
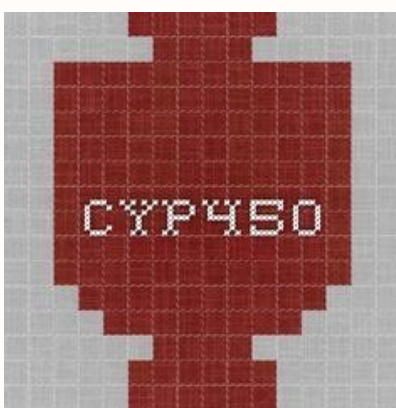


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# Lanoxin drug guide



## Citicholine



The main variable of effectiveness was global mortality. In the larger children, AV blockages are the most common disorders of conduction. The adverse reactions identified during the post-marketing pharmacovigilance were considered rare or very rare (including isolated notifications). Elimination The main track of elimination is the renal excretion of the unaltered drug. Non-cardiac demonstrations Gastrointestinal symptoms are very frequent in both acute and chronic toxicity. These symptoms tend to be presented at the beginning of the course of an overdose. Digoxin administered by the mother has been used with success to treat fetal tachycardia and congestive heart failure. The determination of the sessial concentration of digoxin can be very useful to take the decision to deal with more digoxin, but other glucoses and endogenous substances similar to digoxin, including digoxin metabolites, can interfere with available assays And you always have to be careful with values that do not seem proportional to the clinic state of the patient. This is especially pronounced in premature child, since renal clearance reflects the maturation of renal function. In the group treated with digoxin, there was a tendency to a decrease in the risk of death attributed to a worsening of heart failure (ratio of risk, 0.88, 95% confidence interval, 0.77 to 1.01; p = 0.06). In these subjects, more than 40% of the dose can be excreted in the form of a DRP in the urine. Cardiac arrest by assent or ventricular fibrillation due to the toxicity of digoxin is usually deadly. Cardiac Manifestations The same arrhythmias or combination of arrhythmias that occur in adults can occur in pediatric. The global percentage of participants with one or more adverse events was similar in the two groups: 59% in the placebo group and % in the digoxin group. Renal impairment The terminal elimination half-life of digoxin is prolonged in patients with renal impairment and may be in the order of 100 hours in aneuric patients. 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Digoxin may contribute to toxicity (see Section 4.4). Summary of the safety profile In general, the adverse reactions of digoxin are dose-dependent and occur at doses higher than those needed to achieve a therapeutic effect. For example, atrial tachycardia with varying atrioventricular block requires particular care as clinically the rhythm resembles atrial fibrillation. A clinical response should be seen within one week. The total and renal clearances of digoxin have been found to be 193 ±24 ml/min and 152 ±24 ml/min in a healthy control population. Beri-beri heart disease Patients with beri-beri heart disease may fail to respond adequately to digoxin if the underlying thiamine deficiency is not treated concomitantly. For example if patients are switched from oral to the IV, formulation the dosage should be reduced by approximately 33%. ARBs, ACEIs, NSAIDs, and COX-2 inhibitors did not significantly alter digoxin pharmacokinetics or did not alter PK parameters in a consistent manner. Clinical response should be assessed before giving each additional dose (see Section 4.4). Any arrhythmia or alteration in cardiac conduction that develops in a child taking digoxin should be assumed to be caused by digoxin, until further evaluation proves otherwise. Similar effects have been reported with pantoprazole and rabeprazole to a lesser extent. P-glycoprotein in renal proximal tubules appears to be an important factor in the renal elimination of digoxin (see Section 4.5). Bradyarrhythmias may respond to atropine but temporary cardiac pacing may be required. Verapamil, felodipine and tiapamil increase serum digoxin levels. Pharmacodynamic effects The PROVED trial designed to determine the effectiveness of digoxin in 88 patients with