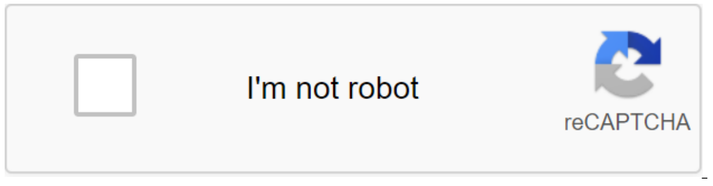
Gardenal gotas bula pdf



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How do garden drops work? Phenobarbital, the active ingredient in kindergarten, is a barbituric with anticonvulsants and... How do garden drops work? Phenobarbital, the active ingredient in kindergarten, is a barbiturate with anticonvulsants and sedative properties, due to the ability to raise the seizure threshold (the amount of stimuli needed to cause cramps), as it acts on the central nervous system (CNS). Contradictions of pediatric garden GotasGardenal should not be used in the following cases: Porfiria (a metabolic disease that manifests itself through skin problems and/or neurological complications), severe respiratory failure, severe liver (liver) or kidney (kidney) failure, and in patients with a history of hypersensitivity (allergy) on barbiturates. Kindergarten is also not suitable for patients using sakvinavira, daclatasvir, dasabovir, paritaprevir, ombitasvir, ladypasvir, sofosbuvir. Kindergarten is also not suitable for alcohol, estrogen and progestogen (female sex hormones) used as contraceptives during lactation. This medicine is not suitable for use by patients with severe respiratory failure, severe liver or renal failure, patients with portile and women during lactation.How to use garden dropsUse the product vertically with a lid on the upper side, rotate it until the seal breaks (Figure 1); Turn the bottle off the drip at the bottom and press lightly with your finger at the bottom of the bottle to start dribble (Figure 2). Dilute the drops in the water. Garden dropsAdultos2 at 3 mg/kg/day at one or fractional dose. children3 to 4 mg/kg/day in one or fractional dose. Assessment of the effectiveness of treatment and dose adjustment should be carried out only after 15 days of treatment. In clinical need, the level of barbiturate should be monitored in blood samples collected preferably in the morning (usually 85 ml in children, i.e. 20 mg/l). There are no studies on the effects of pediatric gardening being introduced with no recommended pathways. Therefore, to ensure the safety and effectiveness of this drug, the reception should only be oral, as recommended by the doctor. Special populations should be reduced in the elderly, alcoholics and patients with impaired kidney and liver function. In the latter case, clinical and laboratory monitoring is recommended, as there is a risk of hepatic encephalopathy (dysfunction of the central nervous system due to liver failure). In the case of severe liver or renal failure, the use of phenobarbital is not contraindicated. Elderly patients impaired liver and kidney function may be more susceptible to adverse reactions, especially changes in coordination and balance. Therefore, it is recommended to be careful and reduce garden doses in the elderly. Abrupt discontinuation of treatment can lead to convulsions and epileptic status, especially in patients with alcoholism. The termination of treatment should be done gradually, under medical guidance. Follow your doctor's advice, always respecting the time, dose and duration of treatment. Do not stop treatment without the knowledge of the doctor. What if I forgot to use Garden Drops? If you forget administering the dose, administer it as soon as possible. However, if you are close to the next dose time, wait for this time, always respecting the dosing interval. Two doses should never be given at the same time. If in doubt, seek advice from your pharmacist or doctor or dentist. Garden drops precautions The treatment of phenobarbital should stop if signs of hypersensitivity, skin reactions (skin) or liver (liver) dysfunction are observed. The dosage should be reduced in patients with renal failure, liver failure is necessary to monitor laboratory parameters as there is a risk of hepatic encephalopathy (dysfunction of the central nervous system due to liver failure) in elderly patients and alcoholics. Drinking alcoholic beverages is strongly discouraged in the treatment of phenobarbital (due to mutual potentiation of the effects of both on the central nervous system). You should avoid drinking any amount of alcohol. Consult your doctor for the use of drugs containing alcohol as excipient. - Children receiving long-term phenobarbital treatment require a combination of preventive treatment of rickets (an abnormality in the bone structure) (from 1200 to 2000 IU/day) or 25 OH-vitamin D3. The risk associated with cramps Arupt discontinuation of treatment for convulsions in pregnant women can lead to aggravation of the disease with harmful effects on the fetus. Treatment should be