SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Scabigard cutaneous suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.02 ml dose contains:

Active substance:
Orf virus $10^{5.4}$ - $10^{6.5}$ $TCID_{50}$

Excipients:

Qualitative composition of excipients and other constituents
Patent Blue V (E 131)
HEPES buffer
Sodium hydrogen carbonate
Eagles Minimum essential medium with non-essential amino acids
Foetal bovine serum
NZ Amine type B
Sucrose
Gelatin
Glutamine
Glycerol
Water for injections

Clear blue-green liquid.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

For the active immunisation of sheep and lambs against orf to reduce clinical signs and/or lesions of the disease.

Onset of immunity: 4 - 8 weeks.
Duration of immunity: at least 1 year.

3.3 Contraindications

Do not use this vaccine on farms or in flocks where orf disease is not a problem.
Do not vaccinate ewes less than 7 weeks before lambing.
Do not vaccinate pregnant ewes except at the recommended stage of pregnancy.
Do not vaccinate ewes or lambs during wet weather.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
The veterinary immunological product is a live virus vaccine, and thus care must be taken to apply the vaccine only to the intended vaccination site and to not contaminate other sites such as mouth, feet, superficial wounds or abraded skin of the animal. Vaccinated lambs may transmit the disease to ewes' udders.

Ewes that are vaccinated prior to lambing should not be moved to the proposed place of lambing until sufficient time has passed for the scabs to drop off (minimum of 7 weeks).
Where indoor housing is practiced, routine cleansing and disinfection of the premises is an important aid in the control of orf. In cases where vaccination of lambs cannot be delayed until turnout, veterinary advice should be sought as to how to minimise the risk of infection.
Ewes with unvaccinated lambs at foot are best to have their vaccination delayed until the lambs are weaned, except in case of emergency. Vaccinate these ewes as for pregnant ewes.

For a period of up to 7 weeks after vaccination, or until the scabs resulting from the vaccine "take" have dropped totally, animals will be shedding virus infected scabs. During this time, vaccinated animals should not be:

- allowed access to lambing pens or pasture where ewes and their lambs will subsequently be grazed,
- allowed to come into contact with unvaccinated sheep and susceptible species,
- marketed, slaughtered or shorn.

Vaccination of ewes before lambing will not provide protective immunity to the lambs via the colostrum. Therefore, if orf disease is a problem in the lamb flock as well, the lambs should also be vaccinated to ensure protection throughout the entire flock.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Orf disease is caused by a virus which is communicable to man. The vaccine is capable of causing a skin infection in humans so should not be used by immuno-suppressed individuals.

In the case of accidental self-administration (injection or scratch), ingestion or spillage onto the skin or into the eye, seek medical advice immediately and show the package leaflet or the label to the physician.

Personal protective equipment consisting of rubber gloves should be worn when handling the veterinary immunological product or dismantling the applicator. Wash hands and arms after vaccination.

Special precautions for the protection of the environment:
Care must be taken not to contaminate the ground area with vaccine or used materials due to the persistence of orf virus in the environment.

3.6 Adverse events

Sheep:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site lump, injection site swelling, injection site granuloma Bacterial skin infection[1]

[1] Specific therapy may be required.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used 7-8 weeks prior to lambing. Do not vaccinate pregnant ewes except at this recommended stage of pregnancy.

Lactation:
Can be used during lactation. Vaccinate ewes with lambs at foot only at the recommended site.

3.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.

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.

3.9 Administration routes and dosage

Dose: 0.02 ml.
Administration: by skin scarification.

This vaccine must be administered to sheep and lambs using an applicator, such as the Scabigard Applicator, that dispenses a 0.02 ml dose of vaccine and prevents back flush.

At the site of vaccination, erythema local to the line(s) of scarification are to be expected as the initial, observable effect, days 1-14 post-vaccination. Vesicles and pustules may then be observed, from approximately day 3-14 post-vaccination, and restricted to the site of scarification. Rupture of these vesicles and pustules, and scab formation, can be expected from about day 7 post-vaccination. These effects are expected in up to 100% of animals treated and are commonly referred to as vaccine "take"; they indicate successful vaccination. In susceptible animals (those at risk of orf virus infection) the aim is to obtain a "take" in each animal vaccinated.

