

**TEMARIL-P- trimeprazine tartrate and prednisolone tablet**  
**Zoetis Inc.**

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**Temaril-P®**

***Temaril-P®***  
***(trimeprazine with prednisolone)***  
***Tablets***

***Antipruritic-Antitussive-Anti-inflammatory***

*For use in dogs*

**CAUTION**

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**DESCRIPTION**

Each tablet contains trimeprazine tartrate (USP) 10-[3-(Dimethylamino)-2-methylpropyl] phenothiazine tartrate (2:1) equivalent to trimeprazine, 5 mg, and prednisolone, 2 mg.

**Action**

The exclusive Temaril-P formula combines the antipruritic and antitussive action of trimeprazine with the anti-inflammatory action of prednisolone. A therapeutic effect is attained by administering the tablets twice daily.

**INDICATIONS AND USAGE**

**1. Antipruritic**

Temaril-P is recommended for the relief of itching regardless of cause. Its usefulness has been demonstrated for the relief of itching and the reduction of inflammation commonly associated with most skin disorders of dogs such as the eczema caused by internal disorders, otitis, and dermatitis (allergic, parasitic, pustular, and nonspecific). It often relieves pruritus which does not respond to other therapy. With any pruritus treatment, the cause should be determined and corrected; otherwise, signs are likely to recur following discontinuance of therapy.

**2. Antitussive**

Temaril-P has been found to be effective therapy and adjunctive therapy in various cough conditions of dogs. Therefore, in addition to its antipruritic action, Temaril-P is recommended for the treatment of "kennel cough" or tracheobronchitis, bronchitis including all allergic bronchitis, and infections and coughs of nonspecific origin. (Coughs due to cardiac insufficiencies would not be expected to respond to Temaril-P therapy.)

As with any antitussive treatment, the etiology of the cough should be determined and eliminated if possible. Otherwise, symptoms are likely to recur following discontinuance of therapy.

**Note:** Temaril-P may be administered to animals suffering from acute or chronic bacterial infections provided the infection is controlled by appropriate antibiotic or chemotherapeutic agents.

## **WARNING**

Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate in offspring. Corticosteroids administered to dogs during pregnancy have also resulted in other congenital anomalies, including deformed forelegs, phocomelia, and anasarca. If a vasoconstrictor is needed, norepinephrine should be used in lieu of epinephrine. Phenothiazine derivatives may reverse the usual elevating action of epinephrine causing a further lowering of blood pressure.

## **PRECAUTIONS AND SIDE EFFECTS**

All the precautions applicable to cortisone and to phenothiazine derivatives apply also to Temaril-P. Possible side effects attributable to corticosteroids include sodium retention and potassium loss, negative nitrogen balance, suppressed adrenal cortical function, delayed wound healing, osteoporosis, elevated levels of SGPT and SAP, and vomiting and diarrhea (occasionally bloody). Cushing's syndrome in dogs has been reported in association with prolonged or repeated steroid therapy. Possible increased susceptibility to bacterial invasion and/or the exacerbation of preexisting bacterial infection may occur in patients receiving corticosteroids. As noted above, however, this problem can be avoided by concomitant use of appropriate anti-infective agents. Possible side effects attributable to phenothiazine derivatives include sedation; protruding nictitating membrane; blood dyscrasias; intensification and prolongation of the action of analgesics, sedatives and general anesthetics; and potentiation of organophosphate toxicity and the activity of procaine hydrochloride.

It should be remembered that the premonitory signs of cortisone overdosage, such as sodium retention and edema, may not occur with prednisolone. Therefore, the veterinarians must be alert to detect less obvious side effects, such as blood dyscrasias, polydipsia, and polyuria.

The appearance and severity of side effects are dose related and are minimal at the recommended dosage level. If troublesome side effects are encountered, the dosage of Temaril-P should be reduced and discontinued unless the severity of the condition being treated makes its relief paramount.

Prolonged treatment with Temaril-P must be withdrawn gradually. Use of corticosteroids, depending on dose, duration, and specific steroid, may result in inhibition of endogenous steroid production following drug withdrawal. In patients presently receiving or recently withdrawn from systemic steroid treatments, therapy

with a rapidly acting corticosteroid should be considered in unusually stressful situations.

## **DOSAGE AND ADMINISTRATION**

The same dosage schedule may be followed for both antipruritic and antitussive therapy.

<b>Weight of Dog</b>	<b>Initial Dosage</b>
Up to 10 lb	1/2 tablet, twice daily
11-20 lb	1 tablet, twice daily
21-40 lb	2 tablets, twice daily
Over 40 lb	3 tablets, twice daily

After 4 days, reduce dosage to 1/2 of the initial dose or to an amount just sufficient to maintain remission of symptoms. Individual animal response will vary and dosage should be adjusted until proper response is obtained.

**Store in a Dry, Cool Place at Temperatures Not Above 25°C (77°F)**

## **HOW SUPPLIED**

100- and 1000-tablet bottles.

