EXTRA STRENGTH PAIN RELIEVER- acetaminophen 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 44-531

Active ingredient (in each tablet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - the common cold
  - backache
  - minor pain of arthritis
  - toothache
  - muscular aches
  - premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 6 tablets (3,000 mg) in 24 hours. Severe liver damage may occur if you take:

- more than 4,000 mg of acetaminophen in 24 hours
- 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.

Ask a doctor before use if you have

liver disease.

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts ore than 3 days
- new symptoms occur
- 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 (1-8000-222-1222) 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 tablets every 4 to 6 hours while symptoms last
  - do not take more than 8 tablets in 24 hours
  - do not take for more than 10 days unless directed by a doctor
- children under 12 years: do not use this product in children under 12 years of age; this will provide more than the recommended dose (overdose) of acetaminophen and may cause liver damage

Other information

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

Inactive ingredients

D&C yellow #10 aluminum lake, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, polyethylene glycol, polyvinyl alcohol, povidone, sodium starch glycolate*, starch, stearic acid, sucralose, talc, titanium dioxide

*may contain this ingredient

Principal display panel

FRED'S®

Extra Strength Non-Aspirin
Pain Reliever
Pain Reliever/Fever Reducer

Acetaminophen
EZ Tabs
100 Tablets - 500 mg each

Tested Against The Active Ingredient In:
Extra Strength TYLENOL® EZ TABS†

†This product is not manufactured or distributed McNeil Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol® EZ Tabs.

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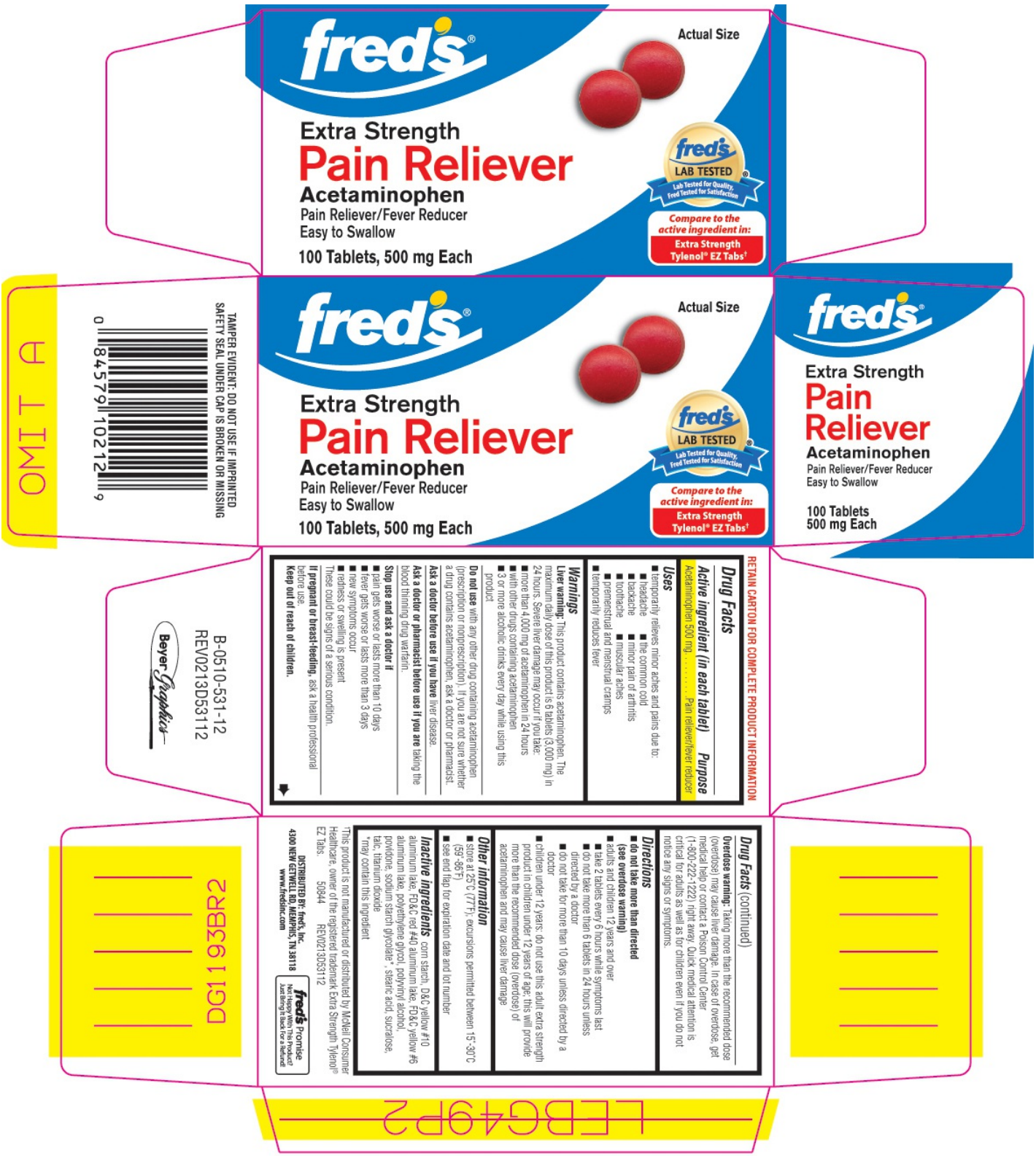
TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING



Fred's 44-531

EXTRA STRENGTH PAIN RELIEVER

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55315-531
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients	
Ingredient Name	**Strength**
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	RED	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	44;531
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55315-531-57	1 in 1 CARTON		
1		125 in 1 BOTTLE		
2	NDC:55315-531-12	1 in 1 CARTON		
2		100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	12/11/2005	

Labeler - FRED'S, INC. (005866116)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(55315-531)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(55315-531)

Revised: 7/2013

FRED'S, INC.