discontinued only on a specialized medical recommendation, taking into account the individual characteristics of the patient. Risks associated with phenobarbital phenobarbital cross the placenta. Maternal and neonatal concentrations are similar. In animalsStadia on animals of the same species (rats) have demonstrated the effect of congenital malformations (the cleft palate). Congenital malformations In humans with phenobarbital, used alone or in combination with other anticonvulsants, is associated with an increase in cases of congenital malformations (defects in the constitution of the organ or organ set), mainly leper lips and cleft palates and cardiovascular abnormalities. Cases of hypospadias (congenital malformations of male genitalia), dysmorphic features of the face (facial malformations), microcephaly (a condition in which the head and brain of the child are much smaller than other people of the same age and sex) and nails and hypoplastic fingers (incomplete or incomplete development of tissues or organs), but causal relationship is not established. These data (from subsequent studies) showed that the risk of malformations in children whose mothers used phenobarbital, without other anticonvulsants associated with treatment during pregnancy, was 4.91%, while in the general population the risk is about 2-3%. The data show that the appearance of malformations depends on the dose of phenobarbital used. Developmental disorders associated with neurological developmental disorders in children exposed to phenobarbital in the womb are contradictory and insufficient to establish a causal link between the use of phenobarbital in pregnant women and neurological developmental disorders. Both monotherapy and polytherapy phenobarbital are associated with unusual effects during pregnancy. Evidence suggests that antiepileptic polytherapy, including valproate, is associated with a higher risk of unusual effects during pregnancy than phenobarbital monotherapy. Given the above data, women of childbearing potential should be informed about the risks and benefits of using phenobarbital during pregnancy. In women of childbearing age should use an effective and continuous method of contraception throughout the treatment with the help of garden and within two months after the end of treatment with Gardenal.Se the woman is planning a pregnancy, the doctor should consider switching to appropriate alternative treatment before conception. If a woman becomes pregnant, the doctor should carefully assess the risks and benefits of garden treatment for the woman and her fetus and whether garden treatment can be continued or should be switched to proper alternative treatment. If treatment with Gardenal should be continued, use Gardenal at the lowest effective dose. As phenobarbital reduces levels of folic acid, folic acid supplementation is recommended before and during pregnancy. In order to identify possible cases of malformations, it is necessary to take part in specialized antenatal follow-up cases. In accordance with the progresses, an adjustment of the dose of phenobarbital may be required. It is also recommended to supplement folic acid, calcium and vitamin K with pregnant women who chronically use phenobarbital because of its interference with the metabolism of these substances. In the case of folic acid supplementation see also the item Drug Interactions.Changes in the ability to drive and operate cars Patients, especially drivers and people working cars, should be aware of the risks of drowsiness and dizziness associated with this drug. During treatment with Pediatric Gardenal, the patient should not drive or drive cars, as his ability and attention may be impaired. Baby Garden GotasGardenal warnings are not specified to treat seizures absence or myoclonic seizures, which can sometimes be exacerbated. Although this is rare, the introduction of anticonvulsant treatment may be accompanied by an increase in the frequency of seizures or the appearance of a new type of seizure in some patients. This increase is not related to fluctuations observed in some forms of epilepsy. In the case of phenobarbital, the reasons for this may be: inappropriate medication choices for type capture/epilepsy for treatment, alteration of convulsive anticonvulsants, or pharmacokinetic interaction with this accompanying drug, toxicity, or overdose. There is no other explanation for this, except for the paradoxical reaction (excitement, involuntary movements, aftershocks). Prolonged treatment with phenobarbital (100 mg per day for 3 months) can lead to addiction. If the treatment is discontinued, the dose should be reduced gradually, under