PRIMOR®: is an antibiotic used for the treatment of skin and soft tissue infections and for urinary tract infections in dogs.

(sulfadimethoxine/ormetoprim)

:: KNOW THE FACTS
Be sure to read this booklet before your dog receives Primor®. You should also review it each time your dog receives a prescription for this treatment.

This booklet is only a summary. It does not replace what your veterinarian has told you. To learn more about Primor®, talk to your veterinarian.

:: WHAT IS PRIMOR®?
Primor® is an antibiotic medicine containing two different antibiotics. One of these is sulfadimethoxine which is a sulfonamide antibiotic. Primor also contains ormetoprim, which enhances the effect of sulfadimethoxine; thus Primor is referred to as a potentiated sulfonamide. Antibiotics, also known as antimicrobials, are used to treat infections caused by bacteria. They do not work against viruses.

Primor® has been shown to be effective in treating specific bacterial infections in the dog, as described below.

:: HOW DOES PRIMOR® WORK?
There are many kinds of bacteria. Some cause infections of the skin and soft tissues, while others cause infections of the urinary tract (kidney and bladder). There are also many kinds of antibiotics. Each one has a special way of fighting bacteria. Some stop bacteria from growing so the animal’s immune system can kill it, while others kill the bacteria directly. Either way, antibiotics work with your dog’s body to clear the infection. Each antibiotic works only against certain bacteria. It may not work against others. To treat your dog's infection, you need the right kind of antibiotic.

Primor® can either inhibit the growth of bacteria or can directly kill the bacteria, depending on the type of infection.

:: WHEN SHOULD PRIMOR® BE USED IN DOGS?
Sometimes, dogs get infections on the surface of their skin, in wounds, or in cuts, or in the soft tissues. Left untreated, these can affect your dog’s overall health. Infections on the skin may cause severe pain, loss of hair, itching, and/or a bad odor. In addition to the pain, if the infection is in a wound, it might slow the healing. If the infected wound is on a leg, you may see your dog start to limp. Primor® is used to treat infections of the skin and soft tissues in dogs.

Dogs can also get infections in their urinary tract (bladder and kidneys). These can cause pain or make your dog feel as if it needs to urinate more often. Other common signs are accidents in the house, and blood in the urine. Left untreated these can cause kidney damage and result in your dog becoming very sick. Primor® can be used to treat urinary tract infections in dogs.
HOW DO VETERINARIANS KNOW WHICH ANTIBIOTIC TO USE?
Veterinarians make this choice based on what they see and know about your pet’s health. This choice may be based on many things such as:
• Examination of your dog
• The body part of your dog that is affected
• The kind of bacteria that is causing the infection
• How difficult it is for you to give your dog an antibiotic

Sometimes your veterinarian may want to take a sample of bacteria from the infection for a culture and sensitivity test. Your veterinarian will recommend this test to help him or her decide which antibiotic to use. The test can be very useful to identify hard-to-treat infections.

WILL PRIMOR® HELP MY PET?
Most dogs given this treatment will respond well. Most signs of the infection start to go away within three days. If they do not, your dog may:
• Have more than one kind of bacterial infection
• Have an infection caused by something other than a bacteria
• Be stressed or have other diseases that weaken the body’s ability to help fight off the infection
• Need a different antibiotic, because the bacteria causing the infection are not bacteria that Primor works against

If your dog doesn’t seem to be getting better, contact your veterinarian. Your veterinarian may do some extra tests. The kind of antibiotic your dog is taking may also be changed.

IS THERE ANY FOLLOW-UP OR MONITORING I SHOULD DO?
You may be asked to bring your dog back at some point during or after treatment. This will depend on:
• What kind of infection your dog has
• How sick your dog is
• If your dog had this infection before

Be sure to follow your veterinarian’s advice. Having your dog checked again may improve its chances of getting well. If you do not follow your veterinarian’s recommendation for a recheck it may also make the infection harder to treat and more costly.

