

HANDY SOLUTIONS ACETAMINOPHEN- acetaminophen tablet, film coated
Navajo Manufacturing Company 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.

Handy Solutions Acetaminophen

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

Pain Reliever/Fever Reducer

Uses

For the temporary relief of minor aches and pains associated with:

• headache • muscular aches • minor arthritis pain • common cold • toothache • menstrual cramps

For the reduction of fever.

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 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.
- for more than 10 days for pain, unless directed by a doctor
- for more than 3 days for fever, unless directed by a doctor

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

- symptoms do not improve
- new symptoms occur
- pain or fever persists or gets worse
- redness or swelling is present

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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

Adults and children 12 years of age and older: Take 2 tablets every 4 to 6 hours as needed. Do not take more than 8 tablets in 24 hours.

Children under 12 years of age: Do not give this adult strength product to children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage.

Other information

- Tamper evident. Do not use if packet is torn, cut or opened
- Store at controlled room temperatures 15° to 30° C (59 to 86°F)

Inactive ingredients

corn starch, hypromellose, maltodextrin*, microcrystalline cellulose*, polyethylene glycol, povidone*, pregelatinized starch*, sodium starch glycolate*, stearic acid, titanium dioxide*

*may contain

Questions or comments?

call 1-800-525-5097

Package Labeling:



HANDY SOLUTIONS ACETAMINOPHEN

acetaminophen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67751-161(NDC:47682-125)
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
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white (white)	Score	no score
Shape	ROUND (ROUND)	Size	12mm
Flavor		Imprint Code	FR;33
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67751-161-01	1 in 1 CARTON	09/21/2016	
1		2 in 1 POUCH; 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	09/21/2016	

Labeler - Navajo Manufacturing Company Inc. (091917799)**Establishment**

Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc.		136941411	relabel(67751-161) , repack(67751-161)

