

EXAPRIN-AC- aspirin,caffeine tablet, film coated **HART Health**

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.

EXAPRIN-AC

Active ingredients (in each caplet)

Aspirin (NSAID*) 500 mg *nonsteroidal anti-inflammatory drug

Caffeine 32.5 mg

Purpose

Pain reliever/fever reducer

Pain reliever aid

Uses

for the temporary relief of minor aches and pains due to

- headache
- muscular aches
- backache pain
- minor arthritis pain
- common cold
- toothache
- menstrual cramps

Temporarily reduces fever

Warnings

Reye's syndrome:

Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye's Syndrome, a rare but serious illness reported to be associated with salicylates.

Allergy alert:

Magnesium salicylate may cause a severe allergic reaction which may include:

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

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)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Do not use if you have ever had an allergic reaction to any pain reliever/fever reducer.

Ask a doctor before use if

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

Ask a doctor or pharmacist before use if you take any drug for diabetes, gout or arthritis

Stop use and ask a doctor if

- an allergic reaction occurs, seek medical help right away
- fever worsens or lasts more than 3 days
- pain worsens or lasts more than 10 days
- you have any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools, or stomach pain that does not get better
- ringing in the ears or loss of hearing occurs
- 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. It is especially important not to use aspirin at 20 weeks or later in pregnancy unless definitely 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. 1-800-222-1222

Directions

Do not take more than directed.

Adults and children 12 years of age and over:

- take 2 caplets with a full glass of water every 6 hours while symptoms persist
- do not take more than 8 caplets in 24 hours unless directed by a doctor

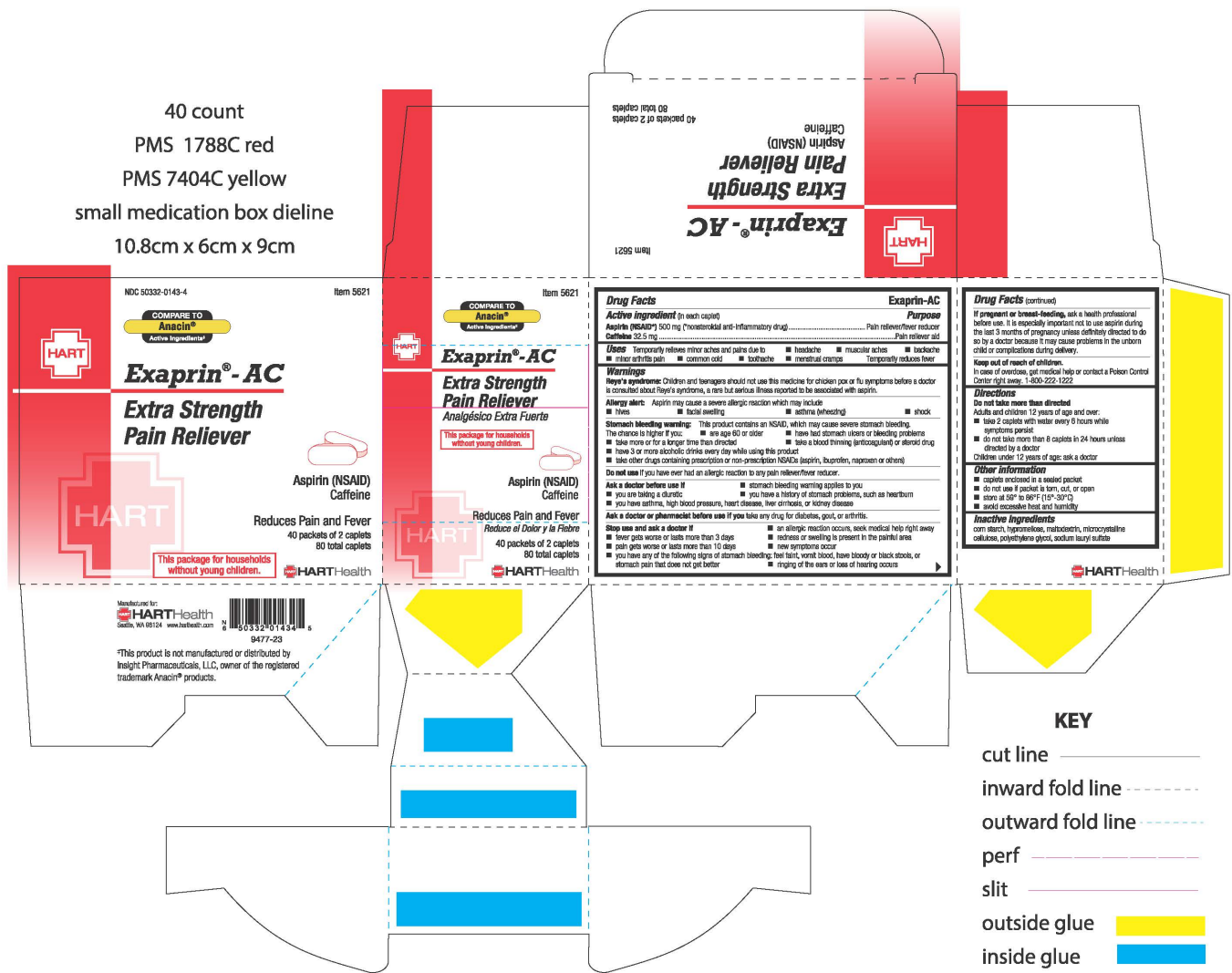
Children under 12 years: ask a doctor

Other information

- caplets enclosed in a sealed packet
- do not use if packet is torn, cut or open
- store at 59° to 86°F (15°-30°C)
- avoid excessive heat and humidity

Inactive ingredients

corn starch, hypromellose, maltodextrin, microcrystalline cellulose, polyethylene glycol, sodium lauryl sulfate



Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50332-0143
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	500 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	32.5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE (Caplet)	Size	17mm
Flavor		Imprint Code	44;413
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50332-0143-3	20 in 1 BAG	01/09/2023	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:50332-0143-4	40 in 1 BOX	01/09/2023	
2		2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:50332-0143-7	100 in 1 BOX	01/09/2023	
3		2 in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:50332-0143-8	200 in 1 BOX	01/09/2023	
4		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 not final	part343	01/09/2023	

Labeler - HART Health (069560969)

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HART Health