

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Carton with 30, 60 or 120 (or two cartons each with 60) tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Epirepress 60 mg tablets for dogs
Phenobarbital

2. STATEMENT OF ACTIVE SUBSTANCES

Phenobarbital 60 mg per tablet

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

30 tablets
60 tablets
120 tablets (plastic container)
120 tablets (2 x 60 tablets- glass bottle)

5. TARGET SPECIES

Dog

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

Prescribed dose

8. WITHDRAWAL PERIOD(S)

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

People with known hypersensitivity to barbiturates should avoid contact with this product.

Children are particularly at risk of intoxication which may prove fatal. Take utmost care that children do not come into contact with the product.

10. EXPIRY DATE

EXP {month/year}

Once opened, use by

Once opened, use within 3 months

11. SPECIAL STORAGE CONDITIONS

Store in the original container.

Keep container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Desitin Arzneimittel GmbH
Weg beim Jäger 214
22335 Hamburg
Germany

Distributed in the UK by:
Virbac Ltd.
UK-Suffolk
IP30 9UP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 14040/4000

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label for plastic container (15 ml) with 30, 60 or 120 tablets and for glass bottle with 30, 60, 120 (2 x 60) tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Epirepress 60 mg tablets for dogs
Phenobarbital

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Phenobarbital 60 mg per tablet

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

30 tablets
60 tablets
120 tablets (plastic container)
120 tablets (2 x 60 tablets- glass bottle)

4. ROUTE(S) OF ADMINISTRATION

For oral use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once opened, use within 3 months.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

9. THE WORDS “Keep the container in the outer carton”

Keep the container in the outer carton.

10. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Desitin Arzneimittel GmbH
Germany

Distributor:
Virbac Ltd.
UK

PACKAGE LEAFLET
Epirepress 60 mg tablets for dogs

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
AND OF THE MANUFACTURING AUTHORISATION HOLDER
RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder and manufacturer responsible for batch release:

Desitin Arzneimittel GmbH
Weg beim Jäger 214
22335 Hamburg
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Epirepress 60 mg tablets for dogs

Phenobarbital

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER
INGREDIENT(S)**

Each tablet contains phenobarbital 60 mg as active substance.

Epirepress are white, round tablets, diameter 7.5 mm, upper side: flat, scored into quadrants, lower side: domed, scored into quadrants.

4. INDICATION(S)

Prevention of seizures due to generalised epilepsy in dogs.

5. CONTRAINDICATIONS

Do not use Epirepress if your dog suffers from:

- Hypersensitivity to barbiturates (the group of medicines phenobarbital belongs to) or to any of the excipients
- Severe impairment of liver function
- Severe renal or cardiovascular/respiratory disorders

Do not use in dogs weighing less than 6 kg

6. ADVERSE REACTIONS

Lack of coordination of muscle movements (ataxia), sleepiness, listlessness and dizziness may occur very rarely at the start of treatment. In some cases, these effects may persist for the entire duration of treatment.

A paradoxical hyperexcitability may be very rarely seen, particularly after first starting therapy. As this hyperexcitability is not linked to overdosage, no reduction of dosage is needed.

Excessive passage of urine (polyuria), excessive or abnormal thirst (polydipsia) and desire to eat (polyphagia) may occur very rarely at average or higher blood concentrations of phenobarbital, but these effects are usually transient and disappear with continued medication.

Sedation and ataxia may very rarely become significant concerns as serum levels reach the higher end of the therapeutic range.

High plasma concentrations may be associated with hepatotoxicity.

Treating dogs with phenobarbital may lower their total thyroxine levels (TT4) or free thyroxine levels (FT4); however this may not be an indication of hypothyroidism. Treatment with thyroid replacement should only be started if there are clinical signs of the disease.

Phenobarbital can have deleterious effects on stem cells from bone marrow. Consequences are immunotoxic pancytopenia and/or neutropenia. These reactions disappear after withdrawal of treatment.

Superficial necrolytic dermatitis may occur after administration of phenobarbital.

