DIPYRIDAMOLE - dipridamole solution AnazaoHealth Corporation

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

DIPYRIDAMOLE

Dear Medical Professional,

Per your order, we have compounded Dipyridamole as 12 mL in a 10 mL vial. The characteristics of this preparation are described below

DESCRIPTION

AnazaoHealth's compounded Dipyridamole vial is a sterile, non-pyrogenic preparation that is 5mg/mL. This vial contains no antimicrobial preservative

INDICATIONS AND USAGE

Dipyridamole is a coronary vasodilator and is indicated as an alternative to exercise in thallium myocardial perfusion imaging for the evaluation of coronary artery disease in patients who cannot exercise adequately

DOSAGE AND ADMINISTRATION

The recommended dose is 0.142 mg/kg/minute (0.57 mg/kg total) or 0.568 mg/kg or 60 mg total dose infused over 4 minutes. Although the maximum tolerated dose has not been determined, clinical experience suggests that a total dose beyond 60 mg is not needed for any patient.

Prior to intravenous administration, dipyridamole should be diluted in at least a 1:2 ratio with 0.45% sodium chloride injection, 0.9% sodium chloride injection, or 5% dextrose injection for a total volume of approximately 20 to 50 mL. Infusion of undiluted dipyridamole injection may cause local irritation.

Myocardial perfusion assessment should be started when maximal vasodilation is reached, usually after 3 minutes, which generally occurs approximately 7 minutes from onset of infusion

ADVERSE REACTIONS

Flushing, chest pain, dyspnea, headache, dizziness, nausea, vomiting, palpitations, arm/back/shoulder pain, arrhythmias, paresthesias, pulmonary edema, asystole myocardial infarcation

Side effects can be easily reversed by an administration of an IV bolus of 50-75 mg of Aminophylline or an infusion of 250-500 mg over 20 minutes

CONTRAINDICATIONS

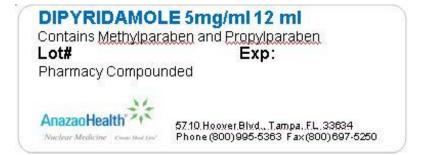
Theophylline therapy, active wheezing, high grade antroventricular block

Storage and Handling

Dipyridamole should be stored at room temperature and protected from light.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Figure 1



DIPYRIDAMOLE

DIPYRIDAMOLI	Ľ.							
dipridamole solution								
Product Information	1							
Product T ype		HUMAN PRESCRIPTIO	N DRUG	Item Code (Source)		NDC	NDC:51808-204	
Route of Administration	1	INTRAVENOUS						
Active Ingredient/A	ctive Moi	ety						
Ingredient Name Basis						Strength	Strength	
DIPYRIDAMOLE (UNII: 64	ALC7F90C)	(DIPYRIDAMOLE - UNI	l:64ALC7F90C)		DIPYRIDAM	OLE	5 mg in 1 mL	
Inactive Ingredients						-	-	
Ingredient Name						Strength		
METHYLPARABEN (UNII: PROPYLPARABEN (UNII:								
Product Characteris	atics							
Color		LLOW	Score					
Shape			Size					
Flavor					Code			
Contains								
Packaging								
# Item Code	Pac	Package Description		Marketing Start Date		Marketing End Date		
1 NDC:51808-204-01	10 mL in	1 VIAL						
Marketing Inform	mation							
Marketing Category	Applicatio	ication Number or Monograph Citation			Marketing Start Date		Marketing End Date	
Unapproved drug other				05/23/2012				

Labeler -	AnazaoHealth Cor	poration (011038762)
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Establishment									
Name	Address	ID/FEI	Business Operations						
Anazao Health Corporation		011038762	MANUFACTURE						

Revised: 5/2012

AnazaoHealth Corporation