

The format of this insert was determined by the Israel Ministry of Health and its content was examined and approved by the Ministry.

Package Insert for a Veterinary Preparation

This medicine is only marketed subject to a veterinarian's prescription

For animal use only

1. Name of the Veterinary Medicinal Product, Its Form, and Strength
PARTOVET VETERINARY

2. The Active Substances and Their Concentration per Dosing Unit

Each 1 ml contains 10 IU of synthetic oxytocin.

3. What Is the Medicinal Product Intended for?

PARTOVET is intended to induce delivery, placenta expulsion, and increased postpartum milk production in cows, mares, nanny goats, ewes, bitches, cats and sows.

Oxytocin is a hormone that affects the myometrium during the last stages of pregnancy, during delivery and for several days thereafter.

Therapeutic group: Synthetic hormones for veterinary use

4. Contraindications:

In case of known hypersensitivity to the active substance or to the excipients, do not treat with this preparation.

The use of this preparation is prohibited in animals with cervical immaturity, fetal disposition, abnormally large embryos, cardiovascular diseases or females with a background of uterine tears.

The medicinal product should be administered with caution in case of toxemia or in the absence of cervical dilatation.

5. Side Effects:

Like all medicines, using this medicinal product may cause side effects in some animals. Do not be alarmed when reading the list of side effects. The animal might not suffer from any of them. This medicine can cause allergic reactions.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects and Drug-related Adverse Events" on the homepage of the Ministry of Health website (www.health.gov.il), which redirects to an online form for reporting side effects, or by clicking on the link: <https://sideeffects.health.gov.il>

6. Target Species

Cows, mares, nanny goats, ewes, bitches, cats and sows.

7. Administration Route and Dose for Each Target Species

PARTOVET is administered via intramuscular, subcutaneous, or intravenous injection (for intravenous injection use half the usual dose and if necessary dilute with water for injection).

Mares and cows	4-6 ml	Sows	2-4 ml
Ewes and nanny goats	1-2 ml	Bitches and cats	0.25-1 ml

The treatment can be repeated if necessary every 40 minutes.

8. How to Use the Preparation

Note: During delivery, complete cervical relaxation should be achieved either naturally or by administering estrogen prior to the administration of oxytocin.

9. Withdrawal Period

0 days

10. Warnings:

- **Special Warnings Regarding Use in the Target Species**

None.

- **Special Warnings Regarding the Safe Use of the Medicinal Product in Animals**

Intravenous administration of this medicinal product: Administration should be very slow preferably concomitantly with an infusion of glucose or saline. Use with caution during toxemia.

- **Special Warnings Regarding the Safety of the Person Administering the Preparation**

People with known sensitivity to any of the preparation's ingredients should avoid contact with the preparation.

The medication must not be administered by a pregnant woman.

Wear gloves when using the medicine.

Avoid contact with the skin and the eyes. In case of contact, wash immediately with plenty of water.

Be very careful to avoid self-injection of this medicinal product. In case of self-injection seek medical advice and show the leaflet of the preparation to the attending physician.

- **Pregnancy and Lactation**

Not to be used in pregnant females before the first signs of delivery.

- **Drug Interactions and Other Forms of Interaction**

Do not use this preparation with corticosteroid preparations, sympathomimetic vasoconstrictors, anesthetics, calcium, estrogens and prostaglandins because they can increase its effect.

- **Overdose**

Overdoses can cause myometrium hyperstimulation and spasms, premature placental separation, bradycardia and arrhythmias, hypertension and even death of the mother and fetus. Intoxication due to water retention is characterized by convulsions, shock and even death of the mother after the intravenous administration of large doses during long periods of

time.

May cause postpartum hemorrhage.

- **Incompatibility**

Given the absence of compatibility studies, do not mix this preparation with other veterinary preparations.

11.Storage Instructions

- Prevent poisoning! This medicinal product and any other medicinal product should be kept in a closed place out of the reach of children and/or babies to prevent poisoning.
- Do not use this medicinal product after the expiry date (Exp. Date), which appears on the package. The expiry date refers to the last day of that month.

Storage conditions:

- Store in a dry place, below 25°C, protected from light.
- Keep out of the reach of children.

Once opened for the first time, use the preparation within 28 days, and terminate any residues thereafter.

12.Instructions Pertaining to the Disposal of the Preparation/Remaining Quantity of the Preparation Once Its Use Is Over

Any remaining quantity of the veterinary medicinal product or waste materials derived from such a veterinary medicinal product should be disposed of according to the disposal instructions set forth by the Ministry of Environmental Protection.

13.Additional Information

- In addition to the active substance, the preparation also contains:
Benzyl alcohol (E1519), Chlorobutanol hemihydrate, Ethanol, Sodium chloride, Acetic acid, Water for injection

What the medicinal product looks like and what the package content is: Clear solution in bottles of different volumes: 10, 50, 100, 250 ml

- **Drug Registration Number:** 083-47-92369
- **Name of the Manufacturer:** Divasa-Farmavic s.a, Barcelona, Spain
- **Name of the Registration Holder:** M.P.VET Ltd., POB 7004, Petah Tikva 49170



Edited in July 2021 pursuant to the directions of the Ministry of Health