EXAPRIN- acetaminophen, aspirin, caffeine and salicylamide tablet
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

Active Ingredients (in each tablet):

Acetaminophen 110mg

Aspirin (NSAID)* 162mg (*nonsteroidal anti-inflammatory drug)

Caffeine 32.4mg

Salicylamide (NSAID)* 152mg (*nonsteroidal anti-inflammatory drug)

Purpose:

Pain Reliever / Fever Reducer

Pain Reliever / Fever Reducer

Pain Reliever Aid

Pain Reliever / Fever Reducer

Uses:

Temporarily relieves minor aches and pains due to
- headache
- backache
- muscular aches
- minor arthritis pain
- the 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 aspirin.

Allergy alert: Aspirin may cause a severe allergic reaction which may include hives, facial swelling, asthma (wheezing), or shock

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 products containing acetaminophen
- 3 more 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 stomach ulcers or bleeding problems
- take more or for a longer time than directed
- take a blood thinning (anticoagulant) or steroid drug
- have 3 or more alcohol drinks every day while using this product
- take other drugs containing prescription or non-prescription NSAIDS (aspirin, ibuprofen, naproxen, others)

Do not use

- with any other drug containing acetaminophen (prescription or non-prescription)
- if you have ever had an allergic reaction to aspirin or any other pain reliever/fever reducer

Ask a doctor before use if

- stomach bleeding warning applies to yo9u
- you have asthma, 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

Ask a doctor or pharmacist before use if you

- take any other drug containing an NSAID
- take a blood thinning (anticoagulant) or steroid drug
- take any drug for diabetes, gout, or arthritis
- do not know if other drugs you are taking contain acetaminophen

Stop use and ask a doctor if

- an allergic reaction occurs, seek medical help right away
- new symptoms occur
- fever worsens or lasts more than 3 days
- pain worsens or lasts more than 10 days
- redness or swelling is present in the painful area
- ringing in the ears or loss of hearing occurs
- 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

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 during the last 3 months of pregnancy unless definitely directed to do so by a doctor because is may cause problems in the unborn child or complications during delivery

Keep out of reach of children

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms. In cas eof overdose, get medical help or contact a Poison Control Center right away. 1-800-222-1222

