ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

(DE) Luminal vet 100 mg tablets for dogs
(AT, BE, DK, ES, FR, NL, PT, SE) Epirepress 100 mg, tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Phenobarbital 100 mg

Excipients:

Qualitative composition of excipients and other constituents
Cellulose, microcrystalline
Maize starch
Gelatin
Lactose monohydrate
Stearic acid
Silica colloidal anhydrous

White, round, flat faceted tablets, diameter 9 mm, with DN imprinted on one side and a cross break line on the other side. The tablet can be divided into equal halves (each 50 mg phenobarbital).

3. CLINICAL INFORMATION

3.1. Target species

Dogs

3.2. Indications for use for each target species

Prevention of seizures due to generalised epilepsy in dogs.

3.3. Contraindications

Do not use in cases of hypersensitivity to the active substance, to any other barbiturates or to any of the excipients.
Do not use in animals with severe impaired hepatic function.
Do not use in animals with serious renal and/or cardiovascular/respiratory disorders.

3.4. Special warnings

The decision to start antiepileptic drug therapy with phenobarbital should be evaluated for each individual case and depends on number, frequency, duration and severity of seizures in dogs.
To achieve successful therapy, administration of tablets must be at the same time each day.
Withdrawal or transition from other types of antiepileptic therapy should be made gradually to avoid precipitating an increase in the frequency of seizures.
Some of the dogs are free of epileptic seizures during the treatment, but some of the dogs show only a seizure reduction, and some of the dogs are considered to be non-responders.

3.5. Special precautions for use

Special precautions for safe use in the target species:

Caution is recommended in animals with:

- impaired hepatic and renal function
- hypovolemia, anemia and
- cardiac or respiratory dysfunction

The chance of hepatotoxic side effects can be diminished or delayed using an effective dose that is as low as possible. Monitoring of hepatic parameters is recommended in case of a prolonged therapy.
It is recommended to assess the clinical pathology of the patient 2-3 weeks after start of treatment and afterwards every 4-6 months, e. g. measurement of hepatic enzymes and serum bile acids. It is important to know that the effects of hypoxia etc. do cause increased levels of hepatic enzymes after a seizure.
Phenobarbital may increase the activity of serum alkaline phosphatase and transaminases. These may demonstrate non-pathological changes, but could also represent hepatotoxicity. Therefore, in the case of suspected hepatotoxicity, liver function tests are recommended.
In stabilised epileptic patients, it is not recommended to switch from other phenobarbital formulations to Luminaletten 15 mg or Luminal 100 mg tablets. However, if this cannot be avoided then additional caution should be taken. This includes more frequent plasma concentration sampling to ensure that therapeutic levels are maintained. Monitoring for increased side effects and for hepatic dysfunction should be conducted more regularly until stabilisation is confirmed.
Withdrawal of therapy with phenobarbital formulations should be made gradually to avoid precipitating an increase in the frequency of seizures.

Due to the formulation, the veterinary medicinal product should not be used in dogs weighting less than 20 kg.
Serum thyroxin may decrease during treatment, but without clinical relevance in most dogs.

With prolonged treatment dependence may occur. Abrupt cessation may precipitate withdrawal seizures.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Barbiturates can cause hypersensitivity. People with known hypersensitivity to barbiturates should avoid contact with the veterinary medicinal product.

Accidental ingestion may cause intoxication and could be fatal, particularly for children. Take utmost care that children do not come in contact with the veterinary medicinal product.
Phenobarbital is teratogenic and may be toxic to unborn and breastfed children; it may affect the developing brain and lead to cognitive disorders. Phenobarbital is excreted in breast milk. Pregnant women, women of childbearing age and lactating women should avoid accidental ingestion and prolonged skin contact with the veterinary medicinal product.
To prevent accidental ingestion of tablets, the container should be closed immediately after withdrawing the required number of tablets for one administration.
It is advisable to wear disposable gloves during administration of the veterinary medicinal product to reduce skin contact.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. If possible, the physician should be informed about the time and amount of ingestion, as this information may help to ensure that appropriate treatment is given.

Wash hands thoroughly after use.

Special precautions for the protection of the environment:

Not applicable.