## **REFERENCES**

1. Knowles JO, Knowles RP: Preliminary reports on an effective antipruritic agent. *Vet Med* 55(8):67-68, 1960.
2. Candlin FT: An agent to aid in control of pruritus. *Vet Med* 56(5):207-208, 1961.
3. Yoxall AT, Hird JRF: *Pharmacological Basis of Small Animal Medicine*. Blackwell Scientific Publications, London, pp. 99-102, 1979.
4. Booth N, McDonald LE: *Veterinary Pharmacology and Therapeutics*, 5th ed. Iowa State University Press, Ames, pp. 564-570, 1982.
5. Davis L: *Handbook of Small Animal Therapeutics*. Churchill Livingstone, New York, pp. 140-142; 459-461; 468-469, 1985.
6. Scott D: Systemic glucocorticoid therapy. *Current Veterinary Therapy*, Kirk WV Saunders, ed., Philadelphia, pp. 988-994, 1980.
7. Lecture: "Rational Steroid Therapy" Duncan C. Ferguson, VMD, PhD, Department of Pharmacology, Cornell University.
8. Kempianen RJ, Lorenz MD, Thompson FN: Adrenocortical suppression in the dog given a single intramuscular dose of prednisolone or triamcinolone acetonide. *Am J Vet Res* 42(2):204-206, 1982.
9. Rogers WA, Ruebner BH: A retrospective study of probable glucocorticoid induced hepatopathy in dogs. *JAVMA* 1977;170(6): 603-605.

Approved by FDA under NADA # 012-437



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Distributed by:



Zoetis Inc.

Kalamazoo, MI 49007

40031413

Revised: May 2020

**PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Label**

<p>LOT/EXP</p>	<p><b>Recommended Dosage</b></p> <p><b>Weight of Dog</b></p> <p>Up to 10 lb      1/2 tablet, twice daily</p> <p>11–20 lb        1 tablet, twice daily</p> <p>21–40 lb        2 tablets, twice daily</p> <p>Over 40 lb      3 tablets, twice daily</p> <p><b>Initial Dosage</b></p> <p>1/2 tablet, twice daily</p> <p>1 tablet, twice daily</p> <p>2 tablets, twice daily</p> <p>3 tablets, twice daily</p> <p>After 4 days, reduce dosage to 1/2 of the initial dose or to an amount just sufficient to maintain remission of symptoms. Individual animal response will vary and dosage should be adjusted until proper response is obtained.</p>	<p><b>Temaril-P<sup>®</sup></b> (trimeprazine with prednisolone)</p> <p><b>Tablets</b> <b>Antipruritic–Antitussive–</b> <b>Anti-inflammatory</b></p> <p><i>For use in dogs</i></p> <p><i>Each tablet contains trimeprazine tartrate USP 10-[3-(Dimethylamino)-2-methylpropyl]-phenothiazine tartrate (2:1) equivalent to trimeprazine, 5 mg, and prednisolone, 2 mg.</i></p> <p><b>Caution:</b> Federal law restricts this drug to use by or on the order of a licensed veterinarian.</p> <p><b>100 tablets</b></p> <p>Approved by FDA under NADA # 012-437</p> <p style="text-align: right;"><b>zoetis</b></p>
<p>40031414</p>	<p><b>See Package Insert for Complete Directions</b></p> <p style="text-align: center;">   <small>TAKE TIME</small>  <small>OBSERVE LABEL DIRECTIONS</small> </p>	<p><b>Store in a Dry, Cool Place at Temperatures Not Above 25°C (77°F)</b></p> <p>Distributed by: Zoetis Inc. Kalamazoo, MI 49007</p>
<p><b>FPO UPC @ 80%</b></p>  <p>0 87219 01395 3</p>		

40031414

**PRINCIPAL DISPLAY PANEL - 1000 Tablet Bottle Label**

**LOT/EXP** 40031415

# Temaril-P®

(trimeprazine with prednisolone)  
**Tablets**  
*Antipruritic–Antitussive–Anti-inflammatory*

*For use in dogs*

Each tablet contains trimeprazine tartrate USP 10-[3-(Dimethylamino)-2-methylpropyl]-phenothiazine tartrate (2:1) equivalent to trimeprazine, 5 mg, and prednisolone, 2 mg.

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**1000 tablets**  
 Approved by FDA under NADA # 012-437

**zoetis**

Store in a Dry, Cool Place at Temperatures Not Above 25°C (77°F)  
 See Package Insert for Complete Directions

**zoetis**  
 Distributed by:  
 Zoetis Inc.  
 Kalamazoo, MI 49007

OBVERSE LABEL DIRECTIONS

TAKE TIME

**FPO: UPC**

0 87219 01397 7

**Recommended Dosage**

Weight of Dog	Initial Dosage
Up to 10 lb	1/2 tablet, twice daily
11–20 lb	1 tablet, twice daily
21–40 lb	2 tablets, twice daily
Over 40 lb	3 tablets, twice daily

After 4 days, reduce dosage to 1/2 of the initial dose or to an amount just sufficient to maintain remission of symptoms. Individual animal response will vary and dosage should be adjusted until proper response is obtained.

40031415

## TEMARIL-P

trimeprazine tartrate and prednisolone tablet

### Product Information

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:54771-8550
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TRIMEPRAZINE TARTRATE</b> (UNII: 362NW1LD6Z) (TRIMEPRAZINE - UNII:76H78MJJ52)	TRIMEPRAZINE	5 mg
<b>PREDNISOLONE</b> (UNII: 9PHQ9Y1OLM) (PREDNISOLONE - UNII:9PHQ9Y1OLM)	PREDNISOLONE	2 mg

### Product Characteristics

<b>Color</b>	gray	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	T100
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-8550-1	100 in 1 BOTTLE		
2	NDC:54771-8550-2	1000 in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA012437	09/30/1960	

**Labeler** - Zoetis Inc. (828851555)

Revised: 1/2023

Zoetis Inc.