medical guidance. As with other anticonvulsants, abrupt discontinuation of treatment can lead to seizures and epileptic status, especially in patients with alcoholism. Suicidal behavior and intentions were reported in patients treating antiepileptic drugs in various indications. Therefore, patients should be monitored for signs of suicidal behavior or intentions and appropriate treatment should be considered. Patients (and their caregivers) should seek immediate medical attention if there are signs of suicidal intent. Severe skin adverse reactions, life-threatening skin reactions (Stevens-Johnson syndrome (a severe form of allergic reaction characterized by blisters in the mucous membranes and large areas of the body) and toxic epidermal necrolysis (severe condition in which most of the skin begins to represent blisters and develops with reddish areas similar to large burns) use of pediatric garden. Patients should be informed of signs and symptoms and carefully monitored for skin reactions. Treatment with pediatric garden should be discontinued if there are symptoms and signs of Stevens-Johnson syndrome or toxic epidermal necrolysis (e.g., progressive skin rash often with blisters or mucous lesions). Adverse reactions of garden dropsVering general reaction (occurs in more than 10% of patients using this medicine). A common reaction (occurring between 1% and 10% of patients using this medication). Unusual reaction (occurs between 0.1% and 1% of patients using this medication). Rare reaction (occurs between 0.01% and 0.1% of patients using this medication). A very rare reaction (occurs in less

than 0.01% of patients using this medication). Unknown reaction (cannot be evaluated based on available data). Congenital, family and genetic diseases. Blood and lymphatic disordersInstimPancytopenia general decrease in cellular elements of blood (white blood cells, aplastic anemia (a disease in which the bone marrow produces insufficient amounts of red blood cells, white blood cells and platelets), agranulocytosis (a noticeable decrease in the number of white blood cells), folic acid deficiency, neutropenia (reducing the number of neutrophils in the blood), leukopenia (reduction of white blood cells), thrombocytopes (reducing the number of blood clots). Psychiatric disordersCommonAnorotic behavior, such as arousal and aggressiveness. Unusual Mood disorders, sleep disorders/insomnia. UnknownDependence.Nervous Disorder SystemCommonSleepiness (difficulty in awakening and sometimes difficulty talking); cognitive impairment, memory impairment. Unusual abnormal coordination and balance disorder. A rare disorder. UnknownAmnesia, dyskinesia (abnormal involuntary body movements). Gastrointestinal disordersCommonNausea, vomiting. Disorders of hepatobiliaryariumComanation gamma-glutamyltransferase, increase of transainase and increase of alkaline phosphatease in the blood. UnknownGepatite.Skin and Subcutaneous Tissue DisordersCommonAllergic dermatitis (in particular, scarlettiniform or morbiliformes various rashes (reddish, Unknown Fixed eruption. Between phenobarbital, phenytoin and carbamazepine, caution is recommended when phenobarbital is replaced by one of these two medications. Disorders of the musculoskeletal and connective systemCommonContracting Dupuytren (a disease that prevents the expansion of one or more fingers of the hand). Unusual arthrosis (joint pain - shoulder syndrome or phenobarbital rheumatism). Unknown Mineral bone density, osteopenia (decreased bone quality), osteoporosis and fractures in patients undergoing long-term treatment with the help of a pediatric garden. If there are serious adverse reactions affecting liver function and/or hypersensitivity or skin reactions, the treatment of the children's garden should be discontinued. Also report this to the company through its customer service. A special population of garden dropsSSinced epileptic pregnant women should consult a specialist doctor as soon as pregnancy is suspected of proper appropriate treatment. This medication should not be used by pregnant women without medical advice. Tell your doctor immediately if you have a pregnancy suspect. Breastfeeding Is not recommended as a potential sex section can lead to insufficient sucking, which in turn can lead to low weight gain in the immediate period after birth. Newbornantiepileptic drugs, especially phenobarbital, can cause: in some cases hemorrhagic syndrome in the first 24 hours of life of newborn mothers are treated with phenobarbital. Oral administration of 10 to 20 mg/day of vitamin K1 in the mother in the month before delivery, and the appointment of appropriate supplements