

**ALLERGY- acetaminophen and diphenhydramine hcl tablet
FRED'S, INC.**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Freds 44-518-Delisted

Active ingredients (in each caplet)

Acetaminophen 500 mg

Diphenhydramine HCl 12.5 mg

Purpose

Pain Reliever

Antihistamine

Uses

temporarily relieves:

- runny nose
- sneezing
- itching of the nose or throat and itchy, watery eyes due to hay fever
- headache
- minor aches and pains

Warnings

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

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

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.
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- liver disease
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- marked 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, especially in children

Stop use and ask a doctor if

- new symptoms occur
- pain gets worse or lasts more than 10 days
- pain gets worse or lasts more than 3 days
- redness or swelling is present

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick 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 directed (see overdose warning)**
- adults and children 12 years and over
 - take 2 caplets every 4 to 6 hours
 - do not take more than 8 caplets in 24 hours
- children under 12 years: do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

carnauba wax, corn starch, croscarmellose sodium, crospovidone, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, silicon dioxide, stearic acid, titanium dioxide, triacetin

Principal Display Panel

FRED'S®

Severe

Allergy

Pain Reliever/Antihistamine

Sinus Pain - **Acetaminophen**

Itchy, Watery Eyes

Runny Nose

Sneezing - Diphenhydramine HCl

Pseudoephedrine Free

24 Coated Caplets

Compare to the active ingredients in:

Tylenol® Severe Allergy*

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol® Severe Allergy.

50844 REV0612D51808

Drug Facts
Active Ingredients
 (in each caplet)
 Acetaminophen 500 mg..... Pain reliever
 Diphenhydramine HCl 12.5 mg..... Antihistamine

Purpose
 temporarily relieves:
 ■ runny nose ■ sneezing
 ■ itching of the nose or throat and itchy, watery eyes
 ■ headache ■ minor aches and pains

Drug Facts (continued)

fred's[®]

Severe Allergy

Pain Reliever, Antihistamine

CONTAINS 2 MEDICINES

Sinus Pain - Acetaminophen
 Itchy, Watery Eyes } Diphenhydramine HCl
 Runny Nose }
 Sneezing }

Pseudoephedrine Free

24 Coated Caplets

fred's
 LAB TESTED
 Lab Tested for Quality
 Food Tested for Satisfaction

Compare to the active ingredients in:
Tylenol[®] Severe Allergy*

Actual Size



0 84579153498 2

OMIT E

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

* This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol[®] Severe Allergy. REV0612051808 509844

DISTRIBUTED BY: fred's, Inc.
 4300 NEW GETWELL RD, MEMPHIS, TN 38118
 www.fredsinc.com

fred's Promise
 Not Happy With This Product? Just Bring It Back For a Refund!

Drug Facts (continued)
 Inactive ingredients: carnauba wax, corn starch, croscarmellose sodium, crospovidone, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose.

Drug Facts (continued)
 polyethylene glycol, povidone, silicon dioxide, stearic acid, titanium dioxide, tracetin

Directions
 ■ do not take more than directed (see overdose warning)
 ■ adults and children 12 years and over take 2 caplets every 4 to 6 hours
 ■ do not take more than 8 caplets in 24 hours
 ■ children under 12 years: do not use this adult product in children under 12 years of age; this product in children under 12 years of age may cause liver damage (overdose) and may cause liver damage

Other information
 ■ store at 25°C (77°F); excursions permitted between 15-30°C (59'-86°F)
 ■ see end flap for expiration date and lot number

When using this product
 ■ marked drowsiness may occur
 ■ avoid alcoholic drinks
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 ■ be careful when driving a motor vehicle or operating machinery
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Ask a doctor or pharmacist before use if you are
 ■ taking sedatives or tranquilizers
 ■ taking the blood thinning drug warfarin

Ask a doctor before use if you have
 ■ liver disease ■ glaucoma
 ■ a breathing problem such as emphysema or chronic bronchitis
 ■ trouble urinating due to an enlarged prostate gland

■ with any other product containing diphenhydramine, even one used on skin
 ■ doctor or pharmacist
 ■ sure whether a drug contains acetaminophen, ask a

medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

damage: In case of overdose, get medical help or contact a Poison Control Center right away. Quick

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Fred's 44-518

ALLERGY

acetaminophen and diphenhydramine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-518
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 68401960MK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRICETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	YELLOW	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	44;518
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-518-08	1 in 1 CARTON		
1		24 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 NOT FINAL	part343	06/06/2005	06/10/2018

Labeler - FRED'S, INC. (005866116)**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(55315-518)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(55315-518)

Revised: 6/2015

FRED'S, INC.