PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton for 30, 100 and 250 tablets}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pexion 100 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Imepitoin 100 mg

3. PACKAGE SIZE

30 tablets
100 tablets
250 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 61700/5063

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bottle of 250 Tablets (100mg)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pexion 100 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Imepitoin 100 mg

100 tablets
250 tablets

3. TARGET SPECIES

Dogs.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp.: {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
{Bottle of 30 and 100 tablets (100mg)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pexion

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

100 mg

30 tablets
100 tablets

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Pexion 100 mg tablets for dogs
Pexion 400 mg tablets for dogs

2. Composition

One tablet contains:

Active substance:
Imepitoin 100 mg
Imepitoin 400 mg

White, oblong, half-scored tablets with embedded logo “I 01” (100 mg) or “I 02” (400 mg) on one side. The tablet can be divided into equal halves.

3. Target species

Dogs.

4. Indications for use

For the reduction of the frequency of generalised seizures due to idiopathic epilepsy in dogs for use after careful evaluation of alternative treatment options.
For the reduction of anxiety and fear associated with noise phobia in dogs.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs with severely impaired hepatic function, severe renal or severe cardiovascular disorders.

6. Special warnings

Idiopathic epilepsy
Because of the nature of epilepsy, the pharmacological response to treatment may vary. Some dogs will be free of seizures, in other dogs a reduction of the number of seizures will be observed, whilst others will be non-responders. For this reason, careful consideration should be given before deciding to switch a stabilized dog onto imepitoin from a different treatment. In non-responders, an increase in seizure frequency may be observed. Should seizures not be adequately controlled, further diagnostic measures and other antiepileptic treatment should be considered. When transition between different antiepileptic therapies is medically required, this should be done gradually and with appropriate clinical supervision.

The efficacy of the veterinary medicinal product in dogs with status epilepticus and cluster seizures has not been investigated. Therefore, imepitoin should not be used as primary treatment in dogs with cluster seizures and status epilepticus.

No loss of anticonvulsant efficacy (tolerance development) during continuous treatment of 4 weeks was observed in experimental studies lasting 4 weeks.

No definitive conclusions can be drawn on the effectiveness of imepitoin as an add-on therapy to phenobarbital, potassium bromide and/or levetiracetam from the limited studies available (see section “Interactions”).

Noise phobia
Efficacy for reduction of anxiety and fear associated with noise phobia has not been tested in dogs younger than 12 months.

Up to 2 days of pre-treatment may be necessary to achieve optimal anxiolytic efficacy in dogs with noise phobia. See section “Dosage for each species, route(s) and method of administration”.

Special precautions for safe use in the target species:
The safety of the veterinary medicinal product has not been tested in dogs weighing less than 2 kg or in dogs with safety concerns such as renal, liver, cardiac, gastrointestinal or other disease.

Anxiolytic drugs acting at the benzodiazepine receptor site, such as imepitoin, may lead to disinhibition of fear-based behaviours. The veterinary medicinal product may therefore result in an increase or decrease in aggression levels.
In dogs with a history of aggression problems, a careful benefit-risk evaluation should be made prior to treatment. This evaluation may include consideration of inciting factors or situations associated with previous aggressive episodes. Prior to initiating treatment in these cases, behaviour therapy or referral to a behaviour specialist should be considered. In these dogs, additional measures to mitigate the risk of aggression problems should be implemented as appropriate before treatment is initiated.

Mild behavioural or muscular signs may be observed in dogs upon abrupt termination of treatment with imepitoin.

The claim for the treatment of noise phobia is based on a pivotal field study which investigated a 3 day course of treatment for a noise event associated with fireworks. Longer treatment durations for noise phobia should be at the benefit-risk assessment of the veterinarian. Consideration should be given to use of a behavioural modification programme.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Ingestion of this veterinary medicinal product may cause dizziness, lethargy and nausea.
In case of accidental ingestion especially by a child, seek medical advice immediately and show the package leaflet or the label to the physician.
To prevent accidental ingestion of tablets, the cap of the bottle should be replaced immediately after withdrawing the required number of tablets for one administration.
Pregnancy and lactation:
The use of the veterinary medicinal product is not recommended in female dogs during pregnancy and lactation.

Fertility:
Do not use in male breeding animals.
See also section "Overdose".

Interaction with other medicinal products and other forms of interaction:
The veterinary medicinal product has been used in combination with phenobarbital, potassium bromide and/or in a small number of cases with levetiracetam and no harmful clinical interactions were observed.

Overdose:
In case of repeated overdose of up to 5 times the highest recommended dose of 30 mg imepitoin per kilogram bodyweight, neurological effects, gastrointestinal-related effects and reversible prolongation of the QT interval have been noted.