3.6. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	Sedation[1] Ataxia[1]
Uncommon (1 to 10 animals / 1 000 animals treated):	Ataxia[2], somnolence[2], apathy[2], dizziness[2]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Polyuria[3], polydipsia[3], polyphagia[3]
Undetermined frequency (cannot be estimated from the available data)	Excitation[4] Hepatopathy[5] Low free thyroxine (FT4)[6], Low thyroxine (T4)[6] Pancytopenia[7], Neutropenia[7] Dermatitis[8]

[1] When serum levels reach the higher end of the therapeutic range.
[2] At the start of treatment but in some cases these effects may persist for the entire duration of treatment.
[3] May occur at average or higher therapeutically active serum concentrations, but these effects are usually transient and disappear with continued medication.
[4] Paradoxical hyperexcitability. Particularly after first starting therapy. As this hyperexcitability is not linked to overdosage, no reduction of dosage is needed.
[5] Plasma concentrations > 35-40 µg/ml may be associated with hepatotoxicity
[6] May be not an indication of hypothyroidism. Treatment with thyroid hormone replacement should only be started if there are clinical signs of the disease.
[7] Immunotoxic, due to deleterious effects on stem cells from bone marrow. These reactions disappear after cessation of treatment.
[8] Superficial, necrolytic.

If adverse reactions are severe, the administered dose should be decreased.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7. Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy:

Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Studies in laboratory animals have indicated that phenobarbital has an effect during prenatal growth, in particular causing permanent changes in neurological and sexual development. Neonatal bleeding tendencies have been associated with phenobarbital treatment during pregnancy.
Maternal epilepsy may be an additional risk factor for impaired foetal development. Therefore, pregnancy should be avoided in epileptic dogs whenever possible. In case of pregnancy, the risk that the medication may cause an increase in the number of congenital defects must be weighed up against the risk of suspending treatment during pregnancy. Discontinuation of treatment is not advised, but the dosage should be kept as low as possible.
Phenobarbital crosses the placenta and, at high doses, (reversible) withdrawal symptoms cannot be ruled out in newborns.

Lactation:

Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Phenobarbital is excreted in small amounts in breast milk and during nursing pups should be monitored carefully for undesired sedative effects. Weaning early may be an option. If somnolence/sedative effects (that could interfere with suckling) appear in nursing newborns, an artificial suckling method should be chosen.

3.8. Interaction with other medicinal products and other forms of interaction

A therapeutic dose of phenobarbital for antiepileptic therapy can significantly induce plasma proteins (such as α1acid glycoprotein, AGP), which bind drugs. Phenobarbital may reduce the activity of some drugs by increasing the rate of metabolism through induction of drug-metabolising enzymes in liver microsomes. Therefore, special attention must be paid to the pharmacokinetics and doses of drugs simultaneously administered. The plasmatic concentration of a range of drugs (for example cyclosporine, thyroid hormones, theophylline, antiepileptics, chloramphenicol, corticosteroids, doxycycline, beta blockers and metronidazole) is decreased in the case of concurrent administration of phenobarbital. The reliability of hormonal contraceptives is lower.
Concurrent use with other drugs having a central depressive action (like narcotic analgesics, morphinic derivates, phenothiazines, antihistamines, clomipramine and chloramphenicol) can increase the effect of phenobarbital.
Cimetidine and ketoconazole are inhibitors of hepatic enzymes: concurrent use with phenobarbital can induce an increase of serum concentration of phenobarbital. Phenobarbital may decrease the absorption of griseofulvin. Concurrent use with potassium bromide increases the risk of pancreatitis.
Use of phenobarbital tablets in conjunction with primidone is not recommended as primidone is predominantly metabolized to phenobarbital.
The following drugs can decrease the convulsive threshold: quinolones, high doses of β-lactam antibiotic, theophylline, aminophylline, cyclosporine and propofol for example. Medications which may alter the seizure threshold should only be used if really necessary and when no safer alternative exists.

3.9. Administration routes and dosage

The required dosage will differ to some extent between individuals and with the nature and severity of the disorder.

Administration route

Oral use.

