

**HANDY SOLUTIONS HEADACHE PAIN RELIEF- acetaminophen, aspirin,
caffeine tablet, film coated
Navajo Manufacturing Company Inc.**

Handy Solutions Headache & Pain Relief

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 250 mg.

Aspirin (NSAID*) 250 mg

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Pain reliever/fever reducer

Pain reliever aid

Uses

temporarily relieves minor aches and pains due to

- headache ■ muscular aches ■ arthritis pain ■ a cold
- toothache ■ premenstrual and menstrual cramps

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening ■ blisters ■ rash

If a skin reaction occurs, stop use and seek medical help right away.

Allergy alert: Aspirin (NSAIDs) may cause a severe allergic reaction which may include:

- hives ■ facial swelling ■ asthma (wheezing) ■ shock

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

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- take more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product

Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat

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 ever have had an allergic reaction to acetaminophen, aspirin or any other pain relievers/ fever reducers

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have a history of stomach problems such as heartburn
- you have asthma
- you have liver disease

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for gout, diabetes, or arthritis
- taking any other drug, or under a doctor's care for any serious condition

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days

- ringing in the ears or loss of hearing occurs
- painful area is red or swollen
- any new symptoms appear

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin at 20 weeks or later in pregnancy unless specifically directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. 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 use more than directed

- drink a full glass of water with each dose

Adults and children: (12 years and over) Take 2 caplets every 6 hours as needed; not more than 8 caplets in 24 hours

Children under 12 years: Ask a doctor

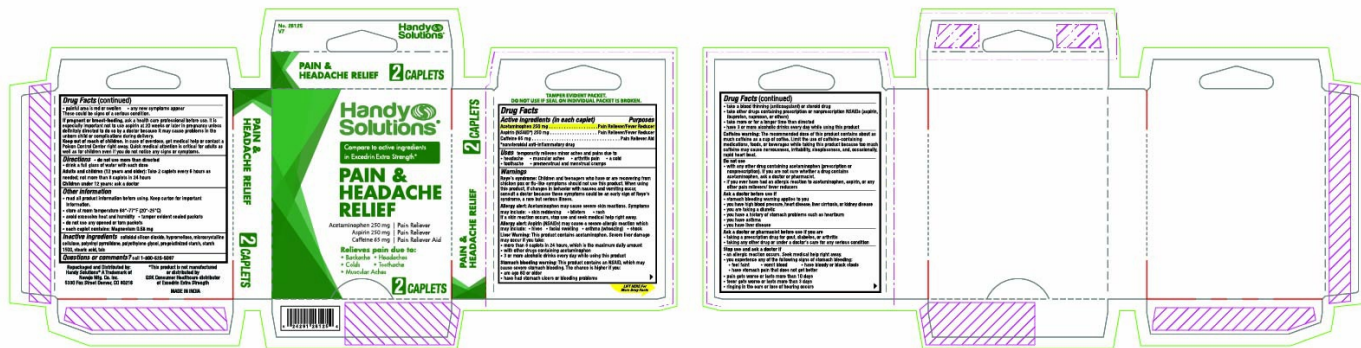
Other information

- read all product information before using. Keep box for important information.
- store at room temperature 68°-77°F (20°-25°C)
- avoid excessive heat and humidity
- tamper evident sealed packets
- do not use any opened or torn packets
- **each caplet contains: Magnesium 0.58 mg**

Inactive ingredients

colloidal silicon dioxide, hypromellose, microcrystalline cellulose, polyvinyl pyrrolidone, polyethylene glycol, pregelatinized starch, starch 1500, stearic acid, talc

Questions or comments? 1-800-525-5097



HANDY SOLUTIONS HEADACHE PAIN RELIEF

acetaminophen, aspirin, caffeine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67751-215(NDC:47682-238)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg

Inactive Ingredients

Ingredient Name	Strength
TALC (UNII: 7SEV7J4R1U)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3W0)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	white ((white to off white with specks))	Score	no score
Shape	CAPSULE ((capsule shaped, biconvex))	Size	18mm
Flavor		Imprint Code	S53
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67751-215-01	2 in 1 CARTON	09/23/2021	
1		2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	09/23/2021	

Labeler - Navajo Manufacturing Company Inc. (091917799)

Establishment

Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc.		136941411	relabel(67751-215)

Revised: 4/2024

Navajo Manufacturing Company Inc.