Food and Drug Administration, HHS  §520.2610

parturition when administered during
the last trimester of pregnancy and
may precipitate premature parturition
followed by dystocia, fetal death, re-
tained placenta, and metritis.¹

(5) Federal law restricts this drug to
use by or on the order of a licensed vet-
erinarian.¹

[40 FR 13838, Mar. 27, 1975, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§520.2605 Trimeprazine tartrate and
prednisolone capsules.

(a) Specifications. Each capsule con-
tains 3.75 milligrams of trimeprazine in
sustained released form (as the tar-
trate) and 1 milligram of prednisolone
(capsule no. 1) or 7.5 milligrams of
trimeprazine in sustained release form
(as the tartrate) and 2 milligrams of
prednisolone (capsule no. 2).

(b) Sponsor. See 000069 in §510.600(c)
of this chapter.

(c) Conditions of use—(1) Amount. Ad-
minister either capsule orally once
daily to dogs as follows:

<table>
<thead>
<tr>
<th>Animal weight (pounds)</th>
<th>Number of capsules per dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Capsule No. 1</td>
</tr>
<tr>
<td>Up to 10</td>
<td>1</td>
</tr>
<tr>
<td>11 to 20</td>
<td>2</td>
</tr>
<tr>
<td>21 to 40</td>
<td>4</td>
</tr>
<tr>
<td>Over 40</td>
<td>6</td>
</tr>
</tbody>
</table>

(2) Indications for use. For the relief of
itching regardless of cause, reduction
of inflammation commonly associated
with most skin disorders of dogs such
as eczema caused by internal disorders,
otitis, and dermatitis (allergic, para-
sitic, pustular, and nonspecific). It is
also used in dogs as adjunctive therapy
in various cough conditions including
treatment of “kennel cough” or
tracheobronchitis, bronchitis including
allergic bronchitis, tonsillitis, acute
upper respiratory infections, and
coughs of nonspecific origin. The prod-
uct may also be administered to dogs
suffering from acute or chronic bac-
terial infections, provided the infection
is controlled by appropriate antibiotic
or chemotherapeutic agents.

(3) Limitations. After 4 days, reduce
dosage to one-half the initial dose or to
an amount sufficient to maintain re-
mission of symptoms. Dosages in indi-
vidual cases may vary and should be
adjusted until proper response is ob-
tained. Do not use the drug in cases of
viral infections involving corneal ul-
ceration or dendritic ulceration of the
cornea. Clinical and experimental data
have demonstrated that corticosteroids
administered orally or parenterally to
animals may induce the first stage of
parturition when administered during
the last trimester of pregnancy and
may precipitate premature parturition
followed by dystocia, fetal death, re-
tained placenta, and metritis. Federal
law restricts this drug to use by or on
the order of a licensed veterinarian.


§520.2610 Trimethoprim and sulfa-
diazine tablets.

(a) Specifications. Each tablet con-
tains 30 milligrams (5 milligrams of
trimethoprim and 25 milligrams of sul-
fadiazine), 120 milligrams (20 milli-
grams of trimethoprim and 100 milli-
grams of sulfadiazine), 480 milligrams
(80 milligrams of trimethoprim and 400
milligrams of sulfadiazine) or 960 milli-
grams (160 milligrams of trimethoprim
and 800 milligrams of sulfadiazine).

(b) Sponsor. See Nos. 000061 and 000856
in §510.600(c) of this chapter.

(c) Conditions of use. (1) The drug is
used in dogs where systemic anti-
bacterial action against sensitive orga-
nisms is required, either alone or as an
adjunct to surgery or debridement with
associated infection. The drug is indi-
cated where control of bacterial infec-
tion is required during the treatment
of acute urinary tract infections, acute
bacterial complications of distemper,
acute respiratory tract infections,
acute alimentary tract infections,
wound infections, and abscesses.

(2) The drug is given orally at 30 mil-
ligrams per kilogram of body weight
per day (14 milligrams per pound per
day), or as follows:

¹These conditions are NAS/NRC reviewed and
deemed effective. Applications for these
uses need not include effectiveness data as
specified by §514.111 of this chapter, but may
require bioequivalency and safety informa-

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§ 520.2611 Trimethoprim and sulfadiazine paste.

(a) Specifications. Each gram (g) of paste contains 67 milligrams (mg) trimethoprim and 333 mg sulfadiazine.

(b) Sponsors. See sponsors in §510.600(c) of this chapter:

(1) No. 000856 for product administered as in paragraph (c)(1)(i) of this section.

(2) No. 000061 for product administered as in paragraph (c)(1)(ii) of this section.

(c) Conditions of use in horses—

(1) Amount. Administer orally as a single daily dose for 5 to 7 days:

(i) 5 g of paste (335 mg trimethoprim and 1,665 mg sulfadiazine) per 150 pounds (68 kilograms) of body weight per day.

(ii) 3.75 g of paste (250 mg trimethoprim and 1,250 mg sulfadiazine) per 110 pounds (50 kilograms) of body weight per day.

(2) Indications for use. For use where systemic antibacterial action against sensitive organisms is required during treatment of acute strangles, respiratory infections, acute urogenital infections, and wound infections and abscesses.

(3) Limitations. Not for use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2612 Trimethoprim and sulfadiazine suspension.

(a) Specifications. Each milliliter (mL) of suspension contains:

(1) 10 milligrams (mg) trimethoprim and 50 mg sulfadiazine; or

(2) 400 mg combined active ingredients (67 mg trimethoprim and 333 mg sulfadiazine).

(b) Sponsors. See sponsor numbers in §510.600 of this chapter:

(1) No. 000061 for use of product described in paragraph (a)(1) for use as in paragraph (c)(1) of this section.

(2) No. 051072 for use of product described in paragraph (a)(2) for use as in paragraph (c)(2) of this section.

(c) Conditions of use—

(i) Dogs—

Amount. Administer 1 mL (10 mg trimethoprim and 50 mg sulfadiazine) per 5 pounds (lb) of body weight once daily, or one-half the recommended daily dose every 12 hours, for up to 14 consecutive days.

(ii) Indications for use. The drug is used in dogs where systemic antibacterial action against sensitive organisms is required, either alone or as an adjunct to surgery or debridement with associated infection. The drug is indicated where control of bacterial infection is required during the treatment