Amount to be administered

The recommended starting dose is 2.5 mg phenobarbital per kg body weight, administered twice daily. Any adjustments to this dose are best made on the basis of clinical efficacy, blood concentrations and the occurrence of undesired effects.
The phenobarbital serum concentration considered to be therapeutically active is between 20-40 µg/ml.
Steady state serum concentrations are not reached until 1-2 weeks after treatment is initiated. The full effect of the medication occurs approximately after 2 weeks, and doses should not be increased during this time.
The phenobarbital serum concentration may be checked after steady state has been achieved, If it is less than 20 µg/ml and/or seizures are not being controlled, the dosage may be increased by 20 % at a time, with associated monitoring of serum phenobarbital levels. If seizures recur, the dose may be increased to a maximum serum concentration of 40 µg/ml. High plasma concentrations may be associated with hepatotoxicity.

The tablet can be divided into equal halves (each 50 mg Phenobarbital). Further division into quarters may be done only in order to facilitate administration to the dog.

For accuracy of dosing, dogs with less than 20 kg should commence therapy with Luminaletten vet tablets.

3.10. Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Clinical signs

Overdosage may result in coma, severe respiratory and cardiovascular depression, hypotension and shock leading to renal failure and death.

Procedures

The primary management measures are intensive symptomatic and supportive therapy with particular attention being paid to the maintenance of cardiovascular, respiratory, and renal functions and of the electrolyte balance. Treatment of overdosage can, if necessary, consist of gastric lavage with activated charcoal administration.

There is no specific antidote, but CNS stimulants (like Doxapram) may stimulate the respiratory centre. Give oxygen support.

3.11. Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12. Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN03AA02

4.2 Pharmacodynamics

The antiepileptic effects of phenobarbital are probably the result of at least two mechanisms, being decreased monosynaptic transmission, which presumably results in reduced neuronal excitability and an increase in the motor cortex's threshold for electrical stimulation.

4.3 Pharmacokinetics

Absorption

As a weak acid, phenobarbital is absorbed well from the gastrointestinal tract following oral administration to dogs, although peak plasma concentrations are not achieved until 4-6 hours after administration.

Distribution

Plasma protein binding of phenobarbital is 45 % and the distribution volume is 0.7 ± 0.15 l/kg. A steady-state serum concentration is achieved 8-15.5 days after treatment is initiated.
Phenobarbital is reasonably fat-soluble and crosses the blood-brain barrier slowly. The barbiturate effect therefore develops slowly, but persists for a long period of time. Due to the moderate fat solubility of phenobarbital, redistribution to adipose tissue occurs slowly. Phenobarbital crosses the placental barrier and enters breast milk.

Metabolism

Phenobarbital is converted in the liver into p-hydroxy-phenobarbital, which, due to a lower antiepileptic effect, no longer makes any significant contribution to the activity of phenobarbital. Barbiturates cause enzyme induction and thereby accelerate their own breakdown.

Elimination

About 25 % of the administered dose is excreted in the urine in unchanged form (elimination half-life: 37-75 hours) and about 75 % is excreted as p-hydroxy-phenobarbital glucuronide and sulphate derivatives and as p-hydroxy-phenobarbital itself. Following daily administration of 5.5 mg phenobarbital per kg bodyweight for 90 days, a lower elimination half-life is observed (from 88.7 ± 19.6 to 47.5± 10.7 hours).
Under alkaline conditions urinary excretion of phenobarbital is accelerated.
There is wide individual variation in the degree of phenobarbital metabolism which is caused by the effect of phenobarbital on microsomal liver enzymes. Variations in elimination half-life are not only seen between animals but also within a single animal.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years
Shelf life after first opening the immediate packaging: 3 months
Any divided tablet portions remaining after 24 hours should be discarded.

5.3 Special precautions for storage

Store in the original container.

This veterinary medicinal product does not require any special temperature storage conditions.
For storage of divided tablets up to 24 h, please use appropriate pill containers.

5.4 Nature and composition of immediate packaging

Carton containing a brown glass container or a white plastic container.
The glass containers (glass type III) are closed by a child-resistant plastic stopper and bellows made of polyethylene.
The white plastic (polyethylene) containers are closed with a white child-proof polypropylene screw cap.

