#### ONLY FOR HEADACHE- acetaminophen, aspirin, 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 Form **HEADACHE**

#### **Drug** Facts

#### Active ingredient (in each geltab)

Acetaminophen 250mg Aspirin 250mg (NSAID\*) Caffeine 65 mg \*nonsteroidal anti-inflammatory drug

#### Purpose

Pain reliever Pain reliever

Pain reliever aid

### Uses:

Temporarily relieves minor aches and pains due to:

• headache • a cold • arthritis • muscular aches • toothache • premenstrual & menstrual cramps

### Warnings:

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flue-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 geltabs 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 or 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 a much caffeine as 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** • 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, or arthritis
- 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 • painful area is red or swollen • pain gets worse or lasts for more than 10 days • fever gets worse or lasts for more than 3 days • any 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 compliments during delivery.

## Keep out of reach of children.

**OVERDOSE WARNING:** Taking more than directed can cause serious health problems. In case overdose. get medical help or contact a Poison Control Center right away.

## 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 geltabs every 6 hours; not more than 8 geltabs in 24 hours
- children under 12 years: ask a doctor

## Other Information:

• store at room temperature between 20-25°C (68 to 77°F) • avoid excessive heat, cold and humidity • close cap tightly after use • read all product information before using.

## Inactive Ingredients:

ammonium hydroxide, black iron oxide, brilliant blue FCF, corn starch, D&C yellow No.10 lake, ethyl cellulose, FD&C blue No.1 lake, FD&C red No.40 lake, gelatin, glycerin, hydroxypropyl methyl cellulose, isopropyl alcohol, isopropyl alcohol - butyl alcohol, lactose monohydrate, light liquid paraffin, microcrystalline cellulose, polysorb 85/70/00, povidone K30, pregelatinised starch, propylene glycol, purified water, shellac glaze, stearic acid, talc, titanium dioxide, triacetin

**Questions or comments?** 

1-833-665-9444. (Mon-Fri 9am-5pm)

### ADULT

## PAIN RELIEVER

## PAIN RELIEVER AID

**TAMPER EVIDENT:** Do not use if imprinted safety seal under cap is broken or missing

## Distributed By: O4 GLOBAL TRADING USA, LLC.

12222 Merit Drive, Suite 1900 Dallas, TX 75251-3209 www.onlyfor.com

## Packaged By: Strive Pharmaceuticals Inc.

East Brunswick, NJ 08816.

## Packaging



#### Drug Facts

Active ingredient (in each geltab) Purpose Pain reliever Acetaminophen 250mg. Pain reliever Aspirin 250mg (NSAID\*)..... Pain reliever aid Caffeine 65 mg... \*nonsteroidal anti-inflammatory drug Uses: Temporarily relieves minor aches and pains due to: ■ headache ■ a cold ■ arthritis ■ muscular aches ■ toothache premenstrua & menstrua 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 
1

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 sthma (wheezing) shock Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take 🔳 more than 8 geltabs in 24 hours, which is the maximum daily amount a 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 or more alcoholic drinks every day while using this product a 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 heart beat. 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 vou have liver disease stomach

Drug Facts (continued)

Ask a doctor defore use if a you have liver disease stormach bleeding warning applies to you a 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, or arthritis

■ 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 ■ painful area is red or swollen ■ pain gets worse or lasts for more than 10 days ■ fever gets worse or lasts for more than 3 days ■ any new symptoms occur These could be signs of a serious condition 2▼

#### Drug Facts (continued)

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.

**OVERDOSE WARNING:** Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away.

#### 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 gettabs every 6 hours; not more than 8 gettabs in 24 hours

children under 12 years: ask a doctor

#### Other Information:

■ store at room temperature between 20-25<sup>o</sup>C (68 to 77°F) ■ avoid excessive heat, cold and humidity ■ close cap tightly after use ■ read all product information before using.

#### Inactive Ingredients:

ammonium hydroxide, black iron oxide, brilliant blue FCF, corn starch, D&C yellow No.10 lake, ethyl cellulose, FD&C blue No.1 lake, FD&C red No.40 lake, gelatin, glycerin, hydroxypropyl methyl cellulose, isopropyl alcohol, isopropyl alcohol - butyl alcohol, lactose monohydrate, light liquid paraffin, microcrystalline cellulose, polysorb 85/70/00, povidone K30, pregelatinised starch, propylene glycol, purified water, shellac glaze, stearic acid, talc, titanium dioxide, triacetin

Questions or comments? 1-833-665-9444, (Mon-Fri 9am - 5om)

Distributed By: O4 GLOBAL TRADING USA, LLC. 12222 Merit Drive, Suite 1900

Dallas, TX 75251-3209 www.onlvfor.com

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

LB7300613295-REV.00-072020

3

# **ONLY FOR HEADACHE**

acetaminophen, aspirin, caffeine	a tablet				
Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Sourc	e)	NDC:7300	6-132
Route of Administration	ORAL		,		
Kutte of Aummistication	ONTE				
Active Ingredient/Active M	•				
	Ingredient Name		Basis of S	0	Strength
ACETAMINOPHEN (UNII: 36209ITL	L9D) (ACETAMINOPHEN - UNI	I:362O9ITL9D)	ACETAMINO	PHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) ASPIRIN				250 mg	
CAFFEINE (UNII: 3G6A5W338E) (CA	AFFEINE - UNII:3G6A5W338E)		CAFFEINE		65 mg
Inactive Ingredients					
	Ingredient Name			S	trength
<b>AMMO NIA</b> (UNII: 5138Q19F1X)	U				J
FERROSOFERRIC OXIDE (UNII: XM	M0 M8 7F357)				
FD&C BLUE NO. 1 (UNII: H3R47K31					
STARCH, CORN (UNII: 08232NY3S.					
D&C YELLOW NO. 10 (UNII: 35SW	·				
ETHYLCELLULOSE, UNSPECIFIEI					
FD&C RED NO. 40 (UNII: WZB9127)	XOA)				
GELATIN (UNII: 2G86QN327L)					
GLYCERIN (UNII: PDC6A3C0OX)					
HYPROMELLOSES (UNII: 3NXW29)	V3WO)				
ISOPROPYL ALCOHOL (UNII: ND2					
BUTYL ALCOHOL (UNII: 8PJ61P61	,				
LACTOSE MONOHYDRATE (UNII:					
LIGHT MINERAL OIL (UNII: N6K57	,				
MICROCRYSTALLINE CELLULOS	<b>SE</b> (UNII: OP1R32D61U)				
SORBITOL SOLUTION (UNII: 8KW					
POVIDONE, UNSPECIFIED (UNII: F					
PROPYLENE GLYCOL (UNII: 6 DC9	9Q167V3)				
WATER (UNII: 059QF0KO0R)					
<b>SHELLAC</b> (UNII: 46 N107B710)					
STEARIC ACID (UNII: 4ELV7Z65AP)	')				
TALC (UNII: 7SEV7J4R1U)					
TITANIUM DIO XIDE (UNII: 15FIX9 V	V2JP)				
TRIACETIN (UNII: XHX3C3X673)					
Product Characteristics					

Color	green (Dark Green - White)	Score	no score
Shape	ROUND	Size	13mm
Flavor		Imprint Code	S77
Contains			

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:73006-132- 95	1 in 1 CARTON	11/15/2020			
1		25 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				
<b>I</b> V	farketing In	formation				
	<b>farketing In</b> Marketing Catego		on Marketing Start Date	Marketing End Date		

Labeler - O4 Global Trading Usa, Llc (081226861)

Revised: 11/2020

O4 Global Trading Usa, Llc