



Australian Pesticides &
Veterinary Medicines Authority

Product Name: SIMPLSEAL
APVMA Approval No: 91411/150493

Label Name:	SIMPLSEAL
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Signal Headings:	FOR ANIMAL TREATMENT ONLY READ SAFETY DIRECTIONS BEFORE OPENING OR USING
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Constituent Statements:	650 mg/g BISMUTH SUBNITRATE
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Claims:	For the prevention of clinical and subclinical mastitis in dairy cows during the non-lactating (dry) period and early post-calving.
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Net Contents:	120 x 4 g syringes 144 x 4 g syringes 864 x 4 g syringes Illegal to sell syringe separately.
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Directions for Use:	
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Restrains:	DO NOT USE in lactating cows.
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Contraindications:	
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Precautions:	
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Side Effects:	
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Dosage and Administration:	During the administration of the product it is important to ensure that infection is not introduced. Accidental introduction of bacteria into the quarter during insertion of the intramammary syringe can result in serious mastitis. Thoroughly clean hands prior to administration and wear clean gloves during administration. Immediately after the last
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milking at drying off, prior to treatment with SIMPLSEAL, the udder should be stripped and each teat thoroughly cleaned with a suitable disinfectant.

Carefully infuse the entire contents of one injector into each teat to form a seal, preventing the ingress of pathogenic bacteria into the udder during the dry period.

After infusion, do not massage or squeeze the teat as this may dislodge the seal.

It is recommended that SIMPLSEAL be used as part of a herd approach to dry cow management and mastitis control. Cows considered likely to be free of subclinical mastitis and at risk for new infection in the dry period should be given SIMPLSEAL at drying off. Other animals should be managed in accordance with an approved mastitis control plan or specific veterinary advice.

For practical purposes, selection criteria may be based on the mastitis and cell count history of individual cows, or recognised tests for the detection of subclinical mastitis, or bacteriological sampling. As a guide, where there has been no episode of clinical mastitis and at least three individual cow cell counts are available, cows with all cell counts below 250,000 cells/mL may be given SIMPLSEAL.

Maiden heifers (first calvers): Administer SIMPLSEAL approximately 4 weeks prior to calving to reduce the risk of post-calving mastitis.

Use in combination with antibiotic therapy: In cows that have sub-clinical mastitis, SIMPLSEAL may be used following administration of a suitable dry cow antibiotic treatment to the infected quarter. The dry cow antibiotics should be administered in accordance with the product label and massaged into the quarter. Following administration redisinfect the teat and infuse SIMPLSEAL as recommended above. After SIMPLSEAL infusion, do not massage or squeeze the teat as this may dislodge the seal.

General Directions:

Milking machine advice: To reduce the potential for SIMPLSEAL accumulation in milking machines and reduce the risk of particles entering milk in the vat, thoroughly hand-strip SIMPLSEAL out of each quarter, 10 to 12 strips per quarter, at the first milking of fresh cows. Where possible, avoid removal of SIMPLSEAL by the milking machine. Keep milk from fresh cows out of the vat for a minimum of 8 milkings (10 milkings in induced cows) or in line with industry standards designed to minimise colostrums entering milk for processing. If possible, use designated clusters and test buckets during this time to minimise adherence to rubberware and milk lines. Clean milking equipment carefully to prevent particles entering the vat. Change filter socks regularly, particularly if residual teat sealant is visible on the filter.

SIMPLSEAL is designed to sit in the teat canal during the dry period. This means that the administration process should focus on ensuring that the product does not travel up in the higher udder tissue. This is in contrast to the administration of antibiotic dry cow therapy which is required to be infused into the udder tissue to ensure efficacy and duration of treatment. Care should be taken when administering SIMPLSEAL to ensure that it stays in the teat canal. Failure to do this may mean that the product has reduced efficacy and may not be fully removed by 8 milkings.

Key points:

- * Plan for the time and labour that treatment takes.
- * More than one person is often needed to do the job well.
- * Ensure people administering SIMPLSEAL are trained adequately in the procedure.
- * Keep the number of cows to be treated after any one milking to a manageable number.

SIMPLSEAL Infusion Instructions:

Thoroughly clean hands prior to administration and wear clean gloves during administration. Immediately after the last milking at drying off, prior to treatment with SIMPLSEAL, the udder should be stripped and each teat thoroughly cleaned with a suitable disinfectant.

After infusion, do not massage or squeeze the teat as this may dislodge the seal.