Pack sizes:
- glass bottle: 1 x 30, 3 x 30 (= 90 tablets) or 6 x 30 tablets (= 180 tablets)
- plastic container: 50, 60, 100, 120 tablets

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]
{Name and address}
<{tel}>
<{fax}>

7. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: [DD month YYYY]

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

[DD month YYYY]

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton with 30, 50, 60, 100, 120 tablets, three cartons each with 30 tablets (90 tablets) or six cartons each with 30 tablets (180 tablets)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Luminal vet 100 mg tablets for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Phenobarbital 100 mg per tablet

3. PACKAGE SIZE

plastic:
50 tablets
60 tablets
100 tablets
120 tablets

glass:
30 tablets
90 (3 x 30) tablets
180 (6 x 30) tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. { mm/yyyy }
Once opened, use within 3 months.

9. SPECIAL STORAGE PRECAUTIONS

Store in the original container.

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

Desitin Arzneimittel GmbH
Weg beim Jäger 214, 22335 Hamburg
Germany

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label for plastic container (15 ml and 30 ml) and for glass bottle [16.5 ml filling volume – 14.5 ml nominal volume]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Luminal vet 100 mg tablets for dogs

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Phenobarbital 100 mg per tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use by ... [space for discard date]

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

(DE) Luminal vet 100 mg tablets for dogs
(AT, BE, DK, ES, FR, NL, PT, SE) Epirepress 100 mg, tablets for dogs

2. Composition

Each tablet contains:

Active substances:
Phenobarbital 100 mg

White, round, flat faceted tablets, diameter 9 mm, with DN imprinted on one side and a cross break line on the other side. The tablet can be divided into equal halves (each 50 mg phenobarbital).

3. Target species

Dogs

4. Indications for use

Prevention of seizures due to generalised epilepsy in dogs.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance, to any other barbiturates or to any of the excipients.
Do not use in animals with severe impaired hepatic function.
Do not use in animals with serious renal and/or cardiovascular/respiratory disorders.

6. Special warnings

Special warnings:

The decision to start antiepileptic drug therapy with phenobarbital should be evaluated for each individual case and depends on number, frequency, duration and severity of seizures in dogs.
To achieve successful therapy, administration of tablets must be at the same time each day.
Withdrawal or transition from other types of antiepileptic therapy should be made gradually to avoid precipitating an increase in the frequency of seizures.
Some of the dogs are free of epileptic seizures during the treatment, but some of the dogs show only a seizure reduction, and some of the dogs are considered to be non-responders.

Special precautions for safe use in the target species:

Use with special caution if your dog suffers from:

- hypovolaemia (decreased blood volume)
- anaemia (decreased number of red blood cells)
- heart disease and/or airway disease
- impaired kidney function
- impaired liver function

The chance of hepatotoxic side effects can be diminished or delayed using an effective dose that is as low as possible. Monitoring of hepatic parameters is recommended in case of a prolonged therapy (see also section 8). It is recommended to assess the clinical pathology of the patient 2-3 weeks after start of treatment and afterwards every 4-6 months, e. g. measurement of hepatic enzymes and serum bile acids. It is important to know that the effects of hypoxia etc. do cause increased levels of hepatic enzymes after a seizure.
Phenobarbital may increase the activity of serum alkaline phosphatase and transaminases. These may demonstrate non-pathological changes, but could also represent hepatotoxicity. Therefore, in the case of suspected hepatotoxicity, liver function tests are recommended.
In stabilised epileptic patients, it is not recommended to switch from other phenobarbital formulations to Luminaletten 15 mg or Luminal 100 mg tablets. However, if this cannot be avoided then additional caution should be taken. This includes more frequent plasma concentration sampling to ensure that therapeutic levels are maintained. Monitoring for increased side effects and for hepatic dysfunction should be conducted more regularly until stabilisation is confirmed.
Withdrawal of therapy with phenobarbital formulations should be made gradually to avoid precipitating an increase in the frequency of seizures.

Due to the formulation, the veterinary medicinal product should not be used in dogs weighing less than 20 kg.

Serum thyroxin may decrease during treatment, but without clinical relevance in most dogs.

