

EMA/734836/2017 EMEA/V/C/004222

#### **EPAR** summary for the public

# Galliprant

grapiprant

This is a summary of the European public assessment report (EPAR) for Galliprant. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use. It is not intended to provide practical advice on how to use Galliprant.

For practical information about using Galliprant, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

#### What is Galliprant and what is it used for?

Galliprant is a veterinary medicine. It is used in dogs to treat pain associated with mild to moderate osteoarthritis, a condition causing swelling and pain in the joints. It contains the active substance grapiprant.

#### How is Galliprant used?

Galliprant is available as tablets and can only be obtained with a prescription. It is given to dogs once daily on an empty stomach at least one hour before the next meal. The dose is based on the bodyweight of the dog and the length of treatment depends on the response. Intermittent treatment may be beneficial in some dogs as signs of osteoarthritis come and go.

For further information, see the package leaflet.

### How does Galliprant work?

Galliprant contains grapiprant, a non-steroidal, non-cyclooxygenase inhibiting anti-inflammatory drug (NSAID), of the piprant class, that works in a different way from other NSAIDs, which block a range of cyclo-oxygenase enzymes. Grapiprant works by blocking a specific target receptor called EP4, through which natural substances called prostaglandins act to produce pain in osteoarthritis. By blocking EP4, grapiprant helps relieve the signs of the condition.



#### What benefits of Galliprant have been shown in studies?

Two field studies were conducted involving dogs mostly with mild to moderate osteoarthritis confirmed by radiography in at least one limb joint. In total, 51% of dogs (120 of 235) were treated successfully with Galliprant at 28 days after the start of the treatment. This compared to 36% of dogs receiving a dummy treatment (82 of 231). Success was assessed by the dog owners and by veterinarians, using scoring systems for pain severity, pain interference and overall life quality.

#### What are the risks associated with Galliprant?

The most common side effect with Galliprant (which may affect more than 1 in 10 animals) is mild and generally short-lived vomiting.

Galliprant must not be given to pregnant, lactating or breeding dogs.

For the full list of side effects and restrictions with Galliprant, see the package leaflet.

# What are the precautions for the person who gives the medicine or comes into contact with the animal?

Hands should be washed after handling the medicine.

If the medicine is accidentally swallowed by a person, the advice of a doctor should be sought immediately. If swallowed by a child, mild and reversible gastrointestinal signs and nausea may be seen.

## Why is Galliprant approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Galliprant's benefits are greater than its risks and recommended that it be approved for use in the EU.

#### Other information about Galliprant?

The European Commission granted a marketing authorisation valid throughout the EU for Galliprant on 9 January 2018.

The full EPAR for Galliprant can be found on the Agency's website: ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports. For more information about treatment with Galliprant, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in November 2017.