DEFENSOL D BLISTER PACK- acetaminophen, diphenhydramine hcl, phenylephrine hci tablet
Menper Distributors, Inc.

Defensol D Blister Pack

Active ingredients (in each tablet)

Acetaminophen 325 mg

Diphenhydramine HCl 12.5 mg

Phenylephrine HCl 5 mg

Purpose

Pain Reliever

Antihistamine/ Cough Suppresant

Nasal Decongestant

Uses

Temporarily relieves these symptoms associated with cold or flu:

- headache
- nasal congestion
- sore throat
- fever
- minor aches and pains
- Temporarily relieves minor aches, pains, and headache as well as those symptoms of hay fever or other upper respiratory allergies:
- runny nose
- sneezing
- nasal congestion
- itching of the nose or throat
- itchy, watery eyes

Temporarily relieves minor aches, pains, headache, and nasal congestion as well as sinus congestion and pressure, and reduces swelling of nasal passages

Warnings

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 8 tablets in any 24-hour period, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Severe throat warning:if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Allergy alert: Acetaminophen may cause severe skin reactions:

- Symptoms may include: skin reddening
- blisters
- rash

if a skin reaction occurs, stop use and seek medical help right away.

Do not use
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure

whether a drug contains acetaminophen, ask a doctor or pharmacist
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for

depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after
stopping the MADI drug. If you do not know if your prescription drug contains MADI, ask a doctor or
pharmacist befaretakingthisprocluct.
■ if you have ever had an allergic reaction to this product or any of its ingredients
■ to sedate a child or to make a child sleepy
■ with any other product containing diphenhydramine, even one used on skin.

Ask doctor before use if you have
- liver desease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- glaucoma
- a breathing problem such as emphysema, asthma, or chronic bronchitis
- taking the blood thinning drug warfarin
- taking any other oral nasal decongestant or stimulant
- taking any other pain relieve/fever reducer
- taking sedatives or tranquilizers

When using this product
- **do not use more than directed**
- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur in children

Stop use and ask a doctor if
- you get nervous, dizzy, or sleepless
- pain or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present

- new symptoms occur

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

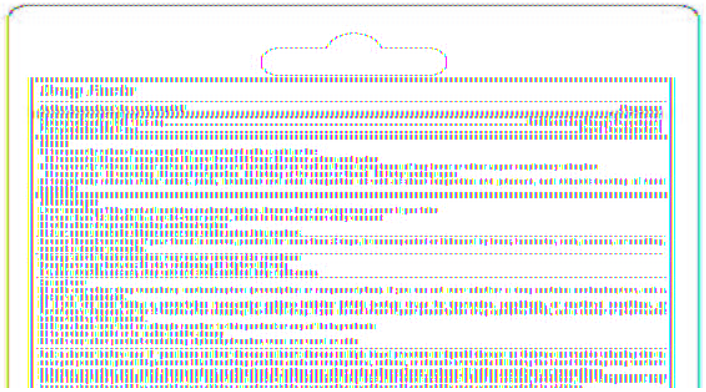
***Directions*: do not take more than 12 tablets in a 24 hour period.**

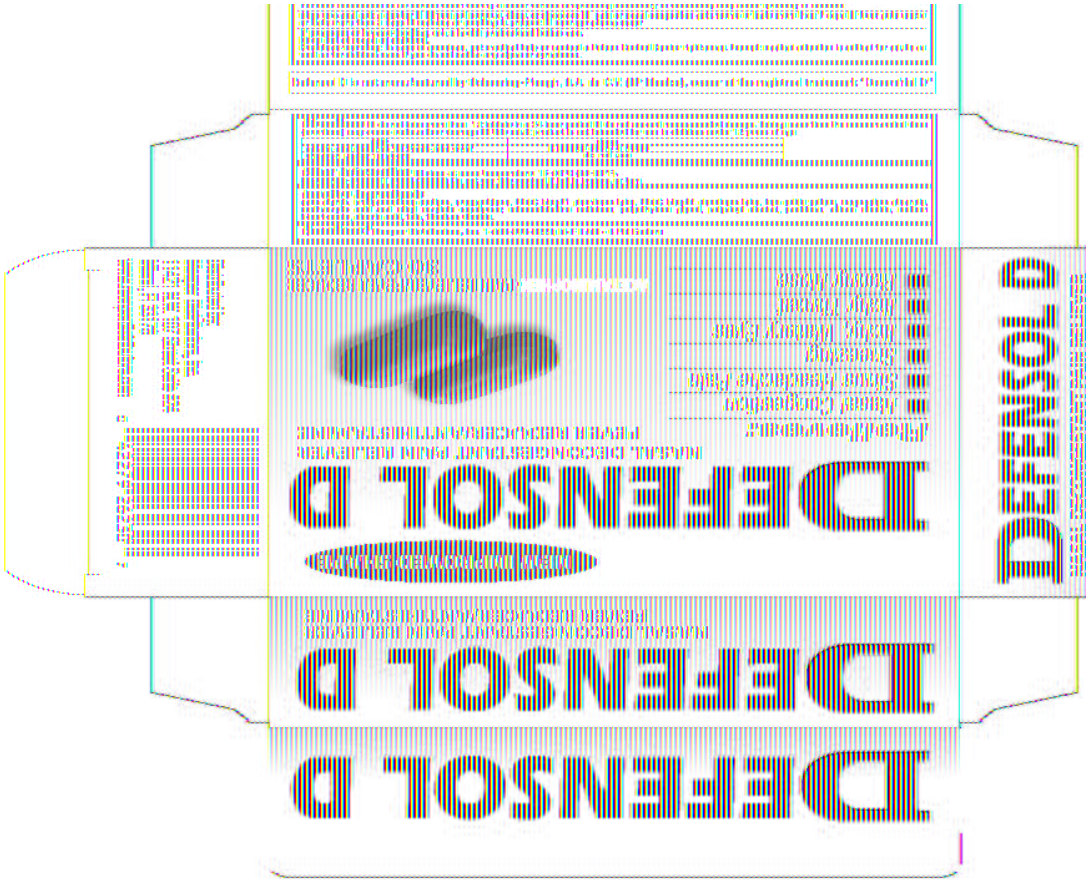
- do not exceed recommended dosage. Taking more than the recommended dose (overdose) may cause serious liver damage. This adult product is not intended for use in children under 12 years of age

age	dose
adults and children 12 years and over	2 tablets every 4 hours
children under 12 years	do not use

Inactive ingredients
corn starch, croscarmellose sodium, crospovidone, FD&C blue#1 aluminum lake, FO&C blue#2 aluminum lake, iron oxide yellow, magnesium stearate, methacrylic acid, and ethyl acrylate copolymer, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, s I con dioxide, sodium bicarbonate, stearic acid, talc, titanium oxide.

Questions? Menper Distributors, Inc. **1-800-560-5223;** M-F 9 AM - 4 PM Eastern





DEFENSOL D BLISTER PACK

acetaminophen, diphenhydramine hcl, phenylephrine hci tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53145-009
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
TALC (UNII: 7SEV7J4R1U)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:2) (UNII: XRK36F13ZZ)	
CROSPOVIDONE (UNII: 2S7830E561)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

Product Characteristics

Color	blue	**Score**	2 pieces
Shape	RECTANGLE	**Size**	10mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53145-009-30	1 in 1 BOX	01/01/2024	
1		30 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/01/2024	

Labeler - Menper Distributors, Inc. (101947166)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc		868734088	manufacture(53145-009)

Revised: 7/2025 Menper Distributors, Inc.