HOW IS PRIMOR® GIVEN TO MY DOG?
A veterinarian must prescribe Primor®. It should not be available to you in any other way. Primor® is available as a tablet.

At home, you can give the Primor® pills to your dog by mouth. Your veterinarian will tell you how and when to do this. An initial high dose of Primor® is given on the first day, followed by lower doses the remaining days.

Always follow your veterinarian’s directions and give this treatment the right way. This can help your dog get better more quickly and stay healthy longer. If you do not understand the directions, call your veterinarian.

HOW LONG DO I HAVE TO GIVE MY DOG PRIMOR®?
You should give the Primor® for as long as your veterinarian told you to give it.

Some dog owners are tempted to stop treatment when their dog is feeling better. This is not a good idea and can be very harmful in the long run. It should be done only if your veterinarian says so. Even though your dog may seem better,
the infection might still be there. So if you stop treating your dog too soon, the infection can come back. It can also be much harder to control.

Shortening the use of these treatments or skipping doses can lead to the growth of resistant bacteria. This kind of bacteria may be bad for your dog as well as other pets and people. So be sure to give all of the treatment exactly as your veterinarian recommended.

If you have trouble giving the treatment to your dog, ask your veterinarian for help.

Does Primor® Have Side Effects?
Primor® is generally well tolerated. However, as with any medicine, side effects may occur. Side effects reported following the use of sulfonamides or potentiated sulfonamides such as Primor® include arthritis (pain and stiffness in one or more legs), fever, anemia (causing weakness or lack of energy), increased thirst, liver problems (elevated liver enzyme levels and/or yellowing of the whites of the eyes or the skin), decreased appetite, vomiting, diarrhea, seizures, increased aggressiveness, stumbling or a change in your dog's behavior. You may notice that your dog's eyes are dry or reddened, which may indicate decreased tear production.

Some pets may be allergic to this kind of medicine. Symptoms of allergic reactions may include swelling of the face, itchy skin, hives, or breathing problems. These problems can sometimes happen very quickly and may be serious. If you think your pet is having a reaction to the medicine, call your veterinarian right away. These kinds of problems must be treated quickly.

Long-term use of Primor® may cause elevated cholesterol, and changes in the thyroid and pituitary glands. These changes are reversible once the drug is stopped. Talk to your veterinarian if you have concerns.

Call your veterinarian if you notice these or any changes in your dog while taking Primor®.

Should Some Dogs Not Get Primor®?
Primor® should not be given to dogs that
• Have history of liver disease
• Have low blood cell or platelet counts
• Have had allergic reactions or have not tolerated other sulfonamide antibiotics in the past

What Else Should I Know About Primor?
As with other sulfonamide antibiotics there is an increase risk of crystals forming in the urine (which may cause blood in the urine or kidney damage) if your dog does not drink enough water while taking Primor. Therefore, make certain that your dog has access to fresh water at all times while taking Primor.

Be sure to tell your veterinarian if your dog is pregnant or nursing, or if you plan to breed your dog. Primor® has not been tested in dogs that are pregnant or breeding, or in nursing puppies.

How Should Primor® Be Stored?
Primor® should be stored at room temperature. Be sure to replace the cap securely after each opening.

Note:
• Primor® is for dogs only
• Primor® must be prescribed by a veterinarian
• Keep out of reach of children
TOKICITY AND SAFETY

Toxicity data for PRIMOR indicate that the drug is safe when used at the recommended dosage. Following oral administration of PRIMOR to dogs at 27.5 mg/kg/day (12.5 mg/lb/day) for 8 weeks, no changes were noted in hematology, blood chemistry, urinalysis, gross pathology, and histopathology, except for elevated serum cholesterol, increased thyroid and liver weights, enlarged basophilic cells in the thymus, and mild follicular thyroid hyperplasia. These changes are known to be associated with prolonged administration of sulfonamides to dogs and have been shown to be reversible.

ADVERSE REACTIONS

Conditions reported following use of sulfonamides or potentiated sulfonamides include polyarthritides, urticaria, facial swelling, fever, haemolytic anaemia, polyptenia, polyuria, hepatitis, vomiting, anorexia, diarrhea, and neurolromatic disorders. In rare instances, neurologic signs including behavioral changes, ataxia, seizures, aggression, and hyporeactivity have been reported. Keratitis sicca, possibly due to prolonged use of sulfonamides, has been reported. Individual animal hypersensitivity may result in local or generalized reactions. Anaphylactoid reactions, although rare, may occur. Antidote: Epinephrine for anaphylactoid reactions.

PRECAUTIONS

Decreased water consumption and acute diarrhea enhance the probability of the formation of sulfonamide crystals in the urinary tract, which can lead to the formation of stones in the kidneys. To prevent these problems, it is recommended that in dogs with acute diarrhea, the dosage of PRIMOR should be reduced. If symptoms persist, a change in medication may be necessary.

CONTRAINDICATIONS

PRIMOR should not be used in dogs showing evidence of liver dysfunction, blood dyscrasias, or in those with a history of sulfonamide hypersensitivity.

DOSEAGE 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 of the rat at 12.5 mg/lb (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:

<table>
<thead>
<tr>
<th>Body Weight (lb)</th>
<th>Up To</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>
<td>1/2</td>
</tr>
<tr>
<td>PRIMOR 240</td>
<td>10</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>PRIMOR 600</td>
<td>20</td>
<td>3</td>
<td>1/2</td>
</tr>
<tr>
<td>PRIMOR 1200</td>
<td>50</td>
<td>1</td>
<td>1/2</td>
</tr>
<tr>
<td>PRIMOR 1200</td>
<td>100</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

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

HOW SUPPLIED

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

STORAGE

Store at controlled room temperature 15°C-30°C (59°F-86°F).

CAUTION

Not for human use. For use in dogs only.

WARNING

Keep out of reach of children.

REFERENCES

5. "BBL" and "Sensi-Disc" are registered trademarks owned by Becton, Dickinson and Company, Paramus, New Jersey.
6. For a copy of the Material Safety Data Sheet (MSDS) or to report adverse reactions call Pfizer Animal Health at 1-800-366-5288.
7. NADA #100-929, Approved by FDA.

BLOOD LEVELS

Therapeutically effective blood levels of both sulfadimethoxine and oxomorphone are obtained and maintained in dogs when using the recommended PRIMOR dosing regimen of 25 mg/lb on day one and of 12.5 mg/lb on following days. Blood levels of sulfadimethoxine and oxomorphone were studied in 2 male and 2 female dogs. The initial drug dose was administered at zero hours. Blood samples were taken at 11 intervals, 6 of which are reported in Table 1. A second dose of PRIMOR was administered immediately following the 24-hour blood samples and blood values were determined 2 hours later (26 hours from the initial dose).

Table 1: Blood levels (mcg/ml) obtained with administration of a 25 mg/lb dose of PRIMOR followed with a 12.5 mg/lb dose at 24 hours

<table>
<thead>
<tr>
<th>Sample</th>
<th>2 hr</th>
<th>6 hr</th>
<th>12 hr</th>
<th>24 hr</th>
<th>26 hr</th>
<th>32 hr</th>
<th>48 hr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfadimethoxine</td>
<td>23.00</td>
<td>41.00</td>
<td>39.00</td>
<td>69.00</td>
<td>67.00</td>
<td>36.00</td>
<td></td>
</tr>
<tr>
<td>Oxomorphone</td>
<td>1.04</td>
<td>0.55</td>
<td>0.09</td>
<td>1.08</td>
<td>0.44</td>
<td>0.03</td>
<td></td>
</tr>
</tbody>
</table>

*Sample collected before administration of the second dose."