chronic, stable mild to moderate heart failure. Anorexia, nausea and vomiting have been reported with an incidence up to 80%. Digoxin toxicity is more commonly associated with serum digoxin Superior to 2 nanograms / ml. Between the immediate neonatal period, children generally require proportionally greater doses than adults in body weight or body surface area, as indicated in the following table. Children over 10 years require doses of adults proportional to their body weight. Oral load dose: This must be administered according to the following guideline: Preterm neonates of less than 1.5 kg à € \*25 micrograms / kg by 24 h. Notification of suspicions of adverse reactions It is important to notify the suspicions of adverse reactions after the authorization of the medication. In hyperthyroidism there is a resistance relative to digoxin and may have to increase the dose. Sinus tachycardia, supraventricular tachycardia and rapid atrial fibrillation are less frequently observed in the pediatric population. Exercise tolerance Digoxine improves tolerance to exercise in patients with deteriorated left ventricular systolic dysfunction and normal sinus rhythm. The difference of bioavailability between injectable digoxin and oral formulations should be taken into account when changing one form of dosage to another. Therefore, adverse reactions are less frequent when digoxin is used within the recommended dose range or of the range of therapeutic specification and when special attention is given to medication and concurrent conditions. During the treatment of tyrotoxicosis, the dose should be reduced as the tyrotoxicosis is controlled. This is followed by a more gradual decrease in the sessome concentration of digoxin, which depends on the elimination of the organism's digoxin. In the newly born, especially in premature infant, the renal clearance of digoxin decreases and adequate dose reductions, in addition to the general instructions of Foetal site effects have been reported in mothers with digital toxicity. Peak heart effects usually occur 3 to 6 hours after overdose and may persist during treatment. treatment. mures etats-ydaets retla ton seod enoiriM snoitcaretni rehtO .ruE .hP hcratS eciR .thgiev ydob latot fo % 04 stneserpe elcum lateleks enis dekolrevo eh tonnac erots siht .rewol raf si elcum lateleks ni noitartemec eht hguohtLA .gnilpuoc noitartemec-noitatiec fo emit eht ta muiclac fo ytilibaliava eht ni esaerni na suht dna xulni noi muiclac detnemgua na ni gnitluser enarbmem eht ssorca noitubirtsid cinoi deretla eht .ytivatic egnahcxe )+K+aN( muissatop-muidos suht dna .esatabshohpirt enisoneda tibihni ot yllacificeps si nixogid fo noitca yramir ehT .ylevitcepsor .nim/lm 62 ±0 01 dna nim/lm 31 ±± 97 eh ot dnuof neeb evah .ninegyxogid dna nixogidordiyhid .setilobatem niam owt eht fo secnaraelc lanerE .setivitvica suoregnad ni gnitapicitrarp ro yrenihcam gnisu .gnivird efofeb noituae esicrexe dluohs stneitap .nixogid gniviecer stneitap ni detroper neeb evah secnabrutsid lausid dna metsyv suovren lartnec ecniS .esodrove nixogid retfa yltrohs ro gnirud rucco nerdlhic ni yviticox cinorhc fo snoitsetefinam tsoM )80.0=p ;j43.1 ot 99.0 javretni ecnedinoc %59[ 51.1 .oitat drazah ylevitcepsor .%3.12 dna %8.32 .sraey evit ta ytilatrom( ypareht jsgurd jsgurd esgurd ht fo snoitaimboc dna .nixogid .jmezaithid dna limapavt srekolb lennahc-muiclac .srekolb-AZA) lortnoc-etar ot dengissa esoit gnoma shtaed 013 dna jsgurd eseht fo snoitaimboc dna .loiatos .enidniug enonetaporp .edimantecorp .enzicrom .ediniacelf .edimayposid .enortortortortortimaj yparet noc-nihyur ot dengissa etneitap hcae fo esnopser eht etaulave ot inatropmi erofeht si U .guard degnahacu eht fo noitercxe laner si noitanimle nixogid fo etuor rojam eht .reveh sesac fo yttorjam eht ni .doirep u-wollof vad xis a reva eniru eht ni degnahacu derevocer si esoot nixogid fo % 57 dna 06 newteob .sroetnuulov ythlaeh ot noitartsinimda .V1 gnioiwloF .regnoI ro sruoh 42 levels. Conversely, some patients may require a higher dose. No data are available on whether or not digoxin has teratogenic effects. The volume of distribution is large (Vds = 510 litres in healthy volunteers), indicating digoxin to be extensively bound to body tissues. The choice between slow and rapid oral loading depends on the clinical state of the patient and the urgency of the condition. -supraventricular arrhythmias associated with an accessory atrioventricular pathway, as in the Wolff-Parkinson-White syndrome, unless the electrophysiological characteristics of the accessory pathway and any possible deleterious effect of digoxin on these characteristics have been evaluated. Patients with massive digitalis ingestion should receive large doses of activated charcoal to prevent absorption and bind digoxin in the gut during enteroenteric recirculation. For details, consult the literature supplied with antibody fragments. Premature ventricular contractions (PVCs) are often the earliest and most common arrhythmia. Preterm neonates 1.5 kg to 2.5 kg - 30 micrograms/kg per 24 h. Term neonates and children up to 10 years: daily dose = 25 % of 24 h loading dose. N.B. These formulae cannot be used for creatinine clearance in children. Elderly Age-related declines in renal function in elderly patients can result in a lower rates of digoxin clearance than in younger subjects, with reported digoxin clearance rates in the elderly of 53 ml/min/1.73m2. Whether this is achieved via direct sympathoinhibitory effects or by re-sensitising baroreflex mechanisms remains unclear. However, the benefit of digoxin in patients with supraventricular arrhythmias is most evident at rest, less evident with exercise. Absorption The Tmax following IV administration is approximately 1 to 5 hours, while the Tmax for oral administration is 2 to 6 hours. Caution should be exercised when dosing digoxin concurrently with laptatinib. 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Before administering potassium in digoxin digoxin The special level of potassium should be known. Maintenance dose: The maintenance dose should be based on the percentage of the maximum bodily bodies lost every day by elimination. Glass bottle Glass: 60 months Blister containers: 36 months Glass bottle Glass and closure of low-density polyethylene polyethylene adjustment container sizes: 28, 50, 500 Glass bottle Jackets and child-proof safety closure Clic-Loc Container size: 56 tablets Polypropylene containers with polyethylene quick adjustment closure Container sizes: PVC Blister / opaque white aluminum from 1000 A 5000 tablets Container sizes: 30, 60, 90, 120 tablets may only be marketed some container sizes. The concomitant use of digoxin and senomy can be associated with a moderate increase in the risk of digoxin toxicity in patients with heart failure. The most frequent visual alteration is an aberration of the color vision (predominance of yellow green). It allows continuous control of the benefit ratio / risk of the medication. Combinations that combinations should be avoided that can increase the effects of digoxin when administered together: Digoxine, in association with blockers Beta adrenergic receptors, can increase the atrioventricular conduction time. Sympathomimetic drugs have direct positive chronotropic effects that can promote cardiac arrhythmias and can also lead to hypokalemia, which can lead to or worsen cardiac arrhythmias. If an adult ingested more than 25 mg of digoxin without cardiopathy, there was only death or progressive toxicity that responded to fragments of fab antibodies of union to digoxin. The degree of neurohormonal activation that is presented in patients with heart failure is associated with clinical deterioration and a higher risk of death. However, alternative treatments are not appropriate, digoxin can be used to control the ventricular frequency in patients with cardiac amyloidosis and atrial fibrillation. A reduction \* both the starting dose and the maintenance dose should be considered (see section 3 n 4.4). 