PACKAGE LEAFLET

For animal treatment only

FLATULEX injectable solution

of vitamin E and selenium for horses, cattle, sheep, goats, pigs

1.NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION 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

FLATULEX
Injectable solution
Vitamin E + Sodium Selenite
(17,00 + 1,67) mg/ml
for horses, cattle, sheep, goats, pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1ml of solution contains:
Active substances:
Vitamin E acetate 17.00 mg
Sodium selenite 1.67 mg

Excipients: Polyoxyl 35 Castor oil (Cremophor EL) , Methylparaben E 218, Water for injections

4. INDICATIONS

FLATULEX is indicated for the prevention and treatment of pathological situations which are associated with deficiency of vitamin E and selenium, such as muscular dystrophy in lambs, kids, calves and pigs, dietary liver necrosis and dietary microangiopathy of the pig, congenital legs weakness in piglets (splay leg) and paralytic myoglobinuria in horses.

5. CONTRAINDICATIONS

None known

6. ADVERSE REACTIONS

None if used as recommended. Overdose causes acute toxicosis from selenium, with symptoms including depression, ataxia, dyspnea with abundant discharge, colic pain and diarrhea.
Rarely, hypersensitivity reactions may occur in horses, cattle and calves.

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
Horses, cattle, sheep, goats, pigs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
Administer intramuscularly or subcutaneously in a single dose.
Horses: 10 ml
Adult Cattle: 10 ml
Calves: 3-5 ml
Adult Sheep and Goats: 3-5 ml
Lambs-Kids: 1-3 ml
Pigs: 5-10 ml
Piglets: 1-3 ml
In severe cases, therapy can be repeated after 6-7 days.
It can also be administered preventatively every 3 months.

9. ADVICE ON CORRECT ADMINISTRATION
Since the therapeutic-toxic range of selenium is small (1:3), do not exceed recommended maximum doses and administer as a single dose.

10. WITHDRAWAL PERIOD(S)
Meat: 28 days
Milk: 0 days

11. SPECIAL STORAGE PRECAUTIONS
Keep out of the sight and reach of children.
Store below 25^0C.
Store in a dry place.
Store protected from light.
Shelf-life after the first opening of the package: 1 month in ambient conditions
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
Special warnings for each target species
None

Special precautions for use in animals:
Since the therapeutic-toxic range of selenium is small (1:3), do not exceed recommended maximum doses and administer as a single dose.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical assistance demonstrating the insert of the product to the doctor.

Pregnancy-Lactation:
It can be safely administered during pregnancy.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes):
Overdose causes acute toxicosis from selenium, with symptoms including depression, ataxia, dyspnea with abundant discharge, colic pain and diarrhea. In these cases, treatment is symptomatic.

Incompatibilities:
None known

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

APRIL 2021

15. OTHER INFORMATION

PACKAGES

Aluminum bottles of 50 ml and 100 ml
Not all pack sizes may be marketed.
The materials used for container of this product are compatible with the contents of the product and do not cause any alterations in its nature or its chemical composition.

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