CONTRAST ALLERGY PREMED PACK- prednisone, diphenhydramine
Shertech Laboratories, LLC

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.

Contrast Allergy PreMed Pack

DESCRIPTION

Contrast Allergy PreMed Pack ™ consists of an administration card containing three Prednisone 50 mg tablets, USP, and one Diphenhydramine Hydrochloride 50 mg capsule, USP, for oral administration.

Contrast Allergy PreMed Pack ™

NDC 16129-101-01

double therapy

Contrast Allergy PreMed Pack ™

PREDNISONE

DIPHENHYDRAMINE

BLISTER PACK CONTAINS:

3 PREDNISONE, USP, 50 mg Tablets; and

1 DIPHENHYDRAMINE HYDROCHLORIDE CAPSULE, USP, 50 mg

Rx only

Select Exam Time ☐ (to the nearest half hour)

Take 1st Dose at ☐ (13 hours prior to exam)

Take 2nd Dose at ☐ (7 hours prior to exam)

Take 3rd Dose at ☐ (1 hour prior to exam)

Remove and use to lock slide

Contrast Allergy PreMed Pack™

www.premedpack.com

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Administration Regimen:
1-50mg Prednisone 13 hours prior to exam time
1-50mg Prednisone 7 hours prior to exam time
1-50mg Prednisone and 50mg Diphenhydramine 1 hour prior to exam time

SHERTECH LABORATORIES

NDC 16129-101-01
US Patent 8556077

Package Includes:
(3) Prednisone 50 mg NDC 0054-0019-25
(1) Diphenhydramine 50 mg NDC 66624-031-10

Distributed by:
Shertech Laboratories, LLC
1185 Woods Chapel Road Duncan, SC 29334

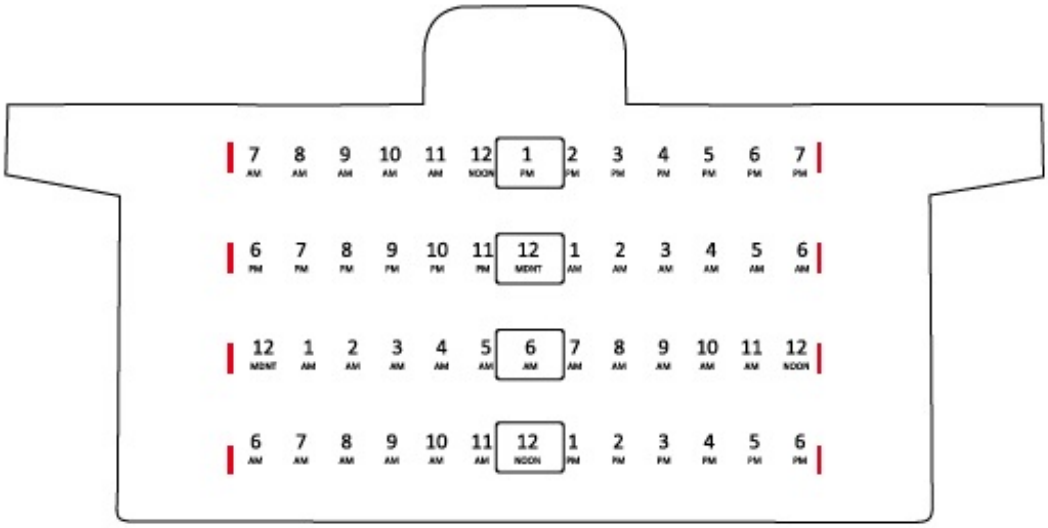
1st
50 mg Prednisone
Take 13 hours prior to exam

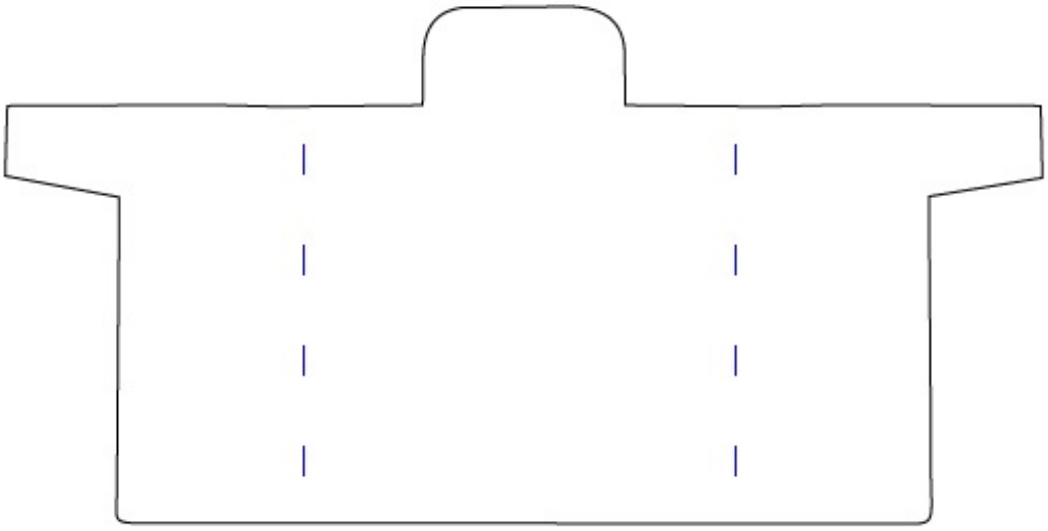
2nd
50 mg Prednisone
Take 7 hours prior to exam

3rd
50 mg Prednisone
50 mg Diphenhydramine
Take 1 hour prior to exam

Take with plenty of water

Caution: Diphenhydramine could cause drowsiness, please use caution when taking this medication.





CONTRAST ALLERGY PREMED PACK

prednisone, diphenhydramine kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:16129-101

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:16129-101-01	1 in 1 BLISTER PACK; Type 1: Convenience Kit of Co-Package	09/13/2016	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1		3

Part 2		1

Part 1 of 2

PREDNISONE

prednisone tablet

Product Information

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PREDNISONE (UNII: VB0R961HZT) (PREDNISONE - UNII:VB0R961HZT)	PREDNISONE	50 mg in 50 mg

Product Characteristics

Color	white	**Score**	score with uneven pieces
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other			

Part 2 of 2

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 50 mg

Product Characteristics			
Color	pink	**Score**	score with uneven pieces
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/13/2016	

Labeler - Shertech Laboratories, LLC (621117279)

Establishment

Name	Address	ID/FEI	Business Operations
Shertech Laboratories, LLC		621117279	manufacture(16129-101)

Revised: 3/2018 Shertech Laboratories, LLC