1. Hygiene: Ensure animals are appropriately restrained in hygienic conditions. Keep syringes clean and DO NOT immerse in water.
2. Clean and dry: The teats should be clean and dry prior to disinfection. If the teats are not clean, wash and dry prior to disinfection.
3. Disinfection Technique: Wearing gloves, thoroughly scrub teat ends with alcohol impregnated wipes (one per teat) and leave to air dry. First, disinfect the two teats further away, then the two closest. Take care to avoid contamination of disinfected teats.
4. Insertion: Ensure teats are dry before insertion. Take care to avoid contamination of the syringe nozzle. Careful insertion of the SIMPLSEAL syringe nozzle with minimum penetration into the teat canal is recommended. Insert SIMPLSEAL into the teats in the opposite order to disinfection. i.e. closest two teats first, then the two furthest away. While administering, gently close off the top of the teat (closest to the udder) when inserting the syringe nozzle to encourage product to remain in the teat cistern and canal, rather than in the udder. Do not massage the teat or udder after insertion of SIMPLSEAL.
5. Teat Spray: After treating each cow, spray teat with your normal teat sanitiser, and mark treated cows with spray mark, raddle or similar.

Administering SIMPLSEAL

<Diagram 1>

SIMPLSEAL Removal in Fresh Cows

1. At the first milking, strip each treated quarter at least 10-12 times or until all SIMPLSEAL has been removed – wear gloves.
2. Keep milk from fresh cows out of the vat for at least 8 milkings after calving (10 milkings for induced cows).
3. Preferably use designated clusters and test buckets for the first 8 milkings. Avoid running milk from SIMPLSEAL treated animals through milk lines during this time.
4. Change filter socks after each milking. Clean milking equipment according to milk factory guidelines, to minimise potential residual buildup of SIMPLSEAL.

Key points:

- * You must remove SIMPLSEAL in fresh cows.
- * Change filter socks after each milking.

This section contains file attachment.

Withholding Periods:	MILK: DO NOT USE in lactating cows or within 4 days of calving. After calving, colostrum or milk from treated dry cows MUST NOT BE USED or processed for human consumption for 96 hours (8 milkings). If premature or unscheduled calving occurs, consult the prescribing veterinarian for advice on handling milk for bobby calves. MEAT: Zero (0) days.
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Trade Advice:	EXPORT SLAUGHTER INTERVAL (ESI): Zero (0) days. Before using this product, confirm the current ESI from Alleva Animal Health on 1-800 ALLEVA (1-800 255 382) or the APVMA website (apvma.gov.au/residues).
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Safety Directions:	May irritate the eyes and skin. Avoid contact with eyes and skin. When using the product, wear disposable gloves. Wash hands after use.
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First Aid Instructions:	First aid is not generally required. If in doubt, contact a Poisons Information Centre (phone Australia 13 11 26) or a doctor.
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First Aid Warnings:	
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Additional User Safety:	Additional information is listed in the safety data sheet (SDS).
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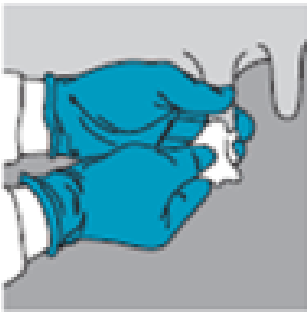
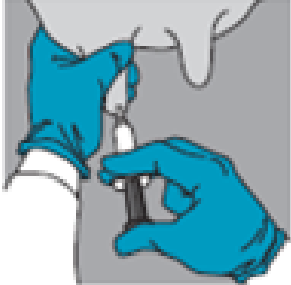

Environmental Statements:	
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Disposal:	Dispose of container by wrapping with paper and putting in garbage.
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Storage:	Store below 30 °C (room temperature).
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General Directions

Diagram 1. Administering SIMPLSEAL

<p>1. Wear gloves. Completely disinfect teat ends – a critical step. Use surgical spirit or alcohol teat wipes (one per teat) and leave to air dry. Start with the teats furthest away.</p>	
<p>2. SIMPLSEAL should be infused so that it remains in the teat canal. Grasp the top of the teat where it joins the udder to prevent SIMPLSEAL from leaving the teat canal. Insert tip of syringe nozzle and gently depress plunger until entire contents have been infused. Discard tube if nozzle is contaminated.</p>	
<p>3. DO NOT massage the teat or udder. SIMPLSEAL must remain in the lower part of the teat. Disinfect with a teat dip or spray.</p>	
<p>4. DO NOT allow animals to lie down on bare ground or in soiled areas for two hours after treatment. Once the group has been treated, walk directly to a clean pasture. Try to minimise the distance walked.</p>	