QUALITY CHOICE EXTRA STRENGTH PAIN RELIEF- acetaminophen tablet
Chain Drug Marketing Association

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.

DRUG FACTS

Active ingredient

Acetaminophen

Purpose

Pain reliever/fever reducer

Uses

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

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dosse of this product is 6 caplets (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

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 more 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 damamge. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 caplets every 4 to 6 hours while symptoms last
  - do not take more than 8 caplets in 24 hours
  - do not take for more than 10 days unless directed by a doctor
- children under 12 years: do not use this adult extra strength 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 25ºC (77ºF); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive Ingredients

Polyvinylpyrrolidone, pregelatinized starch, sodium starch glycolate, stearic acid

QUALITY CHOICE EXTRA STRENGTH PAIN RELIEF

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-978
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**
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	white	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	PH044
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-978-08	1 in 1 CARTON		
1		8 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/23/2014	

Labeler - Chain Drug Marketing Association (011920774)

Registrant - Reese Pharmaceutical Co (004172052)

Establishment

Name	Address	ID/FEI	Business Operations
Reese Pharmaceutical Co		004172052	relabel(63868-978) , repack(63868-978)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest		557054835	manufacture(63868-978)

Revised: 8/2014 Chain Drug Marketing Association