SED-MAX- acetaminophen 500 mg with caffeine 65mg tablet, coated Command Brands, LLC

029 - SED-MAX

Active ingredient(s)

Acetaminophen 500mg
Caffeine 65mg

Purpose

Pain reliever/fever reducer

Pain reliever aid

Uses

temporary relief of 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 8 caplets in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 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 other products 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

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
- painful area is red or swollen
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days

These could be signs of a serious skin condition

Pregnancy/Breastfeeding

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

Keep out of reach of children

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. 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
- 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 of age: ask a doctor

Other information

- store at 20-25C (68-77F)
- do not use if imprinted safety seal under cap is broken or missing
- ■you may report side effects to 1-888-952-0050

Inactive ingredients

corn starch, croscarmellose, crospovidone, D&C red #27 aluminum lake, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, silicon dioxide, stearic acid, titanium dioxide

Principal Display Panel



Sedmax

SED-MAX

acetaminophen 500 mg with caffeine 65mg tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69197-029
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg	
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg	

Inactive Ingredients		
Ingredient Name	Strength	
STARCH, CORN (UNII: O8232NY3SJ)		
CROSCARMELLOSE (UNII: 029TFK992N)		
CROSPOVIDONE (UNII: 2S7830E561)		
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POVIDONE (UNII: FZ 989GH94E)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics			
Color	red	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	AZ;029
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69197-029- 20	1 in 1 CARTON	11/26/2014	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	11/26/2014	

Labeler - Command Brands, LLC (060684113)

Revised: 1/2017 Command Brands, LLC