Amiglyde-V®
(amikacin sulfate injection)

DESCRIPTION
Amikacin sulfate is a semi-synthetic aminoglycoside antibiotic derived from kanamycin. It is C22H43N5O13•2H2SO4, D-streptamine, 0-3-amino-3-anhydro-1,2-deoxy-→[α4)]-N1-(4-amino-2-deoxy-→6)-O-[6-amino-6-deoxy-D-glucopyranosyl (1→4)N-(4-amino-2-hydroxy-1-aminobutyryl)-2-deoxy-→sulfate (2)] (salt).
The aminoglycoside antibiotics in general have limited activity against gram-positive pathogens, although S. pneumoniae and Listeria monocytogenes are susceptible to amikacin as noted above. Amikacin has been shown to be effective against many amikacin-resistant strains due to its ability to resist degradation by aminoglycoside-inactivating enzymes known to affect gentamicin, tobramycin and kanamycin.

CLINICAL PHARMACOLOGY
Endometrial Tissue Concentrations
Comparisons of amikacin activity in endometrial biopsy tissue following intrauterine infusion with that following intramuscular injection of AMIGLYDE-V® in mares demonstrate superior endometrial tissue concentrations when the drug is administered by the intrauterine route. Intrauterine infusion of 2 grams AMIGLYDE-V daily for three consecutive days in mares results in peak concentrations typically exceeding 40 mcg/g of endometrial biopsy tissue within one hour after infusion. Twenty-four hours after each treatment of amikacin is still detectable at concentrations averaging 2 to 4 mcg/g. However, the drug is not appreciably absorbed systemically following intrauterine infusion. Endometrial tissue concentrations following intrauterine injection are roughly parallel, but are typically somewhat lower than corresponding serum concentrations of amikacin.

Safety
AMIGLYDE-V® is non-immunizing to equine endometrial tissue when infused into the uterus as directed (see ADMINISTRATION AND DOSAGE). In laboratory animals as well as equine studies, the drug was generally found to not be irritating when injected intravenously, subcutaneously or intramuscularly.

Although amikacin, like other aminoglycosides, is potentially nephrotoxic, ototoxic and neurotoxic, parenteral (intravenous) administration of AMIGLYDE-V® (amikacin sulfate injection) twice daily at dosages of up to 10 mg/lb for 15 consecutive days in horses resulted in no clinical, laboratory or histopathologic evidence of toxicity. Intrauterine infusion of 2 grams AMIGLYDE-V® 8 hours prior to breeding by natural service did not impair fertility in mares. Such reports must not be used for less than 8 hours following uterine infusion.

INDICATIONS
AMIGLYDE-V® is indicated for the treatment of uterine infections in mares. For treatment of uterine infections in mares, 2 grams (8 mL) of AMIGLYDE-V®, mixed with 200 mL 0.9% Sodium chloride injection, USP and aseptically infused into the uterus daily for three consecutive days, has been found to be the most efficacious dosage.

CONTRAINDICATIONS
There are no known contraindications for the use of AMIGLYDE-V® in horses other than a history of hypersensitivity to amikacin.

PRECAUTIONS
Although AMIGLYDE-V® is not absorbed to an appreciable extent following intrauterine infusion, concurrent use of other aminoglycosides should be avoided because of the potential for additive effects.

ADVERSE REACTIONS
No adverse reactions or other side effects have been reported.

WARNING
Do not use in horses intended for human consumption.

REFERENCES

Zoetis
Distributed by Zoetis Inc.
Kalamazoo, MI 49007

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