State of Indiana
Indiana Horse Racing Commission

Eric Holcomb, Governor **www.in.gov/hrc**

IHRC Advisory Notice to Horsemen and IHRC Licensed Veterinarians

February 22, 2022

Please be aware of recent advisory released by the RMTC regarding products containing Isoxsuprine. **The FDA has withdrawn approval for products containing isoxsuprine (4/D).** As a result of the withdrawal of FDA approval, horsemen and licensed veterinarians are advised against the use of isoxsuprine. It is now listed as a non-approved substance in the ARCI Model Rules Prohibited List. Please note that the only legal compounding of drugs for animal use can involve use of approved human or animal drugs as the starting ingredient. There are no approved human or animal isoxsuprine drugs. Please see https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=530.13. For questions, please contact Dr. Kerry Peterson, IHRC Equine Medical Director. Kepeterson@hrc.in.gov 317-233-3119.

Isoxsuprine Advisory
February 03, 2022

The FDA has withdrawn approval for products containing isoxsuprine (4/D). The full notice, excerpted below, can be found at: https://www.fda.gov/drugs/fda-notification-regarding-isoxsuprine-hydrochloride-drug-products

FDA Notification Regarding Isoxsuprine Hydrochloride Drug Products

On July 15, 2020, FDA announced the final decision of the Commissioner of Food and Drugs, that Vasodilan containing isoxsuprine hydrochloride lacked substantial evidence, consisting of adequate and well-controlled studies, to be effective for specific indications. Vasodilan containing isoxsuprine hydrochloride was part of the Drug Efficacy Study Implementation process. FDA notified manufacturers and labelers of the products (see list below) on Aug. 9. 2021, to stop distributing their isoxsuprine hydrochloride drug products. As of Oct. 13, 2021, all the companies agreed to cease distribution of the unapproved isoxsuprine HCl drugs.

FDA considers isoxsuprine hydrochloride drug products unapproved new drugs that cannot be distributed in interstate commerce without a new drug application approved by FDA. The distribution of any unapproved isoxsuprine hydrochloride drug products, not limited to the drug products listed below, is considered unlawful and subject to enforcement action.

The Prohibited List annexed to the ARCI Model Rules, as a result of the withdrawal of FDA approval, establishes isoxsuprine as a non-approved substance:

S0. NON-APPROVED SUBSTANCES
Any pharmacologic substance that is not approved by any governmental regulatory health authority for human or veterinary use within the jurisdiction is prohibited. This prohibition includes drugs under pre-clinical or clinical development, discontinued drugs, and designer drugs (a synthetic analog of a drug that has been altered in a manner that may reduce its detection)…

ARCI 025-015 Prohibited Practices
(2) Prohibited Substances and Methods:
(a) The substances and methods listed in the annexed Prohibited List may not be used at any place or time, and may not be possessed on the premises of a racing or training facility under the jurisdiction of the Commission, except as a restricted therapeutic use.

The possession of isoxsuprine, even if prescribed prior to the withdrawal of FDA approval, constitutes a violation in jurisdictions where racing Commissions have adopted the Model Rules or comparable language. Horsemen are advised to consult their veterinarians for guidance on proper disposal of any isoxsuprine in their possession.

RMTC Isoxsuprine Advisory, February 2022