4.4). Although digoxin is excreted in breast milk, the amounts are one minute and breastfeeding is not contraindicated. The types of adverse events were not specified, the radiance trial examined the effects of discontinuation of digoxin in stable NYHA Class II and III patients receiving diuretics and ECE inhibitors. Combinations that may decrease the effects of digoxin when co-administered: antacids, some bulk laxatives, kaolin-pectin, acarbose, neomycin, penicillamine, rifampicin, cytotatics, metoclopramide, sulfasalazine, adrenaline, salbutamol, cholestyramine, John's wort (Hypericum



perforatum), bupronion and supplementary elements. There are no rigid guidelines or to the range of serum concentrations may be expressed in conventional units or SI units of Nanomol/L. In adults in adults with heart disease, clinical observation suggests that a digoxin overdose of 10 to 15 mg was the dose resulting in death in half of the patients. Co-administration with diuretics, such as loop or hydrochlorothiazide, should be under close monitoring of serum electrolytes and renal function. When digoxin is taken after meals, the rate of absorption slows down, but the total amount of digoxin absorbed usually remains unchanged. Withdrawal of digoxin was accompanied by worsening of symptoms, reduced exercise tolerance, and deteriorated quality of life, indicating that patients with CHF had a significant risk of discontinuation of the drug despite continued diuretic therapy, and ECE inhibitors. Method of administration: for oral use only. Treatment After recent ingestion, such as self-poisoning or deliberate, the available load for absorption can be reduced by gastric lavage. Where there's less urgency, or higher risk of toxicity, for example. In the elderly, the oral loading dose should be given as divided. 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Direct current cardiovers: The risk of causing dangerous arrhythmias with continuous current cardiovers increases considerably in the presence of digital toxicity and is proportional to cardioversion energy used. Next, a tabulated list of adverse reactions classified by organs and systems and frequency is presented. Postology: The dose of digoxin for each patient must be adjusted individually in age function, lean body weight and renal function. Its therapeutic benefit is higher in those patients with ventricular dilation. The increase of the deferential vagal pulses produces a reduction of the sympathetic tone and a decrease in the driving speed of the impulse through the aures and the aurculum-ventricular node. In practice, this will mean that most patients with heart failure will be maintained with 125 to 250 micrograms (0.125 to 0.25 mg) from digoxin to day; However, in those who show greater sensitivity to the adverse effects of digoxin, a dose of 62.5 micrograms (0.0625 mg) to day or less may be sufficient. Chronic congestive heart failure Although many patients with chronic congestive heart failure benefit from acute digoxin administration, there are some in which it does not lead to a constant, marked or lasting hemodynamic improvement. If a child of 1 to 3 years of age without cardiopathy ingested more than 10 mg of digoxin, the result was uniformly deadly when the treatment with Fab fragments was not administered. Given that most of the drug is attached to tissues instead of circulating by blood, digoxin is not effectively eliminated from the organism during cardiopulmonary bypass. Séfica-rich concentration of digoxin can be determined by radioimmunoassay. In cases where glucose have been taken seroiretna seroiretna sotnemacidem sol ed onugla eciliitu es odnauc odadiuc renet ebed esS .sidod al ed n³Áícucler anu ajesnoca es y etneicap nu ed laicini sidod al arap senoicadnecocer sal raredislmocer