Notice of Consultation on the Prescription Drug List (PDL): Metamizole (dipyrone)

April 23, 2021

Our file number: 21-107779-356

This Notice of Consultation provides an opportunity to comment on the proposal to add metamizole (also known as ‘dipyrone’) to the Prescription Drug List (PDL). Only the Veterinary part of the PDL is proposed to be revised.

The proposed veterinary PDL listing is:

Drugs containing any of the following:	Including (but not limited to):	Qualifier	Effective Date
Metamizole (dipyrone) or its salts	-	-	To be determined following the consultation

Rationale:

Health Canada has received a veterinary drug submission for metamizole (also known as ‘dipyrone’), a pyrazolone non-steroidal anti-inflammatory drug (NSAID). Metamizole is indicated for use as an analgesic, anti-inflammatory, antipyretic and antispasmodic agent in dogs and horses. In Canada, metamizole has been available as a non-prescription, single ingredient veterinary drug since its approval in 1965. Metamizole for human use was withdrawn from the Canadian market in the 1960’s due to the risk of agranulocytosis. Agranulocytosis is not a concern in the animals for which this drug is indicated.

Upon review of the safety and efficacy evidence submitted to Health Canada for the approval of a new metamizole product, it was determined that the following criteria outlined in section C.01.040.3 of the *Food and Drug Regulations* apply to metamizole. Specifically:

- Supervision by a practitioner is necessary:
    - for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in respect of which the drug is recommended for use; and,
    - to monitor a disease, disorder or abnormal physical state, or its symptoms, in respect of which the drug is recommended for use, or

to monitor the use of the drug.

Metamizole is used in the treatment of serious veterinary diseases not easily diagnosed by the public. A thorough veterinary examination is necessary to determine the underlying cause of disease and appropriate intervention. Practitioner expertise is necessary to administer the drug intravenously and monitor for adverse events, as intravenous administration may be related to an increased risk of anaphylactic reactions. Practitioner supervision is also necessary to monitor the effect(s) of the drug and determine if additional intervention(s) is/are required (e.g., surgery). Metamizole should be administered 2 to 3 times per day for a maximum of 1-2 days or as recommended by a veterinarian. Further, practitioner supervision is necessary to ensure that the drug is not used for prolonged periods in animals with known hepatic or renal issues or known coagulopathies, or in combination with corticosteroids, chlorpromazine, phenylbutazone or barbiturates.

The addition of metamizole to the veterinary PDL would also be consistent with the PDL listing of similar veterinary drugs (e.g., meloxicam, phenylbutazone, flunixin meglumine, deracoxib, robenacoxib). It would also align with our international counterparts since metamizole and metamizole combination products have prescription status in other jurisdictions including the USA, Australia, France, Germany and the United Kingdom.

Should this PDL amendment proceed, a veterinary product containing metamizole will be considered a prescription drug under the *Food and Drug Regulations*.

The following Drug Identification Number (DIN) products will be affected by this switch:

- 02229855
- 00319406
- 02279843
- 02231658
- 02500086

Additional information on how Health Canada determines prescription status (or non-prescription status) is available in the Guidance Document: Determining Prescription Status for Human and Veterinary Drugs.

Comments on this proposed change to the PDL should be provided to Health Canada in writing, preferably in electronic format, within 75 days from the date of this notice.

Please send your comments to:

Health Canada
Prescription Drug Status Committee
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1600 Scott Street
Ottawa, Ontario
K1A 0K9
E-mail: hc.drug.prescription.status-statut.dordonnance.des.drogues.sc@canada.ca

Next steps:

All comments will be reviewed and summarised. Should Health Canada proceed with the amendment, a Notice of Intent to Amend the PDL will be posted on the Health Canada website.

Date modified:
2021-04-23