

衛生署藥物辦公室  
藥物資訊及警戒科

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DEPARTMENT OF HEALTH  
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DRUG INFORMATION AND  
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17 Apr 2023

Dear Healthcare Professionals,

**Reducing risks to human and animal health from exposure to N-methyl pyrrolidone in veterinary medicines**

Your attention is drawn to the European Medicines Agency's (EMA) announcement that the Committee for Veterinary Medicinal Products (CVMP) recommended new measures to reduce the risks from exposure to the excipient N-methyl pyrrolidone (NMP) for women who may handle NMP-containing veterinary medicines and animals that are given these medicines. The recommendations address inconsistencies in the product information of veterinary medicines containing NMP, which are marketed in many European Union (EU) Member States.

The CVMP recommended that veterinary medicines that expose the user to amounts of NMP above a certain threshold should not be given to animals by pregnant women or by women who may be pregnant. Furthermore, women who are able to have children should exercise caution when using these medicines. This includes wearing personal protective equipment such as gloves, particularly for pour-on and spot-on products, shampoos, sprays and concentrates for oral solutions.

The Committee also recommended that in the absence of studies demonstrating the safe use of veterinary medicines containing NMP in the target animal species during pregnancy, lactation or lay, NMP-containing veterinary medicines should only be given to animals that are pregnant, lactating, in lay or intended for breeding after assessment of the benefits and risks by the treating veterinarian. To assist veterinarians in their decision-making, the product information must specify the precise quantity of NMP contained in these veterinary medicines.

NMP is an excipient used in some veterinary medicines that is classified as a teratogen (a substance that can cause birth defects following exposure during pregnancy) in laboratory animals. There is therefore the possibility that NMP could cause birth defects in children of women who handle or come into contact with NMP-containing medicines during their pregnancy, and in the offspring of animals given these

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medicines.

More than 1,100 veterinary medicines containing the excipient NMP are available in the EU under various trade names and in different formulations, for use mainly in companion animals and large farm animals. These medicines are available as injections, solutions for infusion, spot-on and pour-on products, shampoos, sheep dips, sprays and concentrates for oral solutions for use in the drinking water of animals or solutions for fish treatment.

Please refer to the following website in EMA for details:

<https://www.ema.europa.eu/en/news/reducing-risks-human-animal-health-exposure-n-methyl-pyrrolidone-veterinary-medicines>

In Hong Kong, there is one registered pharmaceutical product for veterinary use containing NMP as excipient, namely, Fido's Fre-itch Rinse Concentrate (Vet) (HK-61356). This product is registered by Evergreen Pet Supplies Ltd. It is an over-the-counter medicine. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to NMP. In light of the above EMA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Adverse Drug Reaction Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: [adr@dh.gov.hk](mailto:adr@dh.gov.hk)). For details, please refer to the website at Drug Office under "ADR Reporting": <http://www.drugoffice.gov.hk/adr.html>. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,



(Terence MAN)

for Assistant Director (Drug)