HEADACHE RELIEF- acetaminophen, aspirin and caffeine tablet
SMART SENSE (KMART)

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.

STS - 1183 - 2019-1008

Drug Facts

Active ingredients (in each caplet)	**Purpose**
Acetaminophen 250 mg	Pain reliever
Aspirin (NSAID [1]) 250 mg	Pain reliever
Caffeine 65 mg	Pain reliever aid

[1]nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - a cold
  - arthritis
  - muscular aches
  - 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 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)
- have 3 more alcoholic drinks every day while using this product
- take more or for a longer time than directed

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 heartbeat.

Do not use

- if you have ever had an allergic reaction to acetaminophen, aspirin, or any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if

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

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for:
  - diabetes
  - gout
  - arthritis
- taking any other drug, or are 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
- ringing in the ears or loss of hearing occurs

- 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
- new symptoms occur

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 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). 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; do not take more than 8 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information

Inactive ingredients

carnauba wax, colloidal silicon dioxide, hypromellose, microcrystalline cellulose, mineral oil, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

PRINCIPAL DISPLAY PANEL

smart sense

NDC 49738-183-01

COMPARE TO THE ACTIVE INGREDIENTS OF EXCEDRIN(R) EXTRA STRENGTH CAPLETS

EXTRA STRENGTH

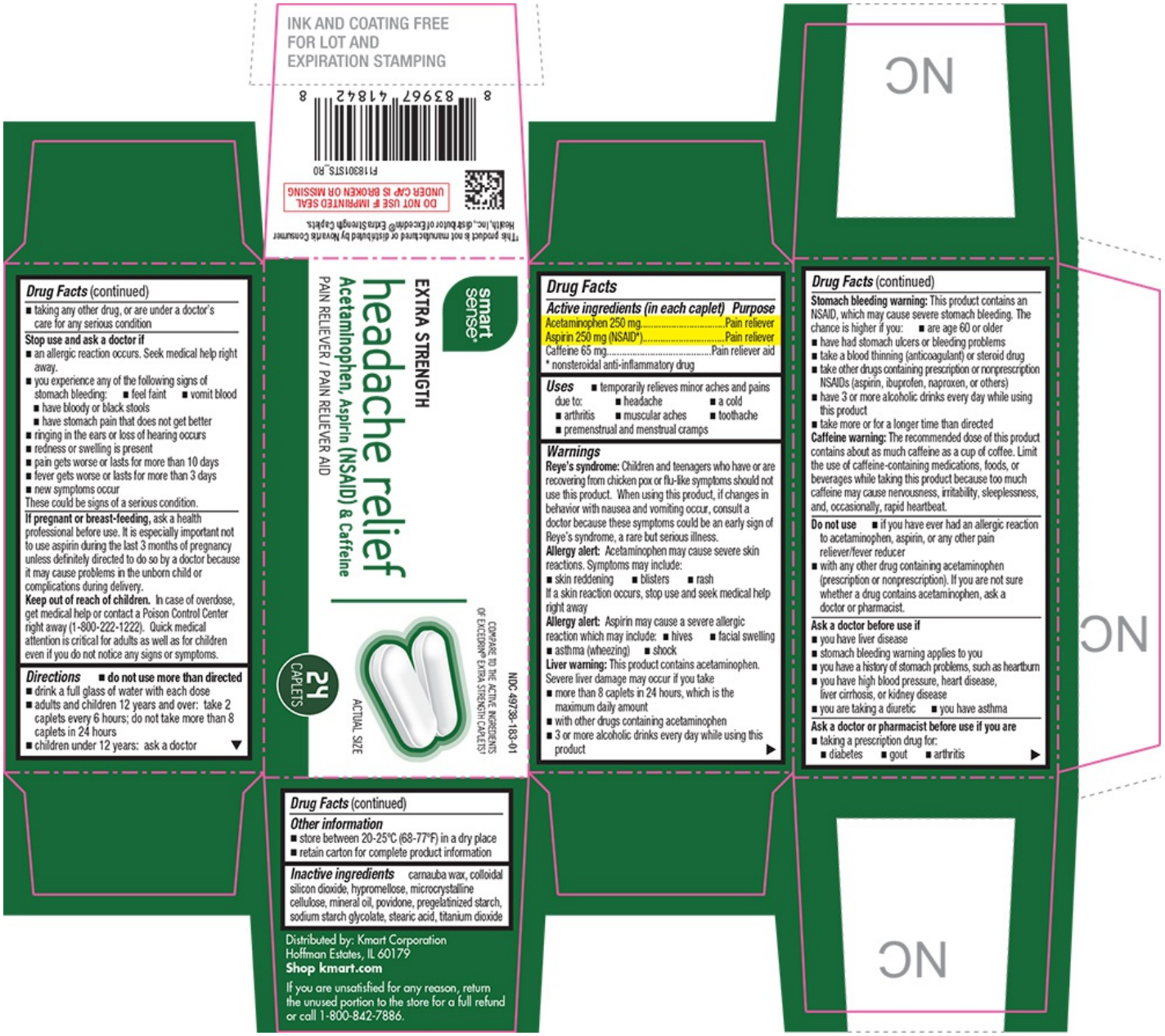
headache relief

Acetaminophen, Aspirin (NSAID) & Caffeine

PAIN RELIEVER / PAIN RELIEVER AID

ACTUAL SIZE

24 CAPLETS



HEADACHE RELIEF

acetaminophen, aspirin and caffeine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49738-183
Route of Administration	ORAL		

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

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	TCL370
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49738-183-01	1 in 1 CARTON	07/27/2017	
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:49738-183-03	1 in 1 CARTON	07/27/2017	
2		100 in 1 BOTTLE, PLASTIC; 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	07/27/2017	

Labeler - SMART SENSE (KMART) (008965873)

Revised: 10/2019 SMART SENSE (KMART)