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Digoxin Tablets IP 0.25mg

AMERICAN
ARRYXIN 0.25
Tablets

Composition

Each uncoated tablet contains:
Digoxin IP.....0.25mg
Excipients.....q.s

Strength

Digoxin IP 0.25 mg

Route of administration

Oral

Posology

The dose of digoxin for each patient has to be tailored individually according to age, lean body weight and renal function.

Suggested doses are intended only as an initial guide.

In cases where cardiac glycosides have been taken in the preceding two weeks the recommendations for initial dosing of a patient should be reconsidered and a reduced dose is advised.

The difference in bioavailability between injectable digoxin and oral formulations must be considered when changing from one dosage form to another. For example if patients are switched from oral to the I.V. formulation the dosage should be reduced by approximately 33%.

Method of administration

For oral use only.

Contraindications

Digoxin is contraindicated in:

- Intermittent complete heart block or second degree atrioventricular block, especially if there is a history of Stokes-Adams attacks.
- Arrhythmias caused by cardiac glycoside intoxication.
- 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. If an accessory pathway is known or suspected to be present and there is no history of previous supraventricular arrhythmias, digoxin is similarly contraindicated.
- Ventricular tachycardia or ventricular fibrillation.
- Hypertrophic obstructive cardiomyopathy, unless there is concomitant atrial fibrillation and heart failure but even then caution should be exercised if digoxin is to be used.

Special warnings and precautions for use

Monitoring

Patients receiving digoxin should have their serum electrolytes and renal function (serum creatinine concentration) assessed periodically; the frequency of assessments will depend on the clinical setting.

Serum concentrations of digoxin may be expressed in Conventional Units of nanograms/ml or SI Units of nanomol/l. To convert nanograms/ml to nanomol/l, multiply nanograms/ml by 1.28.

Arrhythmias

Arrhythmias may be precipitated by digoxin toxicity, some of which can resemble arrhythmias for which the drug could be advised. For example, atrial tachycardia with varying atrioventricular block requires particular care as clinically the rhythm resembles atrial fibrillation.

Severe respiratory disease

Patients with severe respiratory disease may have an increased myocardial sensitivity to digitalis glycosides.

Fertility, pregnancy and lactation

Pregnancy

The use of digoxin in pregnancy is not contraindicated, although the dosage may be less predictable in pregnant than in non-pregnant women, with some requiring an increased dosage of digoxin during pregnancy. As with all drugs, use should be considered only when the expected clinical benefit of treatment to the mother outweighs any possible risk to the developing foetus.

Despite extensive antenatal exposure to digitalis preparations, no significant adverse effects have been observed in the foetus or neonate when maternal serum digoxin concentrations are maintained within the normal range. Although it has been speculated that a direct effect of digoxin on the myometrium may result in relative prematurity and low birthweight, a contributing role of the

underlying cardiac disease cannot be excluded. Maternally-administered digoxin has been successfully used to treat foetal tachycardia and congestive heart failure.

Breast-feeding

Although digoxin is excreted in breast milk, the quantities are minute and breast feeding is not contraindicated.

Fertility

There is no information available on the effect of digoxin on human fertility.
No data are available on whether or not digoxin has teratogenic effects.

Effects on ability to drive and use machines

Since central nervous system and visual disturbances have been reported in patients receiving digoxin, patients should exercise caution before driving, using machinery or participating in dangerous activities.

Undesirable effects

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.

Hence, adverse reactions are less common when digoxin is used within the recommended dose range or therapeutic serum concentration range and when there is careful attention to concurrent medications and conditions.

Overdose

Symptoms and signs

The symptoms and signs of toxicity are generally similar to those described, but may be more frequent and can be more severe.

Signs and symptoms of digoxin toxicity become more frequent with levels above 2.0 nanograms/ml (2.56 nanomol/l) although there is considerable inter-individual variation. However, in deciding whether a patient's symptoms are due to digoxin, the clinical state, together with serum electrolyte levels and thyroid function are important factors. In patients undergoing haemodialysis, digoxin use is associated with increased mortality; patients with low pre-dialysis potassium concentrations are most at risk.

Adults

In adults without heart disease, clinical observation suggests that an overdose of digoxin of 10 to 15 mg was the dose resulting in death of half of the patients. If more than 25 mg of digoxin was ingested by an adult without heart disease, death or progressive toxicity responsive only to digoxin-binding Fab antibody fragments resulted.

Treatment

After recent ingestion, such as accidental or deliberate self-poisoning, the load available for absorption may be reduced by gastric lavage. Gastric lavage increases vagal tone and may precipitate or worsen arrhythmias. Consider pre-treatment with atropine if gastric lavage is performed. Treatment with digitalis Fab antibody usually renders gastric lavage unnecessary. In the rare instances in which gastric lavage is indicated, it should only be performed by individuals with proper training and expertise.

Patients with massive digitalis ingestion should receive large doses of activated charcoal to prevent absorption and bind digoxin in the gut during enteroenteric recirculation.

If hypokalaemia is present, it should be corrected with potassium supplements either orally or intravenously, depending on the urgency of the situation. In cases where a large amount of digoxin has been ingested hyperkalaemia may be present due to release of potassium from skeletal muscle. Before administering potassium in digoxin overdose the serum potassium level must be known.

Storage

Store protected from light and moisture, at a temperature not exceeding 30°C.

Nature and contents of container

10 x 10 Tablets blister pack.

Keep the medicine out of reach of children.

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