact with skin or diluted solution comes into contact with eyes, rinse promptly and thoroughly with water.

If swallowed, wash out the mouth, drink plenty of milk or water and seek medical advice. Show the container to the doctor.

4.6 Adverse reactions (frequency and seriousness)

Strong solutions of chlorhexidine compounds can occasionally give rise to irritation of sensitive tissues such as the conjunctiva. Cetrimide is non-irritant and non-toxic to raw surfaces in the dilutions normally used for local application. Very occasionally individual animals may show some sensitivity to cetrimide, but usually only following prolonged application of solutions.

4.7 Use during pregnancy, lactation or lay

The product may be used in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

Cetrimide, like all quaternary ammonium compounds, is incompatible with soap and similar anionic compounds, with iodine and with alkali hydroxides.

4.9 Amounts to be administered and administration route

Recommended dilutions:- Dilutions are with water, unless otherwise stated.
Distilled water is preferable to tap water.

IN VETERINARY PRACTICE AND ON THE FARM

Injuries

Cleansing wounds, including those that are heavily contaminated	1 in 30
Routine antisepsis at calving or lambing and during minor operations	1 in 100

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

Strong solutions of chlorhexidine compounds can occasionally give rise to irritation of sensitive tissues such as the conjunctiva.
Very occasionally, individual animals may show some sensitivity to cetrimide, but usually following prolonged application of solutions.

Specific antidotes to accidental ingestion of solutions containing cetrimide are mild soap and anionic surfactants.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Savlon Veterinary Antiseptic Concentrate is an anti-microbial preparation with cleansing properties.

5.1 Pharmacodynamic properties

Because of their cationic nature, both chlorhexidine and cetrimide bind strongly to skin surfaces, mucosae and tissues and are therefore poorly absorbed. There are as a consequence no general pharmacological studies available on either active agent administered by this route.

5.2 Pharmacokinetic properties

Radio-labelled chlorhexidine studies in rat, dog, marmoset and rhesus monkey have indicated that chlorhexidine is very poorly absorbed, urinary excretion following oral administration of [^{14}C] chlorhexidine being less than 2% of the dose and biliary excretion being minimal. The one major component found in faeces is chlorhexidine. These data indicate a very low absorption (< 1%) and there is no reason to suspect that any other species will differ in this respect.
Following single oral dosing in rodents (up to 50 mg/kg), excretion studies detected residual [^{14}C] material in the liver and kidneys but not in other tissues.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Industrial methylated spirits 74 OP
Isopropyl Alcohol
Terpineol
Liquid deodoriser S-05372 C/L
Benzyl Benzoate
Sunset Yellow F.C.F. E110
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf-life

The shelf-life of this product shall not exceed 4 years from the date of its manufacture.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

5 L high density polyethylene containers with polyethylene closures.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements.
Do not contaminate ponds, waterways or ditches with this product or used containers.

7 MARKETING AUTHORISATION HOLDER

Schering-Plough Limited,
Schering-Plough House,
Shire Park,
Welwyn Garden City,
Hertfordshire, AL7 1TW,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10277/33/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2001