PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL(S) - Polypropylene container

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PLT™ Tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains: Cinchophen 200 mg
Prednisolone 1 mg

3. PHARMACEUTICAL FORM

Tablet.

4. PACKAGE SIZE

100 tablets
1000 tablets

5. TARGET SPECIES

Dog

6. INDICATION(S)

For the treatment of osteoarthritis in the dog.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage: Recommended dosage is based on 25 mg Cinchophen/kg bodyweight and 0.125 mg prednisolone/kg bodyweight.
This equates to a dose of:

Bodyweight:	
8 kg	1/2 tablet twice daily
16 kg	1 tablet twice daily
24 kg	1 1/2 tablets twice daily
32 kg and over	2 tablets twice daily

The dose should be administered with food.

8. WITHDRAWAL PERIOD (S)

9. SPECIAL WARNING(S), IF NECESSARY

Contra-indications

NB: For full deatails of uses, contra-indications and warnings, see package leaflet. Anti-inflammatory corticosteroids, such as prednisolone, are known to exert a wide range of side-effects, see package leaflet for detailed warnings.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Store in a dry place.

Keep container tightly closed.

Protect from light.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE,

For animal treatment only.

To be supplied only under veterinary prescription.

POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Lilly House
Priestley Road
Basingstoke
Hampshire
RG24 9NL

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4074

17. MANUFACTURER'S BATCH NUMBER

BNo:

PACKAGE LEAFLET:

PLT Tablets

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

Marketing Authorisation Holder:
Elanco Europe Ltd
Lilly House
Priestley Road
Basingstoke
Hampshire
RG24 9NL

Manufacturer for the batch release:
Surepharm Services Ltd
Bretby Business Park
Ashby Road East, Bertby
Burton Upon Trent
DE15 0YZ

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PLT™ Tablets

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

Fawn coloured tablets marked with PLT on one side and double scored on the other. Each tablet contains: Cinchophen 200 mg
Prednisolone 1 mg

4. INDICATION(S)

PLT Tablets are indicated for the treatment of osteoarthritis in the dog.

5. CONTRAINDICATIONS

Not for use in any animal species other than the dog.
Not to be used in animals with the following conditions:
Pregnancy
Severe nephrosis
Circulatory congestive conditions
Hepatitis
Previous adverse reaction to a steroid or
NSAID treatment
Concurrent diuretic therapy or treatment with other NSAIDs or steroids.

Systemic corticosteroid therapy is generally contra-indicated in patients with renal disease and diabetes mellitus.

Should any treated animal show signs of vomiting, diarrhoea, dullness or jaundice, or show no evidence of improvement after 3 days treatment, discontinue therapy.

6. ADVERSE REACTIONS

Anti-inflammatory corticosteroids, such as prednisolone, are known to exert a wide range of side-effects. While single high doses are generally well tolerated, they may induce severe side-effects in long term use and when esters possessing a long duration of action are administered. Dosage in medium to long term use should generally be kept to the minimum necessary to control symptoms.

Steroids themselves, during treatment, may cause Cushingoid symptoms involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g.
redistribution of body fat, muscle weakness and wastage and osteoporosis may result. During therapy effective doses suppress the Hypothalamio-Pituitary-Adrenal axis. Following cessation of treatment, symptoms of adrenal insufficiency extending to adrenocortical atrophy can arise and this may render the animal unable to deal adequately with stressful situations. Consideration should therefore be given to means
of minimising problems of adrenal insuffieiency following the withdrawal of treatment, e.g. a gradual reduction of dosage (for further discussion see standard texts).

Systemically administered corticosteroids may cause polyuria, polydipsia and polyphagia, particularly during the early stages of therapy. Some corticosteroids may cause sodium and water retention and hypokalaemia in long term use. Systemic corticosteroids have caused deposition of calcium in the skin (calcinosis cutis).

Corticosteroids may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections. In the presence of bacterial
infection, anti-bacterial drug cover is usually required when steroids are used. In the presence of viral infections, steroids may worsen or hasten the progress of the disease.

Gastro-intestinal ulceration has been reported in animals treated with corticosteroids and GI tract ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in corticosteroid treated animals with spinal cord trauma. Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes. Gasrto-intestinal upsets have been reported. Should inappetance or vomiting occur, medication should be discontinued and the dog re-examined by a veterinary surgeon.

7. TARGET SPECIES

Dog.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage and Administration:
Recommended dosage is based on 25 mg Cinchophen/kg bodyweight and 0.125 mg prednisolone/kg bodyweight. This equates to a dose of:

Dogs: 8 kg	½ tablet twice daily
16 kg	1 tablet twice daily
24 kg	1½ tablets twice daily
32 kg and over	2 tablets twice daily

The dose should be administered with food.
The length of treatment with PLT Tablets depends on the condition treated and the rapidity of response. If there is no improvement within the first 3 days, the dog should be re-examined by the veterinary surgeon. However, an initial treatment period should not exceed 14 days after which the dog's condition should be re-assessed by a eterinary surgeon and a 14 day treatment-free interval must be observed before continuing with further treatment. During a course of treatment the situation should be reviewed
frequently by close veterinary supervision. Owing to the prednisolone content, at the end of a treatment period dose levels should be reduced gradually.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Keep out of sight and reach of children.

Do not store above 25 □C.

Keep container tightly closed.

Protect from light.

12. SPECIAL WARNING(S)

For Animal Treatment Only

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Container of 100 or 1000 tablets.

Vm 00879/4074

To be supplied only on veterinary prescription.

POM-V

Approved: 22 August 2017