PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Scabigard

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contagious pustular dermatitis vaccine, living (Orf vaccine)
Content per dose (0.02 ml): *Contagious pustular dermatitis (Orf) virus*, $10^{5.4}$ $TCID_{50}$

3. PHARMACEUTICAL FORM

Suspension for cutaneous administration

4. PACKAGE SIZE

50 doses

5. TARGET SPECIES

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero Days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental self-administration is dangerous.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated. Protect from light.
In-use shelf life: 8 hours
Keep the container in the outer carton.

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

Read package leaflet before use..

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

FOR ANIMAL TREATMENT ONLY

POM-V

To be supplied only on veterinary prescription

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

Keep out of the sight and reach of children**.**

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4213

17. MANUFACTURER'S BATCH NUMBER

Batch No.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Scabigard

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Orf virus, $10^{5.4}$ $TCID_{50}$ / dose

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

50 Doses

4. ROUTE(S) OF ADMINISTRATION

For skin scarification in sheep.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero Days

6. BATCH NUMBER

Batch No.

7. EXPIRY DATE

Expiry date:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

POM-V

Vm 42058/4213

Store and transport refrigerated.

Protect from light.

PACKAGE LEAFLET FOR:

Scabigard

Solution for cutaneous administration

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

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

Manufacturer responsible for batch release
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Scabigard
Solution for cutaneous administration

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Active ingredient per dose of 0.02 ml:
Orf virus $10^{5.4}$ - $10^{6.5}$ $TCID_{50}$

4. INDICATION(S)

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.

5. 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.

6. ADVERSE REACTIONS

Effects that characterise the vaccine “take” are described in the section ‘Dosage for each species, route(s) and method of administration’.
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).

7. TARGET SPECIES

Sheep.

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

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.
Refer to Section Operator warnings below 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.

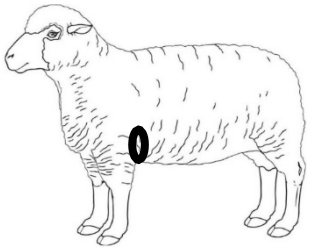


Figure 1: Correct site for vaccine administration.

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.
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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Zero Days.

11. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2°C - 8°C). Protect from light.
Shelf life after first opening the immediate packaging: 8 hours.
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.

Keep out of the sight and reach of children.
Keep the container in the outer carton.

12. SPECIAL WARNING(S)

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.
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.

Operator warnings
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 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.

Interactions
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.
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.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2022

15. OTHER INFORMATION

For animal treatment only.

LEGAL CATEGORY: POM-V

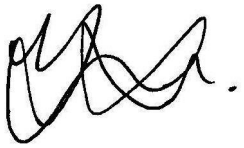
To be supplied only on veterinary prescription.

Pack sizes

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.

MA number: Vm 42058/4213



Approved: 22 June 2022