Susceptible sheep or lambs must "take" in order to become immunised against orf disease. Failure to "take" may be due to poor vaccination technique, improper handling of the vaccine resulting in loss of potency, or because the sheep are already immune. Revaccination once should be considered where a "take" has not occurred.

It is strongly recommended that the effectiveness of vaccination be assessed by examination of a selected group of sheep and/or lambs, one week to 10 days after vaccination. A more or less continuous line of pustules should be visible along the track of the scratch made on the skin. The pustules progress to form scabs which gradually dry and fall off by 7 weeks after vaccination.

Treatment of Ewes (site and method of administration):
Do not vaccinate ewes less than 7 weeks before lambing. The site of administration is behind the elbow or in the axilla (i.e., between the top of the foreleg and the chest wall), to prevent infection of the udder and subsequent transmission to lambs. Refer to Figure 1 below.

Treatment of Lambs (site and method of administration):
Lambs may be vaccinated at any time from birth. Young (i.e. unweaned) lambs should be vaccinated in the axilla. Refer to Figure 1.

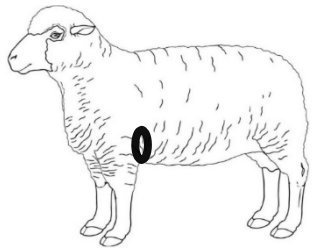

Figure 1: Correct site for vaccine administration.

Vaccinate behind the elbow, in the hairless skin of the axilla.

Restrain the lamb or sheep over a rail or similar with the bare skin exposed. To apply the vaccine, place the Applicator prongs onto the skin and commence making a 4 to 5 cm scratch. The vaccine dose will be evenly deposited along the scratch. The

Applicator must be held at an angle to the skin (approximately 45 degrees). Press firmly to ensure there is sufficient skin damage to enable an effective vaccination "take". The scratch should be just sufficient to break the top layer of the skin but not deep enough to draw blood.

Recommendations when using the Scabigard Applicator:

- Place the vaccine bottle into the plastic sleeve supplied with the Applicator.
- Ensure the Applicator is in an upright position, to avoid scratching the operator.
- Push the bottle, now inside the sleeve, firmly onto the draw off needle until it can go no further.
- Ensure the needle punctures the centre of the rubber circle on the top of the bottle.
- In order to prime the Applicator for vaccine application, ensure the Applicator is in the locked position. Holding the vaccinator so that it points to the ground, press down on the base of the vaccine bottle in a "pump like" action. Priming should take approximately 10 pumps. When the vaccine flows onto the scratcher prongs, the Applicator is primed and ready for use.
- The small drop of liquid, measured to a precise dose, is supported by the Applicator prongs until the product is applied.
- Prior to vaccination of each subsequent animal, the Applicator must be pumped once to recharge the Applicator prongs with a precise dose of vaccine.
- Prior to first vaccination and each subsequent vaccination session, and at the end of each vaccination session, the Applicator should be (re)sterilised. Do not use disinfectants to clean the Applicator as residues may harm the vaccine when next used.
- As frequently as required, wipe the Applicator tip on a piece of cottonwool or tissue to remove grease, dirt and wool collected from the sheep's skin, taking care not to contaminate the hands. It is advisable to have a plastic bag open and pinned up to receive used materials. Sterilise used materials as soon as possible after use.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None known.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

Live viral vaccine.

4.1 ATCvet code: QI04AD01.

To stimulate active immunity against contagious pustular dermatitis (orf) virus.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

Do not administer or treat with surface-active agents such as antiseptics, sprays or dips within 7 days before or after administration of the vaccine. Do not administer corticosteroids or other immunosuppressive drugs within 28 days before or after administration of the vaccine.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 8 hours.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Protect from light.
This product does not contain preservative to reduce or stop micro-organism growth. Therefore, the in-use shelf life and storage conditions must be strictly adhered to.

5.4 Nature and composition of immediate packaging

Cardboard box with 1 glass bottle containing 50 doses of liquid vaccine, sealed with a rubber stopper and aluminium cap.

The Scabigard Applicator is supplied separately.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 42058/5173

8. DATE OF FIRST AUTHORISATION

22 September 2003

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

October 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 22 February 2026