of 1 to 10 mg of vitamin K1 through IV (intravenously) for the newborn shortly after birth, seems to be an effective measure in this condition. Rarely moderate withdrawal syndrome (abnormal movements, ineffective sucking); metabolic of phosphorus and calcium and bone mineralization. Older older patients may be more susceptible to adverse reactions due to reduced liver and kidney function, especially changes in coordination and balance. Therefore, it is recommended to be careful and reduce pediatric garden doses in the elderly. Excipients: glycerol, ethanol 96'GL, new smoked dye, sodium dihydration saccharin, sodium hydroxide, propylene glycol, raspberry essence and purified water. Each 1 ml of children's garden is equivalent to 40 drops and 1 drop equal to 1 mg. Presentation of garden solution DropsOral (drops) 40 mg/ml:Vial with 20 Oral. Pediatric use. Garden overdose dropsIgns and symptomsNausea, vomiting, headache, obsession, mental confusion and even coma, is accompanied by a characteristic neurovegetative state of irregular bradipnei (reduced respiratory rate without a regular picture), obstruction of the bronchus, hypotension (low pressure) may occur after the introduction of high doses. MaintenanceFor the treatment of phenobarbital superdose is recommended: maintenance of airway permeability and mechanical hardware assistance in treatment by inhaling additional oxygen, if necessary; Maintaining blood pressure, hydration and body temperature; Monitoring vital signs, hydroelectric and acid-based balance, with potassium supplementation, if necessary; induction of diuresis. If there is normal diuresis, the yield with alkaline urine alkaline should be increased if possible; Antibiotic therapy; Additional general life-maintenance measures. If you use a large amount of this medication, quickly seek medical attention and take a package or package of leaflets of the drug if possible. Call 0800 722 6001 if you need an additional guide. Medicinal interaction of garden dropsPharmacodynamic interactionsAlcohol; Antidepressant imipramine; Methadone; Other depressants of the central nervous system; derivative morphine (analgesics, anti-course drugs and substitution therapy), benzodiazepines, other non-zzodiazepine anxiolytics (carbamats, captadiam, etifoxin), hypnotics, sedative antidepressants, antipsychotics, antagonists of sedative receptors G1, central antihypertensesies, baclofen, thalomede: may cause aggravation of the central effects of depressive effects, with serious consequences, especially on the ability to drive; Methodrex;Produced from morphine (analgesics, antitumor and substitution therapy), benzodiazepines. Gardenal's effect on other drugsPhenobarbital is a well-characterized inductor of meta-lobling enzymes of the drug, so it can accelerate the metabolism and/or elimination of many classes of drugs, thereby reducing their systemic effects (in the blood), which can lead to a decrease in the effectiveness of associated drugs. The associations are contraindicatedSacinavir, daclatasvir, dasabavira, paritaprevir, ombitasvir, ladypasvir, sofosbuvir. Associations requiring precautionary, clinical monitoring and/or adjustment of the drug during and after discontinuation with phenobarbitalIphosphamid; Oral anticoagulants; protease inhibitor (amprenavir, indinavir, nilfinavir); Cyclosporine, tacrolimus; Corticosteroids (glucocorticoids and systemic mineralocorticoids) ;D igitoxin; Dipidropiridine- Thyroid; Hydrohinidine, quinidine; Itrakonazole; Montelukaste; Theophylline (basic and sais) and aminophyllin; Sinovudin; Estrogens and progestogens (not as hormonal contraceptives); Estrogens and progestogens (used as hormonal contraceptives): there is a decrease in the expected effect of contraception. Alternative methods of contraception should be considered. Associations to be taken into account by estrogens and progestogens (used as hormonal contraceptives); Ritonavir, simeprevir, dolutegravir; Anti-cancer drugs; antiepileptics (lamotrigin); Alprenolol, methoprolol and propranolol (beta-blockers); Carbamazepine; Prokarbazin; Amitriptyline/amitriptyline; Antitrombotics (apixaban, tikagrelor). The effect of other drugs on GardenalFollatesOther interaction with gardenalvalic acid; Felbamato; Progabide; Phenytoin.Tell your doctor or dentist if you use any other medications. Do not use medication without the knowledge of a doctor. It can be dangerous for your health. The effect of the garden substance DropsEfficacyResultsPhenobarbital (active substance) Tablet 50 mg and 100 mg Effectiveness of phenobarbital (active substance) in the fight against epilepsy was confirmed in the study Ismael