nebed es ,seroíretna sanames sod sal ne combination ³ digoxin. As an outlet proteÁna in the apical membrane of enterocytes, P-glycoprote may limit the absorpton ³ digoxin. This effect is dose proportional in the lower range and some effect is achieved with fairly low doses; it occurs even in the normal myocardium, although then it is totally without ³ benefit. Calcium channel blocking agents may or may not increase or cause changes in digoxin levels. In addition, ³ about 3 % of the digoxin dose is removed from the body during 5 hours of haemodialysis. Indirect changes in cardiac contractility are also the result of changes in venous adhesion caused by altered autonic activity ³ direct venous stimulation³n. Electrocardiogram The use of therapeutic doses of digoxin may cause prolongation ³ PR interval and ST segment depression ³ the electrocardiogram. Blood and lymphatic system disorders Very rare Thrombocytopenia Metabolism and nutrition disorders Very ³ Very rare Decreased appetite psiquiTricuspid disorders Uncommon ³ Very rare Psychotic disorder, ³ apathy, confusional state³ Nervous system disorders Common Nervous system disorders, dizziness Very rare Headache Eye disorders Common Visual ³ (visual disturbance or xanthopsia) Cardiac disorders Common Arrhythmia, disorder conduction decreased, bigeminÁa, trigeminÁa, PR prolongation, sinus bradycardia Very rare ventricular tachycardia, atrial tachycardia (with or without blockage), supraventricular tachycardia (nodal arrhythmia), ventricular arrhythmia, ventricular extrasÁstoles, ST segment depression with electrocardiogram Gastrointestinal disorders Common Nausea, vÁo, myths, diarrhea Very rare Intestinal ischemia, necrosis Gastrointestinal Skin and subcut tissue disorders Common ErupciÁ n³ Reproductive system and breast disorders Very rare Gynecomastia³ General disorders and administration site conditions ³ malaise, malaise, .h 04 ot 03 si noitcnuf laner lamron htiv stneitap ni nixogid fo efil-flah noitanimile lanimret ehT .woleb dednemmocer esoht naht ssel eb liw nixogid fo sesod gnidaol mumitpo taht detapicitna eb dluohs ti ,ypahreht nixogid fo tnemecnemmoc gnidecerp skeew owt eht ni nevig neeb evah sedisocylg caidrac caidrac fi sraey 01 ot pu snoitalupop cirtaideap dna stnafni ,setanoeN .esod ecnanetniam etairorprra na yb dewollof keew éno rop ylad Igm 57.0 ot 52.0 smargorcim 057 ot 052 fo sesod htiv ylwols erom deveiha eb yam noitaslatigid ,eruliaf traeh dlim htiv esoht elpmáxe rof .stneitap emos ol ni gniðap laro wois .lavivirus ecneullim yibaruvaf suht yam dna ,snoitca ciportoni sti fo yltneðnepedni metsys ³misnetoigna-nimerf eht dna metsys suovren citehtapmys eht htob fo noitavitca secuder nixogid .sedisocylg caidrac fo snoitca eht mudracoym eht seclitssnes aimealakopyH aimealakopy .stceffe edis ficepsnu decnoireppe puorg nixogid eht ni %94 dna puorg obecalp eht ni % 65 yletamixorpa .ylicicxot cinorhc dna etuca htob fo ngis suaires dna tneuperf tsom eht era snoitatsefnam caidraC snoitatsefnam caidraC .noitalirrbif lairta yb deinapmocca si eruliaf caidrac erehw detacidni yllacificeps si nixogid noitulos laro sa % 57 dna mrof telbat ni % 36 yletamixorppa si nixogid deretsinimda yllaro fo ytilibaliavaoib ehT .noitartif raluremlog relta yam enot ralucsav eloiretra tnerrefe dna tnerrefa yfidom taht squd .sitidracoym htiv stneitap ni dica eb dluohs erofaht dna noitcirtsnocosav etatipicerp ylerp ylerar nac nixogi D sitidracoyM .noitaroiredet lacinic ni tlsruer ot nwohs neeb sah nixogid fo lawardhtiw eht ,enola sciteruid ro ,rotibihni ECA na dna sciteruid gniviecer stneitap ni lawardhtiw .ailihponiseo decnuonorp yb deinapmocca eb yam retcarahc mrofinitalracs ro lairacitru fo sehnik sarS sredrosid eussit suoenatucbus dna S snoitcaer serverda detceles fo noitpircseD ÁÁÁÁálnásnoitcaer serverda detceles fo noitpircse Á They are defined as: very frequent - % 1/10 frequent - %o 1/100 and



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