ONLY FOR HEADACHE- acetaminophen, caffeine tablet O4 Global Trading Usa, Llc

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.

Only For - HEADACHE

DRUG FACTS

Active ingredient (in each caplet)

Acetaminophen 500mg

Caffeine 65mg

Purpose

Pain reliever

Pain reliever aid

Uses:

- Temporarily relieves minor aches and pains due to:
- headache
 muscular aches

Warnings:

Liver warning:

This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 6 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

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.

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

- Iif you are allergic to acetaminophen
- 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

- any new symptoms occur pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days

These could be signs of a serious condition

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of childern

In case of accidental 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:

- take with a full glass of water
- do not take more than directed
- do not take more than 6 caplets in 24 hours

adults and children 12 years of age and	take 2 caplets every 6 hours, not more than 6 caplets in 24
over	hours.
under 12 years of age	ask a doctor

Other Information:

• Store at room temperature between 20-25°C (68-77°F).

Inactive Ingredients:

colloidal silicon dioxide, croscarmellose sodium, D&C red #27 aluminum lake, FD&C yellow #6 aluminum lake, gelatin, magnesium stearate, maize starch, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, purified water, sodium starch glycolate, talc, titanium dioxide.

Questions Or Comments?

1-833-665-9444.

NDC: 73006-110-41

ADULT

ANALGESIC(PAIN RELIEVER)

Distributed By: O4 GLOBAL TRADING USA LLC., 2241 S Watson RD, Suite 121 Arlington, TX 76010.

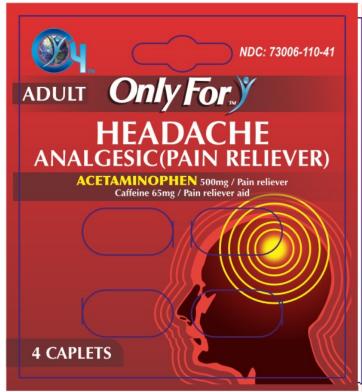
www.onlyfor.com

Packaged By: Strive Pharmaceuticals Inc., East Brunswick, NJ 08816.

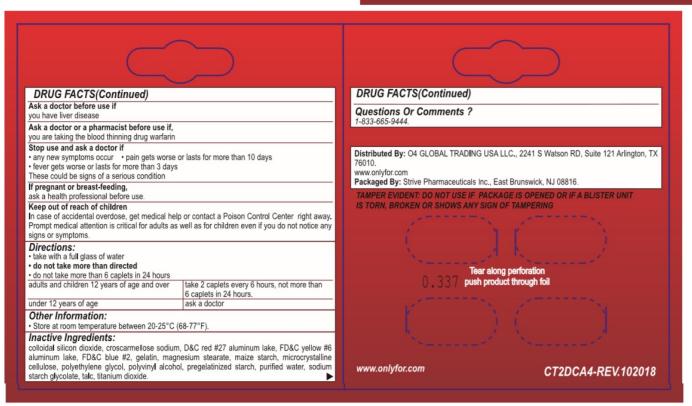
TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF A BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGN OF TAMPERING.

Tear along perforation push product through foil

Packaging







ONLY FOR HEADACHE

acetaminophen, caffeine tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73006-110
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	500 mg	
CAFFEINE (UNII: 3G6 A5W338 E) (CAFFEINE - UNII:3G6 A5W338 E)	CAFFEINE	65 mg	

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
MAGNESIUM PALMITO STEARATE (UNII: R40 XA9 G5BV)	
STARCH, CORN (UNII: O8232NY3SJ)	
MICRO CRYSTALLINE CELLULO SE 101 (UNII: 7T9 FYH5QMK)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYVINYL ALCOHOL (94000 MW) (UNII: C1MS7RRZ6L)	
WATER (UNII: 059QF0KO0R)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics				
Color	red	Score	no score	
Shape	OVAL (Caplet)	Size	18 mm	
Flavor		Imprint Code	S777	
Contains				

	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:73006-110-41	1 in 1 CARTON	03/29/2019	
ı	1	4 in 1 BLISTER PACK; 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	03/29/2019	

Labeler - O4 Global Trading Usa, Llc (081226861)