With long-term treatment, your dog may become dependent on phenobarbital. An abrupt cessation may precipitate withdrawal seizures.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Barbiturates can cause hypersensitivity. People with known hypersensitivity to barbiturates should avoid contact with the veterinary medicinal product.
Accidental ingestion may cause intoxication and could be fatal, particularly for children. Take utmost care that children do not come in contact with the veterinary medicinal product.
Phenobarbital is teratogenic and may be toxic to unborn and breastfed children; it may affect the developing brain and lead to cognitive disorders. Phenobarbital transfers to breast milk. Pregnant women, women of childbearing age and lactating women should avoid accidental ingestion and prolonged skin contact with the veterinary medicinal product.

To prevent accidental ingestion of tablets, the container should be closed immediately after withdrawing the required number of tablets for one administration.
It is advisable to wear disposable gloves during administration of the veterinary medicinal product to reduce skin contact.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. If possible, tell the physician about the time and amount of ingestion, as this information may help to ensure that appropriate treatment is given.

Wash your hands thoroughly after use.

Pregnancy:
Use only according to the benefit-risk assessment by the responsible veterinarian.
Studies in laboratory animals have indicated that phenobarbital has negative effects on prenatal growth, in particular causing permanent changes in neurological and sexual development. Neonatal bleeding tendencies have been associated with phenobarbital treatment during pregnancy.
Maternal epilepsy may be an additional risk factor for impaired foetal development. Therefore pregnancy should be avoided in epileptic dogs whenever possible. In case of pregnancy, the risk that the medication may cause congenital defects must be outweighed against the risk of suspending treatment during pregnancy. Discontinuation of treatment is not advised, but the dosage should be kept as low as possible.
Phenobarbital crosses the placenta and, at high doses, (reversible) withdrawal symptoms cannot be ruled out in newborns.
The safety of the veterinary medicinal product has not been established during pregnancy of dogs.

Lactation:
Use only according to the benefit-risk assessment by the responsible veterinarian.
Phenobarbital is excreted in small amounts in breast milk and during nursing pups should be monitored carefully for undesired sedative effects. Weaning early may be an option. If somnolence/sedative effects (that could interfere with suckling) appear in nursing newborns, an artificial suckling method should be chosen.
The safety of the veterinary medicinal product has not been proven during lactation in dogs.

In cases of pregnancy and lactation please inform your veterinary surgeon. In these cases the dosage of phenobarbital should be kept as low as possible according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

A therapeutic dose of phenobarbital for antiepileptic therapy can significantly induce plasma proteins (such as α1acid glycoprotein, AGP), which bind drugs. Phenobarbital may reduce the activity of some drugs by increasing the rate of metabolism through induction of drug-metabolising enzymes in liver microsomes. Therefore, special attention must be paid to the pharmacokinetics and doses of drugs simultaneously administered. The plasmatic concentration of a range of drugs (for example cyclosporine, thyroid hormones, theophylline, antiepileptics, chloramphenicol, corticosteroids, doxycycline, beta blockers and metronidazole) is decreased in the case of concurrent administration of phenobarbital.
The reliability of hormonal contraceptives is lower.
Concurrent use with other drugs having a central depressive action (like narcotic analgesics, morphinic derivates, phenothiazines, antihistamines, clomipramine and chloramphenicol) can increase the effect of phenobarbital.
Cimetidine and ketoconazole are inhibitors of hepatic enzymes: concurrent use with phenobarbital can induce an increase of serum concentration of phenobarbital. Phenobarbital may decrease the absorption of griseofulvin. Concurrent use with potassium bromide increases the risk of pancreatitis.
Use of phenobarbital tablets in conjunction with primidone is not recommended as primidone is predominantly metabolized to phenobarbital.
The following drugs can decrease the convulsive threshold: quinolones, high doses of β-lactam antibiotic, theophylline, aminophylline, cyclosporine and propofol for example. Medications which may alter the seizure threshold should only be used if really necessary and when no safer alternative exists.

Overdose:

If your dog takes accidentally an overdose of phenobarbital, please inform your veterinary.

Overdosage may result in coma, severe impairment of respiratory (breathing) and cardiovascular functions, low blood pressure and shock leading to kidney failure and death.

The primary management measures are intensive symptomatic and supportive therapy with particular attention being paid to the maintenance of cardiovascular, respiratory, and kidney functions and of the electrolyte balance. Treatment of overdosage can, if necessary, consist of gastric lavage (irrigation of the stomach) with activated charcoal administration.