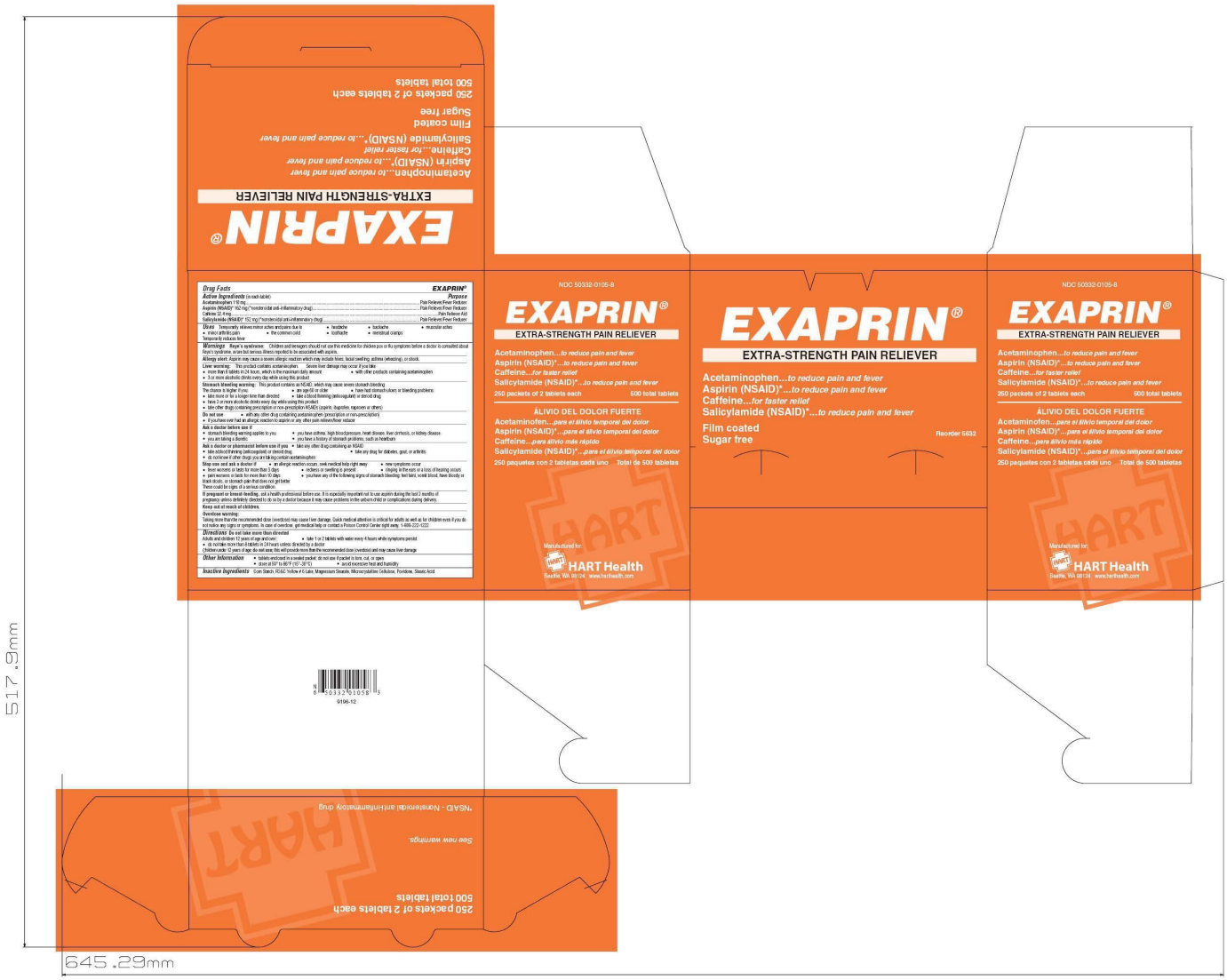
Directions: do not take more than directed.

Adults and children 12 years of age and over:

- take 1 or 2 tablets with water every 4 hours while sympotms persist
- do not take more than 8 tablets in 24 hours unless directed by a doctor

Children under 12 years of age: do not use; this will provide more than the recommended dose (overdose) and my cause liver damage

Inactive Ingredients: Corn Starch, FD&C Yellow #6 Lake, Magnesium Stearate, Microcrystalline Cellulose, Povidone, Stearic Acid



EXAPRIN

acetaminophen, aspirin, caffeine, salicylamide tablet

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:50332-0105

Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (ACETAMINOPHEN)	ACETAMINOPHEN	110 mg
ASPIRIN (ASPIRIN)	ASPIRIN	162 mg
CAFFEINE (CAFFEINE)	CAFFEINE	32.4 mg
SALICYLAMIDE (SALICYLAMIDE)	SALICYLAMIDE	152 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN	
FD&C YELLOW NO. 6	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POVIDONE	
STEARIC ACID	

Product Characteristics

Color	orange	**Score**	no score
Shape	ROUND	**Size**	12mm
Flavor		**Imprint Code**	EXA
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50332-0105-3	20 in 1 BOX, UNIT-DOSE		
1		2 in 1 PACKET		
2	NDC:50332-0105-4	50 in 1 BOX, UNIT-DOSE		
2		2 in 1 PACKET		
3	NDC:50332-0105-7	125 in 1 BOX, UNIT-DOSE		
3		2 in 1 PACKET		
4	NDC:50332-0105-8	250 in 1 BOX, UNIT-DOSE		
4		2 in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/20/1987	

Labeler - HART Health (069560969)