At such doses, the symptoms are not usually life threatening and generally resolve within 24 hours if symptomatic treatment is given.

These neurological effects may include loss of righting reflex (loss of balance), decreased activity, eyelid closure, lacrimation (excessive tears), dry eye (inadequate tears), and nystagmus (unusual eye movement).

At 5 times the recommended dose, decreased bodyweight may be observed.

In male dogs administered 10 times the upper recommended therapeutic dose, diffuse atrophy of seminiferous tubules in the testes and associated decreased sperm counts were seen.

See also section "Fertility".

7. Adverse events

Dogs.

Idiopathic epilepsy:

Very common (>1 animal / 10 animals treated):
Ataxia[1], somnolence[1].
Emesis[1].
Increased appetite[1,2]

Common (1 to 10 animals / 100 animals treated):
Hyperactivity[1].
Apathy[1], anorexia[1], polydipsia[1]
Disorientation[1].
Hypersalivation[1], diarrhoea[1]
Polyuria[1]

Uncommon (1 to 10 animals / 1,000 animals treated):
Aggression[3]

Rare (1 to 10 animals / 10,000 animals treated):
Increased sensitivity to sound[3].
Anxiety[3]
Elevated Creatinine[4]

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Elevated blood urea nitrogen (BUN)[4], elevated cholesterol (total)[4]
Prolapsed of the nictitating membrane[1], impaired vision[1].

[1] Mild and generally transient
[2] At the beginning of treatment
[3] Potentially treatment related. It may also be present during the preictal or postictal period or as behaviour changes which occur as part of the disease itself.
[4] Mild; however generally not exceeding normal reference ranges and not associated with any clinically significant observations or events.

Noise phobia:

Very common (>1 animal / 10 animals treated):
Ataxia[1, 2]
Increased appetite[1,2], lethargy[2].

Common (1 to 10 animals / 100 animals treated):
Emesis[2]
Aggression[2]

Uncommon (1 to 10 animals / 1,000 animals treated):
Hyperactivity[2]
Somnolence[2]
Hypersalivation[2]

[1] Transient. Occurred early in the treatment course. In more than half of the dogs that experienced ataxia during a clinical trial the signs resolved spontaneously within 24 hours in spite of continued treatment and in half of the remaining dogs within 48 hours.
[2] Most events are transient, resolving during or shortly after the end of the treatment course.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:
(UK):
Website: https://www.gov.uk/report-veterinarymedicine-problem/animal-reacts-medicine;
Email: adverse.events@vmd.gov.uk
(IE):
Website: https://www.hpra.ie

8. Dosage for each species, routes and method of administration

Oral use.

Idiopathic epilepsy
Oral administration at a dose range of 10 mg to 30 mg imepitoin per kg bodyweight twice daily, approximately 12 hours apart. Each tablet can be halved for appropriate dosing according to the individual bodyweight of the dog. Any remaining half-tablet should be used for the next dose.

The required dose will vary between dogs and will depend on the severity of the disorder. The recommended initial dose of imepitoin is 10 mg per kg bodyweight twice daily.

Initiate therapy using the bodyweight in kg and the dosing table. If seizures are not adequately reduced following a minimum of 1 week of treatment at the current dose the supervising veterinary surgeon should re-assess the dog. Assuming that the veterinary medicinal product is well tolerated by the dog, the dose can be increased by 50 to 100% increments up to a maximum dosage of 30 mg per kg administered twice daily.

Bioavailability is greater when administered to fasted dogs. The timing of tablet administration in relation to feeding should be kept consistent.

Number of tablets (to be given twice daily) for initiation of epilepsy treatment:

Dose: 10 mg/kg twice daily	Number of tablets per administration	
Bodyweight (kg)	100 mg tablet	400 mg tablet
5	½	
5.1–10	1	
10.1–15	1 ½	
15.1–20		½
20.1–40		1
40.1–60		1 ½
Over 60		2

Noise phobia
Oral administration at a dose of 30 mg imepitoin per kg bodyweight twice daily, approximately 12 hours apart.
Each tablet can be halved for appropriate dosing according to the individual bodyweight of the dog.

Initiate therapy 2 days prior to the day of the expected noise event and continue through the noise event using the bodyweight in kg and the dosing table below.

Bioavailability is greater when administered to fasted dogs. The timing of tablet administration in relation to feeding should be kept consistent.

