DIB

Introduction:

DIB is an intravaginal device which contains progesterone and is used to synchronize estrus in cattle.

Action:

The progesterone released by the device has a marked effect on ovarian follicular dynamics. The supraluteal levels of serum progesterone (>1ng/ml) seen a few minutes after the introduction of the device cause the regression of the dominant follicle and accelerate the appearance of new follicular waves. The discontinuation of secretion of follicular products (estrogen and inhibin) increase the secretion of FSH which will causes a fall in progesterone to subluteal levels (<1ng/ml) which induces an increase in the frequency of LH pulses and the growth and persistence of the dominant follicle with very high concentrations of estradiol which induce estrus and a peak of LH followed by ovulation.

Formula:

Progesterone.....1 g

Silicone …….. .... e.q.

Species which the veterinary medicinal product is intended for:

Bovine

Therapeutic indications:

- Regulation of the oestrus cycle in heifers and cows.
- Treatment of post-partum anoestrus.
- Decrease of the period to next occurring pregnancy.

Dosage:

This product must be used according to the following program:

Indication	Day 0	Day 6	Day 7	Day 8	Day 9	Day 10
Anoestrus	ID+EB2			RD+eCG+PG	EB1	AI
Silent heats	ID+EB2	PG	RD		AI	
Ovarian Cysts	ID		PG		RD	AI
Oestrus Synchronization	ID+EB2		RD+PG	EB1	FTAI	

References:

ID= insert device

RD= remove device

EB1= 1 mg estradiol benzoate

EB2= 2 mg estradiol benzoate

eCG= 400 – 500 IU of eCG

PG= 500 µg Cloprostenol

In heifers reduce dose in both cases.

AI= artificial insemination

FTAI= fixed time artificial insemination

Resynchronization of return to breeding:

It is possible to resynchronize cattle to detect non-pregnant cows. To achieve this devices are re-inserted on day 13 (day 0= artificial insemination), remove on day 20 and the cows are inseminated upon detected estrus on day 21 to 25.

The programs for the use of this product may be modified according to veterinary advice.

Route of administration:

Intravaginal

Toxicity data:

The product has a wide safety margin.

From tolerance studies with target animals it appears that progesterone containing formulations are generally well tolerated.

Data on teratogenicity/ embryotoxicity reveal that no congenital disorders are found after treatment with natural progesterone.

According to the International Agency for the research on Cancer (IARC), progesterone does not exhibit mutagenic activity in most *in vitro* and *in vivo* test performed.

DL_{50} (rabbits) IV = 26.5 mg/kg

DL_{50} (rats) IP = 327 mg/kg

DL_{50} (mouse) IV = 100 mg/kg

DL_{50} (neonate) SC = 70 mg/kg

Pharmaceutical form:

Intravaginal devices

Commercial presentation:

-Bag containing 10 intravaginal devices with Progesterone 1 g each one and 10 removal tails to identify the used device.

Withdrawal period:

MEAT: 0 days.

MILK: 0 days.

Inserts should always be removed at least 24 hours before slaughter.

Precautions:

- Store below 25°C (air conditioning).
- In transport, should be kept in a cool, dry place and protected from light.
- Used devices and packaging should be burnt in an appropriate incinerator, buried in an approved landfill, or disposed of by approved methods.

PRODUCT USE FOR REPRODUCTION MANAGEMENT

VETERINARY USE ONLY

KEEP OUT OF REACH OF CHILDREN

Manufactured by:

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