



**Company Name:** SYNTEX S.A.  
**Product Name:** SYNTEX INTRAVAGINAL DEVICE (DIB)  
**eLabel Application No:** DCNV-27772591E18

<b>Label Name:</b>	DIB-V
<b>Signal Headings:</b>	CAUTION KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY
<b>Constituent Statements:</b>	1 g/Dv PROGESTERONE
<b>Claims:</b>	Intravaginal progesterone device for the regulation of oestrus, treatment of post-partum anoestrus and reduction of calving to conception interval in heifers and cows.
<b>Net Contents:</b>	10 x 30g devices
<b>Directions for Use:</b>	
<b>Restraints:</b>	
<b>Contraindications:</b>	Contraindicated for use in sexually immature heifers. Contraindicated for use in animals with genital infections or abnormal genital tracts. Contraindicated for use less than 21 days after calving.
<b>Precautions:</b>	Animals in poor condition from illness, nutritional or management stress may not respond. Not licensed for re-use.
<b>Side Effects:</b>	
<b>Dosage and Administration:</b>	Oestrus synchronisation and resynchronisation programs and those designed for the treatment of post-partum anoestrus in cows should be carried out in consultation with a registered veterinarian. 1. FOR SYNCHRONISATION OF OESTRUS Insert DIB-V using an approved applicator. Inject the cow with 2 mg of oestradiol benzoate at insertion. Remove the DIB-V 7 days after insertion and inject cow with PGF2a (or

analogue) at manufacturer's recommended dose. Administer 1 mg oestradiol benzoate 24 hours later. If fixed time AI is to be used then it should be carried out at 52-56 hours after device removal.

#### 2. TREATMENT OF POST-PARTUM ANOESTRUS

Insert DIB-V using an approved applicator. Inject the cow with 2 mg of oestradiol benzoate at insertion. Remove the DIB-V 8 days after insertion and inject cow with PGF2a (or analogue) at manufacturer's recommended dose and 400 to 500IU of equine chorionic gonadotrophin. Administer 1 mg of oestradiol benzoate 24 hours after device removal.

#### 3. RESYNCHRONISATION OF OESTRUS

Insert a new DIB-V using an approved applicator 13 days after the first insemination. Inject the cow with 1 mg of oestradiol benzoate at the time of insertion of the device. Remove the DIB-V 7 days after insertion. Administer 0.5 mg oestradiol benzoate 24 hours later. Cows can inseminated upon detected oestrus on-days 21 to 25.

#### 4. VETERINARY SPECIALIST USE

DIB-V will normally elevate plasma progesterone levels to a minimum of 2 ng/mL for the first 3 days of treatment and above 1.5 ng/mL on day 7. It may be used for specialist treatments where priming at these levels is beneficial, but only under specialist veterinary supervision.

**WARNING:** This device may cause vaginal irritation in some cows and heifers which may be manifested by cloudy or bloody mucus on the outside of the device on removal. This reaction is generally self limiting and usually clears between the time of device removal and insemination.

#### General Directions:

Wear protective gloves when handling the devices.

1. Dip the device applicator in a non-irritating antiseptic solution.
2. Place one device into the applicator so the wings are folded and only the tips of these wings protrude from the front of the applicator.
3. Dip the front portion of the loaded applicator into a suitable veterinary obstetrical lubricant.
4. Lift the tail of the animal and wipe the vulva lips clean with disposable tissues.
5. With the tail lifted, insert the loaded applicator, sloping slightly upwards, through the vulva and then forward, without forcing, into the forward portion of the vagina.
6. Release the removal tail, grasp the handle of the plunger and ease back the barrel of the applicator towards the handle.
7. With the device correctly placed with the wings opened in the front portion of the vagina, only the removal tail should be hanging from the vulva.
8. Repeat STEP 1 before re-using the applicator.

Removal:

1. Withdraw each device by a gradual pull on the removal tail.

#### Withholding Periods:

Meat: 0 days, Milk: 0 days. Inserts should always be removed at least 24 hours before slaughter.

#### Trade Advice:

EXPORT SLAUGHTER INTERVAL (ESI): 0 days.

The ESI on this label was correct at the time of label approval. Before using this product confirm the current ESI with the distributor on 1800 038 037 or the APVMA website (<http://www.apvma.gov.au/residues>).

#### Safety Directions:

#### First Aid Instructions:

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.

<b>First Aid Warnings:</b>	
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<b>Additional User Safety:</b>	
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<b>Environmental Statements:</b>	
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<b>Disposal:</b>	Dispose of empty container and used devices by wrapping with paper and putting in garbage.
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<b>Storage:</b>	Store below 25°C (Air conditioning).
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