Number of tablets (to be given twice daily) for noise phobia treatment:

Dose: 30 mg/kg twice daily	Number of tablets per administration	
Bodyweight (kg)	100 mg tablet	400 mg tablet
2.5 – 3.9	1	
4 – 5.9	1 ½	
6 – 7.9	2	
8 – 10.9	3	
11 – 15.9		1
16 – 22.9		1 ½
23 – 29.9		2
30 – 36.9		2 ½
37 – 43.9		3
44 – 49.9		3 ½
50 – 55.9		4
56 – 71.9		4 ½
72 – 80		5

9. Advice on correct administration

Each tablet can be halved for accurate dosing according to the individual bodyweight of the dog.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the bottle after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 61700/5063 (100mg)
Vm 61700/5064 (400mg)

Pack sizes of high-density polyethylene bottle each containing 30, 100 or 250 tablets with a child resistant closure.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

Local representatives and contact details to report suspected adverse reactions:
UK (GB)
Boehringer Ingelheim Animal Health UK Limited
Bracknell, RG12 8YS, UK
Tel: +44 1344 746957

UK(NI) and IE:
Boehringer Ingelheim Vetmedica GmbH
D-55216 Ingelheim/Rhein, Germany
Tel: +353 1 291 3985

17. Other information

Clinical trials in epilepsy:
In a European field trial that compared the efficacy of imepitoin to phenobarbital in 226 dogs with newly diagnosed idiopathic epilepsy, 45% of cases from the imepitoin group and 20% from the phenobarbital group were excluded from the efficacy analysis for reasons that included failure to respond to treatment. In the remaining dogs (64 dogs for Pexion and 88 dogs for phenobarbital), the following clinical results were observed: Mean frequency of generalised seizures was reduced from 2.3 seizures per month in the imepitoin group and from 2.4 seizures per month in the phenobarbital group to 1.1 seizures per month in both groups after 20 weeks of treatment. The difference between imepitoin and phenobarbital groups in the seizure frequency per month after treatment (adjusted for baseline difference) was 0.004, 95% CI [-0.928, 0.935]. During the evaluation phase of 12 weeks, the proportion of generalised seizure-free dogs was 47% (30 dogs) in the imepitoin group and 58% (51 dogs) in the phenobarbital group.

Though efficacy may not be complete, imepitoin is considered to be a suitable treatment option in some dogs because of its safety profile.

The safety of both treatments was evaluated in the full analysis data set (or safety data set, i.e. 116 animals in the imepitoin group and 110 animals in the phenobarbital group). Increasing doses of phenobarbital were associated with increasing levels of the liver enzymes ALT, AP, AST, GGT, and GLDH. In comparison, none of the five enzymes increased with increasing doses of imepitoin. A slight increase in creatinine values compared to baseline was observed in the imepitoin-treated dogs. However, the upper limit of the confidence interval for creatinine remained within the reference range at all visits. Additionally, fewer adverse events were noted for polyuria (10% vs 19% of dogs), polydipsia (14% vs 23%) and marked sedation (14% vs 25%) when comparing imepitoin to phenobarbital. Please refer to section "Adverse events" for further details.

In a US field trial that compared the efficacy of imepitoin at a fixed dose of 30 mg/kg twice daily to a placebo in 151 dogs with idiopathic epilepsy during a treatment period of 84 days, the proportion of generalized seizure-free dogs was 21% (21 dogs out of 99; 95 % CI [0.131; 0.293]) in the imepitoin group and 8% (4 dogs out of 52; 95% CI [0.004; 0.149]) in the placebo group. 25% of dogs did not respond to the treatment with imepitoin (same or increased frequency of seizures).

Clinical trial in noise phobia:
In a placebo-controlled field trial with a treatment duration of 3 days, the efficacy of imepitoin was investigated in dogs diagnosed with noise phobia during the traditional New Year's Eve fireworks. For the efficacy analysis, 226 dogs (104 imepitoin, 122 placebo) were eligible (at least one dose of medication & data for evaluation of co-primary endpoints), and the following results were observed for the two co-primary endpoints:

1. Owner assessed overall effect of study treatment (based on signs during a noise event and a comparison to signs during a previous noise event(s) without treatment: The cumulative odds of a good or excellent effect were significantly greater in the imepitoin group compared with the placebo group (Odds Ratio = 4.689; $p < 0.0001$, 95% CI [2.79;7.89]).
2. Owner-reported measure of their dog's anxiety symptoms (based on Lincoln Sound Sensitivity Scale) during a noise event: The sum scores showed a statistically significant treatment effect favouring imepitoin with a difference in anxiety score between imepitoin and placebo of -6.1; $p < 0.0001$, 95% CI [-8.6;-3.6].

POM-V

Gavin Hall
Approved: 22 July 2025