There is no specific antidote, but CNS stimulants (like Doxapram) may stimulate the respiratory centre. Give oxygen support.

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):
lack of coordination of muscle movements (ataxia) [1], sedation[1]
Uncommon (1 to 10 animals / 1 000 animals treated):
lack of coordination of muscle movements (ataxia) [2], sleepiness[2], listlessness[2] and dizziness[2]
Very rare (< 1 animal / 10 000 animals treated, including isolated reports):
excessive passage of urine (polyuria) [3], excessive or abnormal thirst (polydipsia) [3] and desire to eat (polyphagia) [3]
Undetermined frequency (cannot be estimated from the available data)
Excitation[4], hepatopathy[5], low free thyroxine (FT4)[6], low thyroxine (T4)[6], pancytopenia[7], neutropenia[7], dermatitis[8]

[1] When serum levels reach the higher end of the therapeutic range.
[2] At the start of treatment but in some cases these effects may persist for the entire duration of treatment.
[3] May occur at average or higher blood concentrations, but these effects are usually transient and disappear with continued medication.
[4] Paradoxical hyperexcitability. Particularly after first starting therapy. As this hyperexcitability is not linked to overdosage, no reduction of dosage is needed.
[5] High plasma concentrations may be associated with hepatotoxicity.
[6] May be not an indication of hypothyroidism. Treatment with thyroid hormone replacement should only be started if there are clinical signs of the disease.
[7] Immunotoxic, due to deleterious effects on stem cells from bone marrow. These reactions disappear after cessation of treatment.
[8] Superficial, necrolytic.

If adverse reactions are severe, the administered dose should be decreased.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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 its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

Route of administration

Oral use.

Dosage

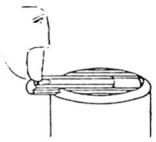
The recommended starting dose is 2.5 mg phenobarbital per kg body weight given twice daily. Your veterinary may adjust the dose if necessary, on the basis of clinical efficacy, blood concentrations and the occurrence of undesired effects.
The tablet can be divided into equal halves (each 50 mg phenobarbital). Further division into quarters may be done only in order to facilitate administration to the dog.

9. Advice on correct administration

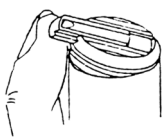
Dog owners should be advised to administer the veterinary medicinal product at the same time points each day to ensure successful treatment.

To ensure the therapy is properly administered, it is essential to have the phenobarbital blood levels measured. The phenobarbital serum concentration which is effective for seizure control is between 20-40 µg/ml. If the serum concentration is too low and/or seizures are not sufficiently controlled, the dose may be increased by 20 % at a time, with associated monitoring of serum phenobarbital levels, up to a maximum serum concentration of 40 µg/ml.
The full effect of the medication occurs approximately after 2 weeks, and doses should not be increased during this time.
For accuracy of dosing, dogs with less than 20 kg should commence therapy with Luminaletten vet tablets.

Instruction for opening the child resistant cap of the glass bottle:



Pull the slide (located in the middle of the stopper) outwards by gripping the groove with the index finger.



Push the slide upwards with the thumb - the stopper then lifts out.
Before closing, push the slide fully forward. Then press the stopper into container until it is fully engaged. After each use the container should be closed properly.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in the original container.
This veterinary medicinal product does not require any special temperature storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and container after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 3 months

For storage of divided tablets up to 24 hours, please use appropriate pill containers.
Any divided tablet portions remaining after 24 hours should be discarded.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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 or pharmacist 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

Carton containing a brown glass container closed by a child-resistant plastic stopper and bellows, or a white plastic container with a white child-proof polypropylene screw cap.

Pack sizes:
- glass bottle: 30, 90 (3 x 30) and 180 (6 x 30) tablets.
- plastic container: 50, 60, 100, 120 tablets

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

[DD month YYYY]

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary)

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:

[To be completed nationally]
{Name and address}
<{tel}>
<{fax}>

Local representatives and contact details to report suspected adverse events:
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder:

[To be completed nationally]
{Name and address}
<{tel}>
<{fax}>