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

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dog

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Route of administration

The tablets should be given to your dog by mouth only.

Dosage

The recommended starting dose is 2.5 mg phenobarbital per kg body weight given twice daily. Your veterinary surgeon 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 halves or quarters to ensure accurate dosing.

9. ADVICE ON CORRECT ADMINISTRATION

Dog owners should be advised to administer the veterinary medicinal product at approximately the same time 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.

Epirepress tablets can be quartered by pressing on the flat, scored upper side of the tablet with a finger or thumb. The domed, scored lower side of the tablet should be on a firm surface.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in the original container. Divided tablets should also be stored in the original container.

Keep the container in the outer carton.

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 container: 3 months

12. SPECIAL WARNING(S)

Special warnings for each target species:

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 dogs are free of epileptic seizures during the treatment, but some dogs show only a seizure reduction, and some dogs are considered to be non-responders.

Special precautions for use in animals:

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 between phenobarbital formulations. 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 or transition to or from another type of antiepileptic therapy should be made gradually to avoid precipitating an increase in the frequency of seizures.

Serum thyroxine 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:

People with known hypersensitivity to phenobarbital or other barbiturates should avoid contact with this veterinary medicinal product.

It is advisable to wear disposable gloves when handling the product, to reduce skin contact.

Phenobarbital is a teratogen and developmental neurotoxicant and transfers to breast milk.

The product should not be administered by pregnant women, women intending to become pregnant or whose pregnancy status is unknown, as well as lactating women.

Ingestion of Phenobarbital can cause neurotoxicity which may prove fatal. Take utmost care that children do not come into any contact with the product. Children are particularly at risk of intoxication.

To prevent accidental ingestion of tablets, the container should be closed immediately after withdrawing the required number of tablets for one administration. Part tablets should be placed back into the container and used at the next administration, as even part tablets pose a health risk to small children if ingested. The container should be stored in a safe place out of the sight and reach of children.

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 after use.

Pregnancy:

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.

In case of pregnancy, the risk that the medication may cause congenital defects must be outweighed against the risk of suspending treatment during pregnancy.

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:

Phenobarbital enters the mother's milk in small amounts and suckling offspring should be monitored for signs of undesired sedation. 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 protein (such as α 1 acid glycoprotein, AGP), which bind drugs. Therefore, special attention must be paid to the pharmacokinetics and doses of drugs simultaneously administered.

The plasmatic concentration of cyclosporine, thyroid hormones and theophylline is decreased in the case of concurrent administration of phenobarbital. The effectiveness of these substances is diminished too.

Concurrent use with potassium bromide increases the risk of pancreatitis.

Concurrent use with other drugs having a central depressive action can result in an increase of the effect of central depressive drugs.

Phenobarbital may enhance the metabolism of, and therefore decrease the effect of, antiepileptics, chloramphenicol, corticosteroids, doxycycline, beta blockers and metronidazole.

The reliability of oral contraceptives is lower.

Phenobarbital may decrease the blood concentration of griseofulvin by reducing its absorption and/or inducing hepatic microsomal enzymes.

The following drugs can decrease the convulsive threshold: quinolones, high doses of β -lactam antibiotic, theophyllin, aminophyllin, 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.

Use of phenobarbital tablets in conjunction with primidone is not recommended as primidone is predominantly metabolized to Phenobarbital.

Overdose (symptoms, emergency procedures, antidotes):

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

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 central nervous system (CNS) stimulants like Doxapram may stimulate the respiratory centre. Give oxygen support.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. This should be in accordance with the Misuse of Drugs Regulations 2001.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2020

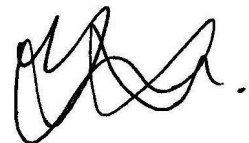
15. OTHER INFORMATION

Pack size: 30, 60, 120 tablets. Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder, distributed in the UK by:

Virbac Ltd.
UK-Suffolk
IP30 9UP

Vm 14040/4000

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 24 November 2020