DEBENIXO (Merrell)
Composition: Each specially coated tablet contains: Decapryn (doxylamine succinate) 10 mg; Pyridoxine hydrochloride 10 mg.
Actions: Debendox provides the actions of 3 unrelated compounds. Dicyclomine hydrochloride relieves smooth muscle spasm of the gastrointestinal tract. Doxylamine succinate, an antihistamine, provides anti-nauseant and anti-ematic activity. Pyridoxine hydrochloride provides B6 supplementation to help avoid pyridoxine deficiency that may occur during pregnancy. Studies indicate that pyridoxine also has an anti-nauseant activity. The action of Debendox is delayed by a special coating.
Indications: Debendox is indicated only for nausea and vomiting of pregnancy which are unresponsive to conservative measures and are sufficiently distressing to require drug intervention.
Dosage: Two tablets at bedtime. The delayed release characteristics of the formulation provides for maximal effectiveness during the morning hours when nausea and vomiting are most likely to occur. In severe cases or when nausea occurs during the day, one additional tablet in the morning and another in mid-afternoon.
Contra-indications: Known idiosyncrasy to any of the ingredients. Myasthenia gravis, obstructive disease of the gastrointestinal tract, paralytic ileus, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis.
Precautions and Warnings: Because of its dicyclomine content, Debendox should be used with caution by patients known to have or suspected of having glaucoma, by patients with autonomic neuropathy, hepatic or renal disease, ulcerative colitis, hyperthyroidism, coronary heart disease, congestive heart failure, cardiac arrhythmias, hypertension and hiatal hernia. With overdosage, a curare-like action may occur.
Because of potential drowsiness and blurred vision, patients should be warned not to engage in activities requiring mental alertness such as operating motor vehicles or other machinery, or perform hazardous work while taking Debendox.
Use in Pregnancy: Studies in rats and rabbits have revealed no indication of drug-induced foetal abnormalities in doses of Debendox up to 30 times the maximum human dose in the rat and 15 times the maximum human dose in the rabbit; nor have the individual ingredients, doxylamine or dicyclomine induced foetal abnormalities in these animal species in doses up to 90 times the maximum human dose. There have been a large number of epidemiological studies of Debendox. Although there have been some reports of congenital malformations associated with its administration in early pregnancy, a causal relationship has not been established. For no medicinal product can a small risk of teratogenic effect be excluded with absolute certainty and so the use of any drug during early pregnancy should be avoided if at all possible.
When a decision has been made to use drug therapy in the treatment of nausea and vomiting of pregnancy, the physician should be aware that Debendox has been the subject of a considerably larger number of epidemiologic studies searching for a risk of birth defects than have other anti-nauseants.
Adverse Reactions: The adverse reactions that may occur are those of the individual ingredients. Dicyclomine hydrochloride may cause xerostomia, urinary hesitancy and retention, blurred vision and tachycardia, palpitations, mydriasis, cycloplegia, increased ocular tension, loss of taste, headache, nervousness, drowsiness, weakness, dizziness, insomnia, nausea, vomiting, constipation, bloated feeling, severe allergic reaction or drug idiosyncrasies including anaphylaxis, urticaria and other dermal manifestations. Doxylamine succinate may cause drowsiness, vertigo, nervousness, epigastric pain, headache, palpitation, diarrhoea, disorientation, or irritability. Pyridoxine hydrochloride is a vitamin that is generally recognized as having no adverse effects.
Pack: 30 tablets: (white coated).

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