

**TRIMEPRAZINE WITH PREDNISOLONE- trimeprazine with prednisolone tablet
ZYVET ANIMAL HEALTH INC.**

**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 Trimeprazine with Prednisolone 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:* Trimeprazine with Prednisolone 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:* Trimeprazine with Prednisolone has been found to be effective therapy and adjunctive therapy in various cough conditions of dogs. Therefore, in addition to its anti pruritic action, Trimeprazine with Prednisolone 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 Trimeprazine with Prednisolone 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: Trimeprazine with Prednisolone may be administered to animals suffering from acute or chronic bacterial infections provided the infection is controlled by appropriate

antibiotic or chemotherapeutic agents.

WARNINGS:

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.

Keep Trimeprazine with Prednisolone Tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

CONTACT INFORMATION:

To report suspected adverse drug experiences, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact ZyVet Animal Health Inc. at 1-877-779-9838. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>

PRECAUTIONS AND SIDE EFFECTS:

All the precautions applicable to cortisone and to phenothiazine derivatives apply also to Trimeprazine with Prednisolone. 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 Trimeprazine with Prednisolone should be reduced and discontinued unless the severity of the condition being treated makes its relief paramount.

Prolonged treatment with Trimeprazine with Prednisolone 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.

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.

**Store at 20° to 25°C (68° to 77°F), excursions permitted to 40°C (104°F).
Protect from light.**

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 ANADA # 200-784



Manufactured by:

Zydus Animal Health and Investments Limited, Ahmedabad, India

Distributed by:

ZyVet Animal Health Inc.

