NON-ASPIRIN - acetaminophen tablet
Etex Pharm Co., Ltd

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 Ingredients (in each tablet)

Acetaminophen 500mg

Purpose
Pain Reliever/fever reducer

Warnings

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

- more than 8 tablets in 24 hours, which is the maxium 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.
- if you are allergic to acetaminophen or any of the inactive ingredients in 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

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

These could be sign of a serious condition

If pregnant or breast-feeding

ask a health professional before use.

Keep out of reach of children.

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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 tablets every 4 to 6 hours as needed • do not take more than 8 tablets in 24 hours • do not use 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 6 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

Other Information

- **do not use if imprinted safety seal under cap is broken or missing.**
- store between 20-25°C (68-77°F)
- see end panel for lot number and expiration date

Inactive Ingredients

benzalkonium chloride, boric acid, edetate disodium, purified water, sodium borate, and sodium chloride

non-aspirin 50 tablet

Uses

temporarily relieves minor aches and pains due to:

- headache
- muscular aches

- backache
- arthritis
- the common cold
- toothache
- menstrual cramps
- temporarily reduces fever

NON-ASPIRIN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43459-0153
Route of Administration	ORAL		

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

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	13mm
Flavor		**Imprint Code**	A500
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:43459-0153-6	1 in 1 BOX		
1		50 in 1 BOTTLE		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC monograph not final	part343	08/01/2010	

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acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43459-0152
Route of Administration	ORAL		

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

Product Characteristics			
Color	white	**Score**	no score
Shape	CAPSULE	**Size**	17mm
Flavor		**Imprint Code**	A500
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:43459-0152-6	1 in 1 BOX		
1		40 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/15/2010	

Labeler - Etex Pharm Co., Ltd (631034449)

Registrant - Etex Pharm Co., Ltd (631034449)

Establishment

Name	Address	ID/FEI	Business Operations
Etex Pharm Co., Ltd		631034449	manufacture

Revised: 6/2010 Etex Pharm Co., Ltd