

TENSION HEADACHE RELIEF- acetaminophen and caffeine tablet
SPIRIT PHARMACEUTICALS 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.

VALUMEDS™ TENSION HEADACHE RELIEF

Drug Facts

<i>Active ingredients (in each caplet)</i>	<i>Purposes</i>
Acetaminophen 500 mg	Pain reliever
Caffeine 65 mg	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, beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat.

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

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 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 overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms. 1(800)222-1222

Directions

- **do not use more than directed**
- adults and children 12 years and over; take 2 caplets every 6 hours; not more than 6 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- store at 20°-25°C (68°-77°F)
- close cap tightly after use
- read all product information before using. Keep this box for important information.

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, D&C Red#27, FD&C Blue#2, FD&C Yellow#6, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, purified water, stearic acid, talc, titanium dioxide

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL

Compare to the active ingredients in EXCEDRIN® TENSION HEADACHE*

Tension Headache Relief

Acetaminophen & Caffeine

Pain Reliever/ Pain reliever aid

LOT
EXP:



DO NOT USE IF PRINTING OPERATIONS ARE IN PROGRESS
SAFETY SEAL UNDER CAPS IS BROKEN OR DAMAGED

Drug Facts (continued)

Stop use and ask a doctor if

- any new symptoms occur
- pain/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.

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24 CAPLETS

MAUMEDS

TENSION HEADACHE RELIEF

ACETAMINOPHEN AND CAFFEINE

PAIN RELIEVER/PAIN RELIEVER AID

EXCEDRIN® TENSION HEADACHE*

Compare to the active ingredients in



24 CAPLETS

MAUMEDS

TENSION HEADACHE RELIEF

ACETAMINOPHEN AND CAFFEINE

PAIN RELIEVER/PAIN RELIEVER AID

EXCEDRIN® TENSION HEADACHE*

Compare to the active ingredients in



READ AND KEEP CAPTION FOR COMPLETE WARNINGS AND INFORMATION

Drug Facts

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- 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

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

*This product is not manufactured or distributed by Novartis Consumer Health, Inc., owner of the registered trademark Excedrin®.

DISTRIBUTED BY
SPIRIT PHARMACEUTICALS, LLC.
RONKONKOMA, NY 11779

ORG 10/17

VALUMEDS

Compare to the active ingredient in
Excedrin® Tension Headache*

**TENSION
HEADACHE
RELIEF**
Acetaminophen,
500 mg
Caffeine, 65 mg

pain reliever/
pain reliever aid
100 caplets



Actual Size

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY
SEAL UNDER CAP IS BROKEN OR MISSING**

Drug Facts

Active ingredients (in each caplet) *Pain reliever*
Acetaminophen 500 mg Pain reliever aid
Caffeine 65 mg Pain reliever aid

Uses ■ temporarily relieves minor aches and pains due to:
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Drug Facts (continued under label)

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Distributed By:
Sprit Pharmaceuticals, LLC
Rochester, NY 11779
OR1312/19



LOT:
EXP:



Drug Facts (continued)

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Inactive ingredients
colloidal silicon dioxide, croscarmellose sodium, D&C Red #7, FD&C Blue # 2, FD&C Yellow #6, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pre-gelatinized starch, purified water, stearic acid, talc, titanium dioxide

Questions or comments? 1-888-333-9792

TENSION HEADACHE RELIEF

acetaminophen and caffeine tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0190
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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	Score	no score
Shape	OVAL (CAPSULE SHAPED TABLET)	Size	18mm
Flavor		Imprint Code	S431
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0190-2	1 in 1 CARTON	04/10/2018	
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:68210-0190-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/10/2018	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LIMITED		915664486	manufacture(68210-0190)

