Sulfadimethoxine is a white, almost tasteless and odorless powder. Chemically, it is 3,4-diamino-5,6-dihydro-2H-1,2,4-triazinyl (sulfadimethoxine) (27.5 mg/kg) of body weight. Continue treatment for at least 2 days after remission of clinical signs; do not extend treatment for more than 21 consecutive days. Suggested dosage schedule follows:

**INDICATIONS AND USAGE:** Primor is for the treatment of skin and soft tissue infections caused by certain organisms sensitive to sulfadimethoxine and ormetoprim. It is intended for use in dogs and cats to treat the following skin and soft tissue infections caused by Escherichia coli, Staphylococcus spp., and Proteus mirabilis susceptible to sulfadimethoxine/ormetoprim.

**CONTRAINDICATIONS:** Primor should not be used in dogs showing a history of sulfonamide hypersensitivity. Safety in breeding dogs has not been established.

**WARNINGS:**

1. **Overdose in Mammals:** Overdose in animals is usually the result of accidental ingestion. Symptoms and signs of overdose may consist of gastrointestinal upset, epistaxis, and generalized hypothermia. These signs are believed to be associated with decreased adenosine triphosphate (ATP) levels and decreased plasma concentrations of glucose and other nutrients. Glucose levels in blood and urine may be decreased.

2. **Judicious Use:** Use Primor under the supervision of a veterinarian.

3. **Developmental Toxicity Studies:** Primor has been evaluated in fertility and embryonic studies in rats and rabbits at dosages that were 50 times or more the recommended human dosage. No adverse effects were noted. The safety of the use of Primor in association with the use of other drugs or chemicals has not been established.

4. **Drug Interactions:** Primor may be administered concurrently with other antimicrobial drugs, but the effectiveness of the combination has not been established.

5. **Susceptibility Testing:** Susceptibility testing of isolates obtained from the site of infection should be performed by standard techniques to determine the minimal inhibitory concentration (MIC) of Primor. The susceptibility of organisms to sulfonamides or potentiated sulfa-methoxazole and trimethoprim (BBL® Disc® SXT*). Specimens for susceptibility testing should be cultured on the appropriate media with or without the presence of the antibiotic combination being tested in the appropriate dilution. Potentiated sulfonamides have been shown to exhibit bactericidal as well as bacteriostatic action.

6. **Other Antimicrobials:** Primor may be used in combination with other antimicrobial agents with demonstrated effectiveness against the isolate. The combination of sulfadimethoxine and ormetoprim is recommended for the treatment of infections caused by Proteus mirabilis, Pseudomonas aeruginosa, Enterobacter, K. pneumoniae, and Citrobacter freundii (242). The combination of sulfadimethoxine and ormetoprim is recommended for the treatment of infections caused by Proteus mirabilis, Pseudomonas aeruginosa, Enterobacter, K. pneumoniae, and Citrobacter freundii (242). The combination of sulfadimethoxine and ormetoprim is recommended for the treatment of infections caused by Proteus mirabilis, Pseudomonas aeruginosa, Enterobacter, K. pneumoniae, and Citrobacter freundii (242). The combination of sulfadimethoxine and ormetoprim is recommended for the treatment of infections caused by Proteus mirabilis, Pseudomonas aeruginosa, Enterobacter, K. pneumoniae, and Citrobacter freundii (242). The combination of sulfadimethoxine and ormetoprim is recommended for the treatment of infections caused by Proteus mirabilis, Pseudomonas aeruginosa, Enterobacter, K. pneumoniae, and Citrobacter freundii (242). The combination of sulfadimethoxine and ormetoprim is recommended for the treatment of infections caused by Proteus mirabilis, Pseudomonas aeruginosa, Enterobacter, K. pneumoniae, and Citrobacter freundii (242). The combination of sulfadimethoxine and ormetoprim is recommended for the treatment of infections caused by Proteus mirabilis, Pseudomonas aeruginosa, Enterobacter, K. pneumoniae, and Citrobacter freundii (242). The combination of sulfadimethoxine and ormetoprim is recommended for the treatment of infections caused by Proteus mirabilis, Pseudomonas aeruginosa, Enterobacter, K. pneumoniae, and Citrobacter freundii (242).
Ormetoprim is a white, almost tasteless powder. Chemically, it is N1-diamino­pyrimidine. The structure formula is:

\[
\text{N} \quad \text{S} \quad \text{ll} \quad \text{ll} \quad \text{FPO}
\]

Visual Code Bars: 1, 6

Primor is an antimicrobial drug containing sulfadimethoxine/ormetoprim. Primor discs are bacteriostatic agents. Sulfonamides competitively inhibit folic acid metabolism of bacteria, depriving them of folate coenzymes. Sulfadimethoxine/ormetoprim thus blocks 2 sequential steps of the folate synthesis pathway.

In vitro and in vivo, Primor is effective for the treatment of a wide range of susceptible to Primor in vitro, but in vivo significance has not been determined for some canine pathogens.

