# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Scabigard

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

per dose of 0.02 mL

**Active ingredient**
Orf virus $10^{5.4}$ - $10^{6.5}$ $TCID_{50}$

**Excipients**
For a full list of excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Solution for cutaneous administration

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Sheep.

### 4.2 Indications for use, specifying the target species

For the active immunisation of sheep and lambs against Orf to reduce clinical signs and/or lesions of the disease.
Immunity develops within 4-8 weeks of vaccination and is protective against severe signs of contagious pustular dermatitis for at least 12 months.

### 4.3 Contraindications

The vaccine should not be used 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.

### 4.4 Special warnings for each target species.

None

### 4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals

i. Special precautions for use in animals

Scabigard 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.

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.
Do not vaccinate ewes or lambs during wet weather.
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.

ii. Special precautions to be taken by the person administering the 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 insert or label to the physician. Rubber gloves should be worn when handling this product or dismantling the Applicator. Hands and arms should be washed after vaccination.

## 4.6 Adverse reactions (frequency and seriousness)

Effects that characterise the vaccine "take" are described in section 4.9.

Secondary bacterial infection may be observed in association with the scarification wounds; specific therapy may be required.

In post marketing experience, injection site reactions, such as a lump, swelling and in some cases granulomatous lesions at the site of skin scarification were observed very rarely.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

## 4.7 Use during pregnancy, lactation or lay

No adverse effect has been recorded as a result of the use of this vaccine during pregnancy, at 7-8 weeks prior to lambing; do not use within 7 weeks of lambing. Do not use in other stages of pregnancy.

Lactating ewes can be vaccinated; ewes with lambs at foot should only be vaccinated at the recommended site.

## 4.8 Interaction with other medications

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.

## 4.9 Amounts to be administered and administration route

Dosage: 0.02 ml administered 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. Refer to Section 4.5 ii) for information on risks to the operator.

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):**
Vaccinate pregnant ewes 7-8 weeks before lambing. 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 (ie. unweaned) lambs should be vaccinated in the axilla. Refer to Figure 1.

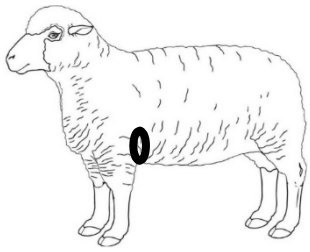

Figure 1: Correct site for vaccine administration.

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 cotton-wool 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. Burn or sterilise used materials as soon as possible after use.

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

None known

### 4.11 Withdrawal period

Zero days.

## 5. IMMUNOLOGICAL PROPERTIES

Live viral vaccine.

**ATC vet code:** QI04AD01.

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

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

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

## 6.2 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.

## 6.3 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

## 6.4 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.

## 6.5 Nature and composition of the 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.

## 6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

# 7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

## 8. MARKETING AUTHORISATION NUMBER

Vm 42058/5173

## 9. DATE OF FIRST AUTHORISATION

22 September 2003

## 10. DATE OF REVISION OF THE TEXT

November 2024

*Gavin Hall*

Approved 15 November 2024