Pennington, NJ 08534

Rev.: 04/24

PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Label

Trimeprazine with Prednisolone

Tablets

Antipruritic-Antitussive-Anti-inflammatory

For use in dogs

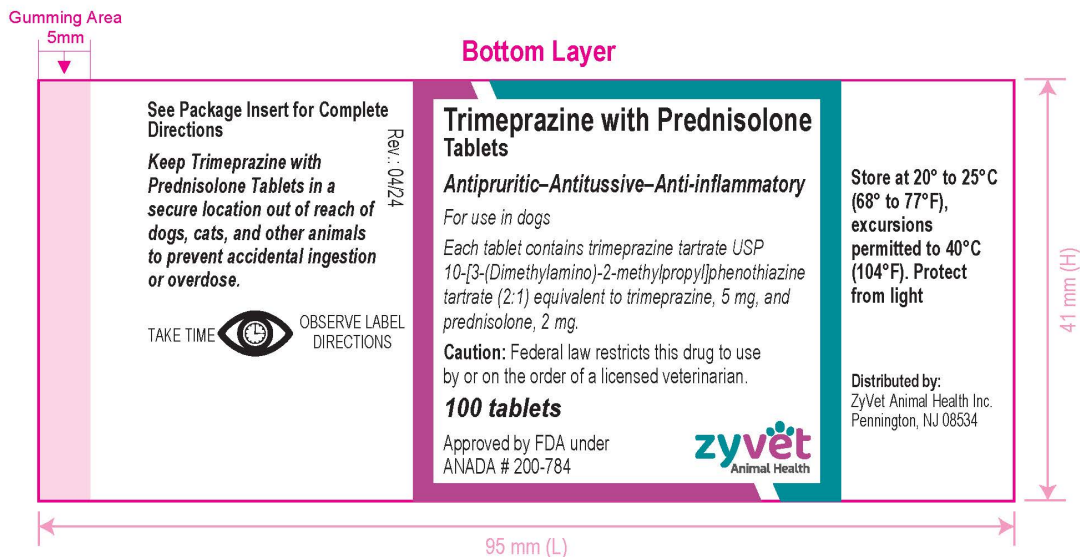
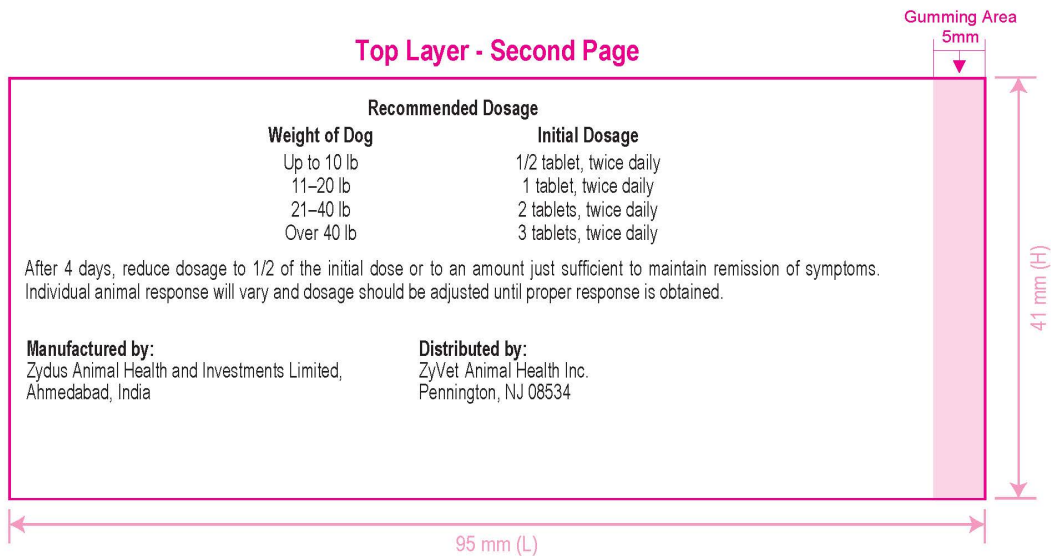
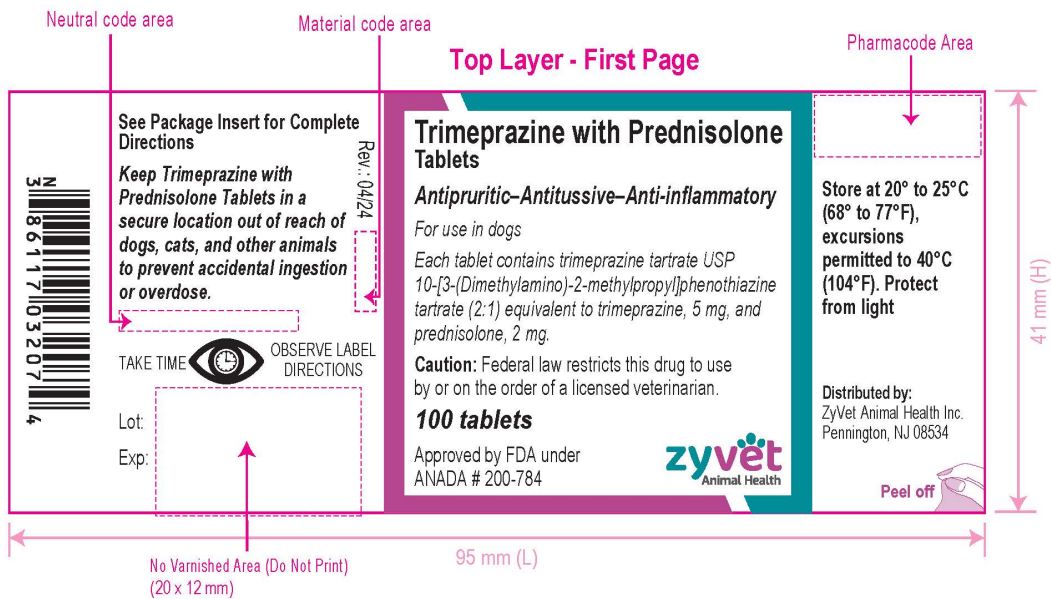
Each tablet contains trimeprazine tartrate USP

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

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100 tablets

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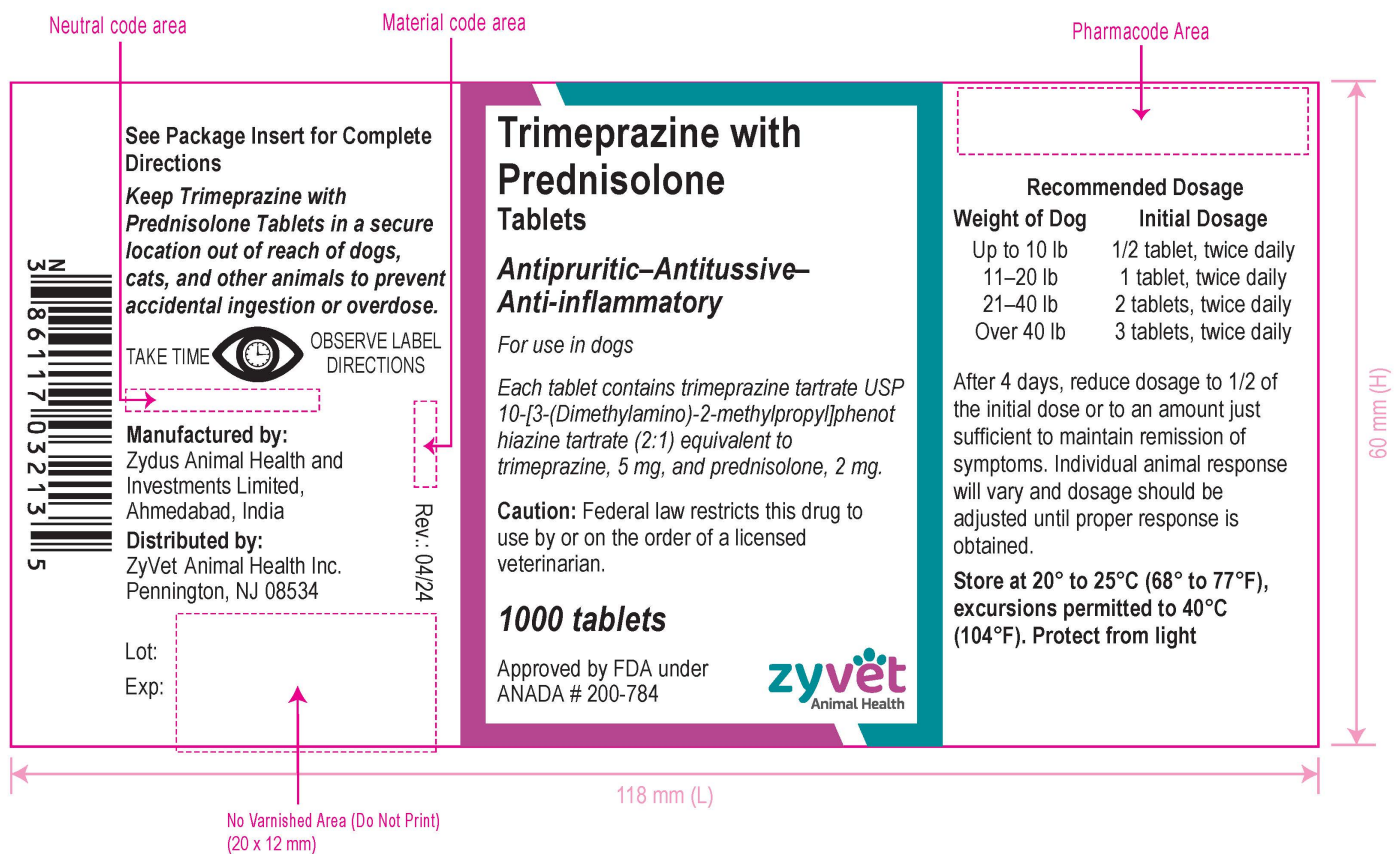
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TRIMEPRAZINE WITH PREDNISOLONE

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Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:86117-032
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Product Characteristics

Color	GRAY	Score	2 pieces
Shape	ROUND	Size	9mm
Flavor		Imprint Code	17V
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86117-032-07	100 in 1 BOTTLE		
2	NDC:86117-032-13	1000 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200784	07/30/2024	

Labeler - ZYVET ANIMAL HEALTH INC. (117047560)

Registrant - ZYVET ANIMAL HEALTH INC. (117047560)

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ZYVET ANIMAL HEALTH INC.