The following text is currently approved by the National Organization for Medicines (E.O.F.) in Greece and is subject to changes at any time.

PACKAGE LEAFLET

For animal treatment only

OXYTOCIN/ PROVET injectable solution

of oxytocin for Mares, Cows, Sows, Ewes, Goats, Dog, Cat

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

Marketing Authorisation Holder:
PROVET S.A.
120, Eleftherias Avenue, Eleousa, Zitsa, 45500 Ioannina, Greece
Tel.: +30 2105508500, +30 2105575770-3
E-mail: vet@provet.gr

Manufacturer responsible for batch release:
PROVET S.A. (FACTORY)
Nikiforou Foka & Ag.Anargyron, Thesi Vrago,
193 00 Aspropyrgos, Attiki, Greece

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

OXYTOCIN/ PROVET
injectable solution
Oxytocin 10 IU/ ml
for Mares, Cows, Sows, Ewes, Goats, Dog, Cat

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

1 ml of solution contains:
Active substance: 10 I.U. Oxytocin/ ml
Excipients: Chlorobutanol hemihydrate, Ethanol (96%), Acetic acid (99.8%), Water for injection

4. INDICATIONS

OXYTOCIN injectable solution is recommended for the support of natural parturition, enhancement of uterine contractions during parturition, uterine atony, treatment of postpartum haemorrhages, retained placenta, uterine prolapse, speed up of uterine involution, neurogenous agalactia, particularly in sows postpartum or in cases of endometritis, usually accompanied by fever. In cases of endometritis should be administered the appropriate antibiotic.

5. CONTRAINDICATIONS

Oxytocin should not be administered in cases of dystocia caused by natural causes, e.g. large embryo, abnormal position of the fetus (due to blockage of the genital tract).

6. ADVERSE REACTIONS

None reported

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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Mares, Cows, Sows, Ewes, Goats, Dog, Cat

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Administered by subcutaneous or intramuscular injection.

Mares-Cows: 4-6 ml
Sows: 1-3 ml
Ewes-Goats: 1-2 ml
Dogs-Cats: 0.25 – 1 ml

The product may be administered by slow intravenous injection at one third (1/3) of the dose rates mentioned above. For treatment of agalactia the dosage may be increased. When using oxytocin for obstetrics, originally administer low doses. Full dose should only be given when no results are seen within 15 minutes after administration.

9.ADVICE ON CORRECT ADMINISTRATION

Special precautions for use in animals

When oxytocin is used auxiliary in parturition, it is prior necessitate the control of cervical dilation to avoid the risk of fetal death or uterine rupture.

Large doses may cause a delay of parturition due to uncoordinated, intense uterine contractions that inhibit the view of the fetus, especially in gestation with large number of embryos.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Not required. However, it is recommended the careful handling of hypodermic syringes and needles to avoid accidental self-injection and it is advisable to take the usual aseptic measures. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

10. WITHDRAWAL PERIODS

Meat and offal's: 0 days
Milk: 0 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 25ºC.
Shelf-life after the first opening of the package: 7 days
Avoid the contamination of the content during the use.
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Do not administer large dose in the first administration, for this might delay instead of speeding up parturition. Oxytocin should not be administered if the cervix is not dilated, due to the risk of uterine rupture.

Adrenaline at normal levels results in drastic reduction of the effectiveness of oxytocin in uterus and breast. Since it is desirable to use the action of oxytocin as a whole, the treated animals should remain calm.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14.DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

SEPTEMBER 2012

15. OTHER INFORMATION

PACKAGES

Vials of 10 ml and 50 ml
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorization holder.

under veterinary medical prescription

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN