A. INGREDIENT NAME:

SULFADIMETHOXINE

B. Chemical Name:

(2,6-dimethoxy-pyrimidin-4-yl)sulphailamide

C. Common Name:

Arg.-Lenterap, Denm.-Suloplan, Ital.-Bensulfa,Chemiosalfa, Crozinal, Deltin, Diasulfa, Diazinol, Dimetossilinia, Fultamid, Ipersulfa, Levisul, Micromega, Neosulfamyd, Redifal, Risulpir, Ritarsulfa, Sulfabon, Sulfadomus, Sulfaduran, Sulfastop, Sulfomikron,Tempodiazina, Pol.- Madroxine,S. Afr.- Jatsulph, Lensulpha, Pansulph, Sulfathox, Spain-Dimetoxan, Oxazina,Sulf-reten.

D. Chemical grade or description of the strength, quality, and purity of the ingredient:

Assay (tit.) 99%

E. Information about how the ingredient is supplied:

White Crystals from Dilute Alcohol

F. Information about recognition of the substance in foreign pharmacopeias:

Indian Pharmacopeia
British Pharmacopeia 1988
British Pharmacopeia 1993, VOL I

G. Bibliography of available safety and efficacy data including peer reviewed medical literature:

Weinstein, L. A review of sulphadimethoxine. *New Engl. J. Med.* 1960; 263:842.

Vree, T. B. Pharmacokinetics. N1-glucuronidation and N4-acetylation of sulfadimethoxine in man. *Pharm. Weebl. (Sci)*, 1990;12:51-59.

1998-34581-02-39-BDL26

Marusich, W. L., Ogrinz E.f., and Hecht. B. Safety of Sulfadimmethoxine in turkeys *Poultry Science*, 1971;50(2):513-517.

Marusich, W. L., Ogrinz, E., and Brand, M. Safety and compatibility of Sulfadimethoxine in chickens. *Poultry Science*, 1969;48(1):210-216.

Maestrone, G., Thompson, E., and Yeisley, H. Rofenaid at a 0.02% dose level in feed was effective prophylactically and therapeutically against an experimentally induced Escherichia coli airsac. The activit of Rofenaid compared very favorable with that of the aproved dose level of NF-180. *Avian Diseases*, 1979;23(3): 682-687.

Porapnev, F. V.and Skuratovich, A. A. Sulfamonomethoxin and Sulfadimethoxin in patients. *Antibiotiki*. 1973;18(5): 453-456.

Ames, T. R., Casagranda, C. L.,a nd Werdin, R.E. Effect of sulfadimethoxine-ormetoprim in the treatment of calves with induced Pasteurella pneumonia. *American Journal of Veterinary Research*, 1987;48(1): 17-20.

H. Information about dosage forms used:

Tablets

I. Information about strength:

500mg

J. Information about route of administration:

Orally

K. Stability data:

Melts at about 201-203°
Storage stabilities (decay half-lives at -20° C) 567 days
Stable in fortified chicken liver and thigh muscle tissues during frozen storage for 1 year at -20 and -70 °C.

L. Formulations:

M. Miscellaneous Information:

SULFADIMETHOXINE

The rodent oral LD50 is >10 g/kg.

This drug can produce allergies, hypersensitivity, Stevens-Johnson syndrome. The powder is an eye and skin irritant. It is not known if the drug is mutagenic, teratogenic or carcinogenic.

Its present use is in veterinary medicine as an antibacterial drug. It is on the FDA withdrawal list.

REFERENCES

1. Thomas GK, Millar RG, Anstis PW. Stability of sulfonamide antibiotics in spiked liver tissue during frozen storage. Journal of AOAC International 1997; 80(5):988-95.

2. Reimerdes EH, Seydel JK. [Significance of acid stability of sulfonamides for the determination of their N4-metabolites]. [German] Arzneimittel-Forschung 1969; 19(11):1863-8.

3. Parks OW. Stability of sulfaquinoxaline, sulfadimethoxine, and their N4-acetyl derivatives in chicken tissues during frozen storage. Journal of AOAC International 1994; 77(2):486-8.

4. Marusich WL, Ogrinz EF, Hecht B, et al. Safety of sulfadimethoxine potentiated mixture (Rofenaid), a new broad spectrum coccidiostat-antibacterial, in turkeys. Poultry Science 1971; 50(2):512-7.

5. Marusich WL, Ogrinz E, Brand M, et al. Safety and compatibility of sulfadimethoxine potentiated mixture (Ro 5-0013), a broad spectrum coccidiostat-antibacterial, in chickens. Poultry Science 1969; 50(1):210-6.

6. Gates NL, Rich JE, Myers LL, et al. Efficacy of selected antimicrobial agents in treating diarrheal disease in neonatal lambs. Veterinary Medicine, Small Animal Clinician 1979; 74(5):707-9.

7. Maestrone G, Thompson E, Yeisley H, et al. Prophylactic and therapeutic activity of Rofenaid-40A in an experimental Escherichia coli airsac infection in chickens. Avian Diseases 1979; 23(3):682-7.

8. Potapnev FV, Skuratovich AA. [Comparative evaluation of therapeutic efficacy of sulfamonomethoxin and sulfadimethoxin in patients with gonorrhea]. [Russian] Antibiotiki 1973; 18(5):453-6.

9. Mitrovic M, Schildknecht EG. Comparative chemotherapeutic efficacy of Agribon (sulfadimethoxine) and other agents against coccidiosis in chickens and turkeys. Poultry Science 1973; 52(4):1253-60.

10. Mitrovic M, Bauerfeind JC. Efficacy of sulfadimethoxine in turkey diseases. Avian Diseases 1971; 15(4):884-93.

11. Orton CT, Hambly LR. Efficacy studies on potentiated sulfadimethoxine as a chicken coccidiostat. Poultry Science 1971; 50(5):1341-6.

12. Ames TR, Casagranda CL, Werdin RE, et al. Effect of sulfadimethoxine-ormetoprim in the treatment of calves with induced Pasteurella pneumonia. American Journal of Veterinary Research 1987; 48(1):17-20.