Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Scabivax Contagious pustular dermatitis (Orf) vaccine
Suspension for skin scarification

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

per dose (0.03 ml)	
Active substance(s)	
Contagious pustular dermatitis virus minimum	100 MID[1]
Excipient(s)	
Green dye (E142)	6.0 micrograms

[1] - Minimum Infective Dose

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Suspension for skin scarifacation.

A green-coloured suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep/lambs from 2 days old.

4.2 Indications for use, specifying the target species

Active immunisation of sheep to reduce the lesions of Orf. Immunity develops in approximately 2 weeks, and the vaccine provides protection for at least 6 months.

4.3 Contraindications

Do not use on farms or in flocks where Orf is not a problem.
Do not vaccinate ewes less than 8 weeks before lambing.

4.4 Special warnings for each target species

Animals may develop Orf subsequent to vaccination but the severity and duration for the disease is usually less than in non-vaccinated animals.
In a disease outbreak draft off all affected animals, keep in isolation from the main flock. The remainder of the flock should be vaccinated as soon as possible.
However, some animals may show typical signs of Orf following vaccination due to infection becoming established before immunity develops. These animals should also be drafted into the isolated group of infected sheep.

4.5 Special precautions for use

i) Special precautions for use in animals

For a period of 8 weeks subsequent to vaccination, animals will shed virus and virus infected scabs. During this period vaccinated ewes should not be given access to the lambing pens or pasture where ewes and their lambs will subsequently be grazed.
Vaccinated animals should not be allowed to come into contact with unvaccinated animals for at least eight weeks after vaccination.
Experience suggests that where Orf is a problem in ewes and/or lambs in a lambing flock, vaccination of both ewes and lambs is necessary.
Vaccination of young lambs may cause spread of the disease to ewes' udders.
The vaccine virus has the potential to spread. There is a possibility that the vaccine virus may infect dogs if fed unskinned sheep carcases from recently vaccinated animals.
Human Orf infection through cuts on arms and hands can occur following contact with recently vaccinated sheep.
There is a possibility that vaccine virus may spread from vaccinated sheep to susceptible goats.

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

Orf is transmissible to man, therefore care should be taken when handling or using the vaccine.
Vaccinators should wear gloves during vaccination and the hands and arms should be carefully washed after vaccination has been completed.
Special care should be taken to avoid contamination if any cuts or scratches are present on the hands.
Accidental self-administration should be followed by disinfection of the wound with a hypochlorite preparation.
If lesion develops, seek medical advice and show package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Since Scabivax contains a living strain of the Orf virus, most of the vaccinated sheep may develop mild local lesions shortly after vaccination. These will resolve within 4 weeks but some scabs may persist for 5 weeks.
Pyrexia may occur 9-14 days following vaccination, which will resolve within 5 days.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy up to 8 weeks before lambing.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either used on the same day or at different times) has not been demonstrated.

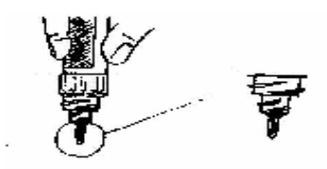
Care should be taken to avoid treatment of the animals near the period of vaccination with substances or medicaments that might interfere with the "take" of this live vaccine.

4.9 Amounts to be administered and administration route

Basic Vaccination Scheme:
Scabivax should be used 3-4 weeks before the disease symptoms normally develop, typically in fattening lambs in autumn and in new born lambs in spring.
Lambs may be vaccinated from 2 days old.
Ewes should be vaccinated before disease is anticipated.

Administration:

Unscrew outer and inner seal caps to expose wire prongs.



Invert and tap the applicator to allow a droplet of vaccine to fall onto the vaccination site.

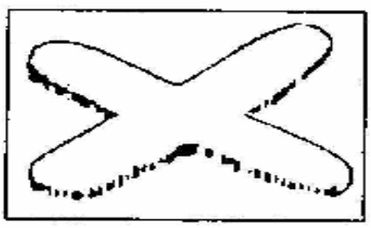
Mark thighs with two scratches in X formation through the droplet.

The recommended sites of vaccination are:

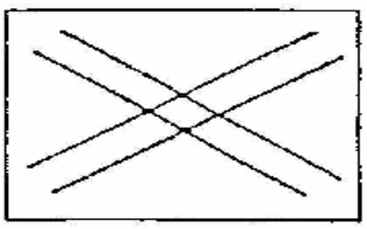
1. Pregnant ewes, or ewes with lambs at foot should be vaccinated on the outside of the fold of skin found on either side of the underside of the base of the tail. This minimises the handling of pregnant ewes and in those with lambs at foot reduces the chance of lambs becoming infected through contact with the ewes vaccination site.
2. Young (i.e. unweaned) lambs should be vaccinated on the skin between the top of the foreleg and the chest wall, as this area is seldom nuzzled by other lambs or ewes.
3. Older lambs and other classes of ewes can conveniently be vaccinated on the skin of the inner aspect of the thigh.

Special Notes:

1. Where lambs of less than 14 days of age are being vaccinated it is suggested that only one vaccination scratch is applied rather than a cross being applied.
2. Before each scratch make sure that the end of the applicator is loaded with vaccine.
3. Make the scratch in the skin sufficiently deep to ensure that the surface is broken and that the vaccine is deposited in the scratch. If the vaccine has been correctly applied the vaccine colouration should be apparent along the entire length of each scratch.
4. The flow of vaccine may reduce or stop due to the build up of grease and/or wool on the prongs. If this occurs, clean the prongs with a tissue and move the wire up and down in the applicator.
5. Scabivax is a living virus vaccine and the vaccination site must not be contaminated with disinfectants or insecticides (dips) as these would inactivate the vaccine.
6. Between 7 and 10 days after vaccination a random sample of the flock should be examined to ensure that there has been a satisfactory vaccine ‘take’. This appears as a raised area of the skin, whitish in colour. The thin brown line of a healing scratch is not sufficient. Sheep which do not show a satisfactory reaction may have developed immunity prior to vaccination but should be revaccinated in case the failure of a satisfactory ‘take’ was due to faulty vaccination technique.



Successful Take
Raised area of skin whitish in colour



Unsuccessful Take
Thin brown line of healing scratch

7. The vaccination of housed lambs should be delayed where possible until turnout to avoid contamination of the buildings.

Re-vaccination Scheme:
On most properties Orf is only a problem during a limited period of the year and annual vaccination usually proves adequate. However, in circumstances where a severe and constant disease risk exists booster doses should be given at 5-6 monthly intervals.

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

The application of more than one drop of vaccine (overdose) has no adverse effect on the animal other than as described in section 4.6.

4.11 Withdrawal Period(s)

8 weeks

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Live viral vaccine. ATCvet Code: QI04AD01
To stimulate active immunity against contagious pustular dermatitis virus

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Neomycin Sulphate
Nystatin
Polymyxin B Sulphate
Green dye (E142)
Phosphate buffered saline

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 9 months.
Once opened, use immediately

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C).
Protect from light.

6.5 Nature and composition of immediate packaging

1 x 50 dose applicator pack consisting of a plastic vial and integral applicator. The applicator consists of wire prongs inserted into a base cap, the protruding tips protected by a seal cap, and covered by an outer cap. The vial contains 1.8 ml of vaccine.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/256/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5th February 2009

10 DATE OF REVISION OF THE TEXT

June 2012