

**ACETAMINOPHEN 500MG CAFFEINE 65MG- acetaminophen 500mg caffeine 65mg tablet
Strive Pharmaceuticals Inc**

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.

Headache - Dolor de Cabeza (Acetaminophen 500mg; Caffeine 65mg)

Acetaminophen 500mg; Caffeine 65mg

colloidal silicon dioxide, croscarmellose sodium, D&C red #27, FD&C blue #2, FD&C yellow #6, magnesium stearate, maize starch, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, polyvinyl alcohol, sodium starch glycolate, talc, titanium dioxide

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

*temporarily relieves minor aches and pains due to:

- headache
- muscular aches

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

- if you are allergic to acetaminophen
- with any other drug containing acetaminophen (prescription or non prescription). 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

Ask a doctor or a pharmacist before use if

you are taking the blood thinning drug warfarin

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- new symptoms occur
- painful area is red or swollen

These could be signs of a serious condition

If pregnant or breast-feeding,

ask a health professional before use

Keep out of reach of children

Overdose warning: 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.

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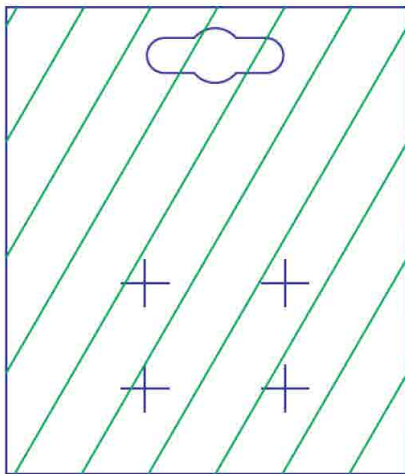
Pain reliever ; Pain reliever aid

- store at room temperature between 20 °C - 25 °C (68 °F - 77 °F)

4 TABLETS NDC: 70692-110-41

SoloPara
DOLOR DE CABEZA
 (HEADACHE)

Acetaminophen 500mg, Caffeine 65mg



LOT: _____
 EXP: _____

DRUG FACTS

Active ingredient (in each caplet)	Purpose
Acetaminophen 500mg	Pain reliever
Caffeine 65mg	Pain reliever aid

Uses:

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

Warnings:

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Do not use

- if 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.

Ask a doctor before use if
 you have liver disease

LIFT PANEL FOR CONTINUED DRUG FACTS ▶

DRUG FACTS (Continued)

Ask a doctor or a pharmacist before use if you are taking the blood thinning drug warfarin

Stop use and ask a doctor if

- any new symptoms occur
- 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

These could be signs of a serious condition.

If pregnant or breast-feeding,
 ask a health professional before use.

Keep out of reach of children

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 over	take 2 caplets every 6 hours, not more than 6 caplets in 24 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, FD&C blue #2, FD&C red #27 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maize starch, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, polyvinyl alcohol, sodium starch glycolate, talc, titanium dioxide.

DRUG FACTS (Continued)

Questions Or Comments?
 1-833-663-9444

READ AND KEEP WITHER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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

TAKE EN EVIDENT DO NOT USE IF PACKAGE IS OPENED OR IF A BUSTER UNIT IS TORN, BURSTEN OR SHOWS ANY SIGN OF TAMPERING!

Tear at arrows
 push through foil

www.onlyfor.com CT2DCA4-REV.102018

ACETAMINOPHEN 500MG CAFFEINE 65MG
 acetaminophen 500mg caffeine 65mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70692-110
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4RIU)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

Product Characteristics

Color	red	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	S777
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70692-110-41	4 in 1 PACKAGE; Type 0: Not a Combination Product	12/20/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part343	12/20/2018	