Ormetoprim potentiates the activity of sulfadimethoxine. This in vitro and in vivo is more active than sulfadimethoxine. Sulfadimethoxine/ormetoprim shows enhanced in vitro and in vivo activity (potentiation) over that of either compound used alone. In order, this potentiation results in a reduction of the minimum inhibitory concentrations of Primor in vitro, which is yet to be determined in vivo.

The susceptibility of organisms to Primor Tablets should be determined using a potentiated sulfonamide disc containing sulfadimethoxine/ormetoprim. The presence or absence of sulfadimethoxine susceptibility in the organism is determined using a sulfadimethoxine (Microscan Disc® SXT*). Specimens for susceptibility testing should be collected prior to initiation of therapy.

In an experimentally induced, controlled soft tissue infection study in dogs, the therapeutic efficacy of Primor was significantly greater than the 2 individual compounds when administered separately, providing clear evidence of the potentiation of sulfadimethoxine.

The following potencies: 120 mg, 240 mg, 600 mg, and 1200 mg.

Following oral administration of Primor to dogs at 27.5 mg/kg/day, significant (27.5 mg/kg/day) of body weight. Continue treatment for at least 2 days posttherapy, make certain dogs maintain adequate water intake. If dogs do not improve within 2-3 days, reevaluate the diagnosis. Safety in breeding dogs has not been established.

Adverse Reactions: Conditions reported following use of sulfonamides in the potentiated sulfonamides include polyarthritis, urticaria, facial swelling, fever, hemolytic anemia, polydypsia, polyuria, vomiting, diarrhea, anorexia, and diarrhea. Antidote: Epinephrine for anaphylactoid reactions.

Dosage and Administration: Administer an initial oral dose of 25 mg/kg (55 mg/lb) of body weight on the first day of treatment. Administer subsequent daily doses at the rate of 12.5 mg/kg (27.5 mg/lb) of body weight for at least 1 more day after resolution of clinical signs. Do not administer treatment for more than 15 consecutive days. Suggested dosage schedule follows:

<table>
<thead>
<tr>
<th>Body Weight (lb)</th>
<th>No. of Tablets First Day</th>
<th>No. of Tablets Subsequent Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primor 120</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>1 1/2</td>
</tr>
<tr>
<td>Primor 240</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>20</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>30</td>
<td>1 1/2</td>
</tr>
<tr>
<td>Primor 600</td>
<td>25</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>30</td>
<td>1</td>
</tr>
<tr>
<td>Primor 1200</td>
<td>50</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>1</td>
</tr>
</tbody>
</table>

Formula: "Disc® SXT*). Specimens for susceptibility testing should be collected prior to initiation of therapy.

For optimal therapeutic effect: (1) the drug must be given early in the course of the disease; (2) therapeutically effective levels must be maintained in the body throughout the treatment period; (3) treatment should continue for at least 2 days after resolution of clinical signs; and (4) the causative bacterial agents must be sensitive to the drug.

Toxicity and Safety: Toxicity data for Primor indicates that the drug is safe when used at the recommended dosage. Following administration of Primor to dogs at 25 mg/kg/day (55 mg/lb) for 6 weeks, no changes were noted in hematology, blood chemistry, urinalysis, gross pathology, and histopathology, except for elevated serum cholesterol, insulin levels, and urinary sediment. Proctocolonic ulceration and proctocolitis have been reported in dogs treated with sulfadimethoxine, but these changes are known to be associated with pathological abnormalities of sulfonamides in dogs and have been shown to be reversible.

Primor is available as scored tablets for the following potencies: 120 mg, 240 mg, 600 mg, and 1200 mg.

SUSPECTED OVERDOSE: Symptoms of acute sulfonamide toxicity include agitation, tremors, ataxia, hyperthermia, convulsions, diarrhea, vomiting, and death. Antidote: Epinephrine for anaphylactoid reactions.

Dosage and Administration: Administer an initial oral dose of 25 mg/kg (55 mg/lb) of body weight on the first day of treatment. Administer subsequent daily doses at the rate of 12.5 mg/kg (27.5 mg/lb) of body weight for 1-2 days after resolution of clinical signs. Do not administer treatment for more than 15 consecutive days. Suggested dosage schedule follows:

<table>
<thead>
<tr>
<th>Body Weight (lb)</th>
<th>No. of Tablets First Day</th>
<th>No. of Tablets Subsequent Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>zgotis</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Distributed By: Pfizer Animal Health
Kalamazoo, MI 49001

REFERENCES:

For optimal therapeutic effect: (1) the drug must be given early in the course of the disease; (2) therapeutically effective levels must be maintained in the body throughout the treatment period; (2) treatment should continue for at least 2 days after resolution of clinical signs; and (4) the causative bacterial agents must be sensitive to the drug.

Toxicity and Safety: Toxicity data for Zotile indicates that the drug is safe when used at the recommended dosage. Following administration of Zotile to dogs at 25 mg/kg/day (55 mg/lb) for 6 weeks, no changes were noted in hematology, blood chemistry, urinalysis, gross pathology, and histopathology, except for elevated serum cholesterol, insulin levels, and urinary sediment. Proctocolonic ulceration and proctocolitis have been reported in dogs treated with sulfadimethoxine, but these changes are known to be associated with pathological abnormalities of sulfonamides in dogs and have been shown to be reversible.