SUMMARY OF PRODUCT CHARACTERISTICS
Veterinarian Prescription only medicine
For animal use only

1. NAME FORM AND STRENGTH OF THE VETERINARY MEDICIN

Loxicom 0.5 mg/ml, oral suspension

2. ACTIVE INGREDIENTS

Each ml Contains:
Meloxicam 0.5mg

Also contains:
Sodium Benzoate 1.5 Mg

For a full list of excipients, see section 12 “further information”

3. Indications for use

Dogs: Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders
Cats: Alleviation of inflammation and pain in chronic musculo-skeletal disorders

Therapeutic Group: NSAID’s

4. Contraindications

Do not use in pregnant or lactating animals.
Do not use in animals suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs and cats less than 6 weeks of age.

5. Adverse reactions (frequency and seriousness)

Typical adverse reactions of non-steroidal anti-inflammatory drugs (NSAIDs) such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure have occasionally been reported.
In very rare cases, haemorrhagic diarrhoea, haematemesis, gastrointestinal ulceration and elevated liver enzymes have been reported.
These adverse reactions occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting adverse events due to drug treatment" found on the home page of the Ministry of Health website (www.health.gov.il) which refers to the online form for reporting adverse events, or by entering the link:

https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

6. **Target Species**:
   Dogs and Cats

7. **Amounts to be administered and administration route**

Oral use.
To be administered with food or directly into the mouth.
Shake well before use.
The suspension is given using the Loxicom measuring syringe provided in the package.
Particular care should be taken with regard to the accuracy of dosing.
Carefully follow the instructions of the veterinarian.

Dogs:
Initial treatment is a single dose of 0.2 mg meloxicam/kg bodyweight (i.e. 4 ml/10 kg bodyweight) on the first day.
Treatment is to be continued once daily by oral administration (at 24 hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg bodyweight (i.e. 2 ml/10 kg bodyweight).

A clinical response is normally seen within 3-4 days.
Treatment should be discontinued after 10 days at the latest if no clinical improvement is apparent.
Avoid introduction of contamination during use.
The treatment duration depends on the observed clinical response. For longer term treatment the dose can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation.

Cats:
Initial treatment is a single oral dose of 0.1 mg meloxicam/kg body weight on the first day.
Treatment is to be continued once daily by oral administration (at 24 hour intervals) at a maintenance dose of 0.05 mg meloxicam/kg body weight.
Do not exceed the recommended dose.
A clinical response is normally seen within 7 days.
Treatment should be discontinued after 14 days at the latest if no clinical improvement is apparent.

Meloxicam has a narrow therapeutic safety margin in cats and clinical signs of overdose may be seen at relatively small overdose levels. To ensure administration of a correct dose, body weight should be determined as accurately as possible.
Response to long-term therapy should be monitored at regular intervals by a veterinary surgeon.

8. **Withdrawal period**
   Not applicable.

9. **Special warnings and precautions for use:**

- Special precautions for use in animals:

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.

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

People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician.

- Use during pregnancy, lactation or lay

Do not use in pregnant or lactating animals.

- Interaction with other medicinal products and other forms of interaction:

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects.
Loxicom must not be administered in conjunction with other NSAIDs or glucocorticosteroids.
Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such drugs should be observed for at least 24 hours before commencement of treatment with Loxicom. The treatment free period, however, should take into account the pharmacological properties of the products used previously.
In Cats: Concurrent administration of potential nephrotoxic drugs should be avoided.

- Overdose:

In the case of overdose, symptomatic treatment should be initiated.

10. Storage instructions

- Storage conditions: Store below 25^{o}c in room temprature.
- Prevent poisoning! This medicine and any other medicine should be kept in a safe place out of the reach of children and / or infants and thereby prevent poisoning.
- Do not use this medicine after the exp date on the package. The expiration date refers to the last day of that month.
- After fırst opening of the packaging can be used up to 6 months.

11. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products:

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed as toxic waste. Do not dispose of sewage.

12. FURTHER INFORMATION:

In addition to the active ingredient the product also contains:
Sodium Benzoate , Glycerol, Sodium Dihydrogen Phosphate Dihydrate, Povidone K30, Xanthan Gum, Disodium Phosphate Dihydrate, Citric Acid Anhydrous, Simethicone Emulsion, Purified water

Pharmaceutical form:

Pale yellow oral suspension.

Packaging size:

- 5ml, 15ml and 30ml polyethylene terephthalate screw bottles and a 1ml measuring syringes
  Not all packaging sizes may be marketed

Registration holder: Comex Ltd, Nablus Rd. No.1, POB 19943, Jerusalem 97200

Manufacturer: Norbrook Laboratories Limited , Station Works, Newry, Northern Ireland, BT35 6JP, UK

Product registration number: 152-44-33608-00

This leaflet has been reviewed and approved by the MoH : 07/2014