S. involving 117 patients with a history of epilepsy who were treated with phenobarbital (active substance) as a drug of choice. These patients were monitored for between 6 months and 10 years. The conclusion was that phenobarbital (active substance) is a good drug that will be used as a first line in the treatment of epilepsy, especially in developing countries. Nimaga also published a low-dose study of phenobarbital (active substance) to prove effective in the treatment of epilepsy. The time of observation ranged from 5 to 13 months with an average age between men and women between 27 and 28 years. The presented result is summarized in low doses of phenobarbital (active substance) for children and adults as effective in the prevention of epilepsy. Wang U.S. et al. published a study proving the effectiveness of phenobarbital (active substance) involving 2,455 patients with pre-diagnosis. Patients, 68%, began to receive phenobarbital (active substance) as monotherapy within 12 months. The drug was well tolerated with low side effects, where only 1% of patients discontinued treatment. Bibliographic referencesSMael S., Indonesian Pediatrics 30: 97- 110. 1990K. Nimaga et al. Bulletin of the World Health Organization 2002, 80 (7)Wang W. q. et al. Neurology. Lancet Vol 5 January 2006.Fenobarbital (active substance) Oral solution 40 mg/mlA the effectiveness of pediatric phenobarbital (active substance) can be proven in a study of cavallazzi conducted with 78 patients 02 to 82 years old. Forty-nine patients who used phenobarbital (active substance) were separated and followed for 3 years, only dose adjustments were performed. The author concluded that partial, hypnetic, generalized primary or secondary epilepsy should always be initiated by phenobarbital (active substance), due to its good therapeutic effectiveness, its low cost, dosing and small fluctuations in blood levels combined with very few side effects. Bibliographic referencesCavallazzi L.O. Arc. Cat Honey. C: Vol. 14 No 4 - December 1985Source:Occupational Medicine Professional Bull®. Pharmacological characteristicsIntic ingredient phenobarbital (active substance) is phenobarbital (active substance), barbituric, used as an anticonvulsant and sedative. Pharmacokinetic characteristicsAbsorbtionApporptioned 80% of the injected phenobarbital dose (active substance) is absorbed by the gastrointestinal tract. Maximum plasma concentration occurs within about 8 hours in adults and 4 hours in children. The distribution of phenobarbital (active substance) to plasma proteins is approximately 60% in children, while in adults the binding of phenobarbital (active substance) to plasma proteins is about 50%. MetabolismIt is metabolized in the liver to an inactive hydroxyled derivative, which is then glycouroconjugated or sulfoconcugated. Elimination is allocated by the kidneys in the same form (especially if the urine is alkaline). In children, semi-rescue plasma is 40 to 70 hours, and in adults - from 50 to 140 hours, which is slightly higher in elderly patients and in patients with renal or liver failure. Phenobarbital (active substance) is spread throughout the body, especially in the brain due to its liposulobtion. It crosses the placental barrier and is excreted in breast milk. The special population OfElderlyPlasmama is increasing in the elderly. Liver deficiency is a half-expect with liver failure. Renal failure is a half-expect in patients with liver or renal failure. Source: Gardenal Medicine Professional Bull®. Kindergarten GotasGardenal care storage should be kept at room temperature (between 15 and 30oC). Number of packages and expiration dates: see do not use expired medicines. Keep it in the original packaging. Characteristics of the drugClinic liquid, pink coloring and raspberry smell. Before use, watch the appearance of the medicine. If it is on its expiration date and you notice any changes in appearance, contact your pharmacist know if you can use it. All medicines must be kept within the reach of children. GotasMS 1.1300.0306Farm. Resp.: Sylvia Regina BrolloCRF-SP N 9,815 8Regist: Sanofi-Aventis Pharmacotica Ltda.Av. Mj. Silvio de M. Padilla, 5200 - Sao Paulo - SPCNPJ 02.685.377/0001-57Manufactured by: Sanofi-Aventis Pharmacology Ltd.Rua Conde Domingos Papaiz, 413 - Suzano - SPCNPJ 02.685.377/0008-23Ind'stria Brasileira® TrademarkSale on prescription. It can only be sold with withholding income. Editor's NoteData 2019-01-08Rating NameRating 5 5 gardenal gotas bula profissional. gardenal gotas bula anvisa. gardenal gotas bula pdf. gardenal infantil gotas bula. gardenal pediatrico gotas bula. gardenal em gotas bula. gardenal gotas 40 mg bula