

EXTRA STRENGTH PAIN RELIEVER- acetaminophen, aspirin, and caffeine tablet
SPIRIT PHARMACEUTICALS LLC

VALUMEDS EXTRA STRENGTH PAIN RELIEVER

Drug Facts

<i>Active ingredient (in each caplet)</i>	<i>Purpose</i>
Acetaminophen 250 mg	Pain reliever
Aspirin 250 mg (NSAID) *	Pain reliever
Caffeine 65 mg	Pain reliever aid

* nonsteroidal anti-inflammatory drug

Uses

temporarily relieves minor aches and pains due to:

- headache
- a cold
- arthritis
- muscular aches
- sinusitis
- toothache
- premenstrual & menstrual 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

Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

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.

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
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Stomach bleeding warning

This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause 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 an NSAID (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 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 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 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
- high blood pressure
- you have asthma

Ask a doctor or pharmacist before use

- any other drug containing an NSAID (prescription or nonprescription)
- a blood thinning (anticoagulant) or steroid drug
- 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 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 appear

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

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.

Directions

- do not use more than directed (**see Overdose Warning**)
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 caplets every 6 hours; not more than 8 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- **Each caplet contains:** Magnesium 0.58 mg
- store at controlled room temperature 20° - 25° C (68° - 77° F)
- read all product information before using. Keep this box for important information

Inactive ingredients

colloidal silicon dioxide, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, stearic acid, talc

Questions or comments

1-888-333-9792

DISTRIBUTED BY

SPIRIT PHARMACEUTICALS, LLC.

RONKONKOMA, NY 11779

PRINCIPAL DISPLAY PANEL - 24 CAPLET BOTTLE CARTON

VALUMEDS™

**EXTRA STRENGTH
PAIN RELIEVER**

ACETAMINOPHEN, ASPIRIN (NSAID) AND CAFFEINE

PAIN RELIEVER/PAIN RELIEVER AID

24 CAPLETS

LOT:
EXP:

0 402321 60524 6

017-0024

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

Compare to the active ingredients in
EXCEDRIN® EXTRA STRENGTH*

EXTRA STRENGTH PAIN RELIEVER

ACETAMINOPHEN, ASPIRIN (NSAID) AND CAFFEINE

PAIN RELIEVER/PAIN RELIEVER AID

24 CAPLETS



016 07171

Drug Facts (continued)

any other drug, or are under a doctor's care for any serious condition.

Stop use and ask doctor if:

- allergic reaction occurs. Seek medical help right away.
- fever, sore throat, or other symptoms of infection develop.
- stomach pain that does not get better.
- bleeding or black stools.
- itching in the ears or loss of hearing occurs.
- skin gets worse or lasts for more than 10 days.
- fever gets worse or lasts for more than 3 days.
- any new symptoms appear.

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 specifically 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: In case of overdose, get medical help or attention, even if symptoms seem mild. Black stools and red urine/stool are a medical emergency. If you do not notice any signs or symptoms, you do not need any more.

Directions

- do not use more than directed. **(See Overdose Warning.)**
- drink a full glass of water with each dose.
- adults and children 12 years and older: 2 caplets every 6 hours, not more than 8 caplets in 24 hours.
- children under 12 years: ask a doctor.

Other information

- each caplet contains: Acetaminophen 650 mg, Aspirin 325 mg.
- store at controlled room temperature 20° - 25° C (68° - 77° F).

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EXTRA STRENGTH PAIN RELIEVER

ACETAMINOPHEN, ASPIRIN (NSAID) AND CAFFEINE

PAIN RELIEVER/PAIN RELIEVER AID

24 CAPLETS

Drug Facts

Active ingredient (in each caplet): Acetaminophen 650 mg, Aspirin 325 mg (NSAID), Caffeine 65 mg. Pain reliever and fever reducer. "Nonsteroidal anti-inflammatory drug."

Uses: Temporarily relieves minor aches and pains due to:

- headaches
- toothaches
- muscular aches
- stomach aches
- aches and pains of rheumatoid arthritis
- aches and pains of osteoarthritis
- aches and pains of menstrual cramps

Warnings:

- Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or the flu symptoms should not use this product. When using this product, changes in behavior with vomiting and/or persistent pain may be signs of Reye's syndrome, a rare but serious illness.
- Allergy alert:** Aspirin may cause a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing), shock, and difficulty breathing.
- Acetaminophen may cause severe skin reactions. Symptoms may include: skin redness, blisters, rash.
- If a skin reaction occurs, stop use and seek medical help right away.
- 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.
- For most alcohol drinkers, every day, while using this product.
- Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug.

Drug Facts (continued)

(NSAID), which may cause stomach bleeding. The chance is highest 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 an NSAID (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 as much caffeine as a cup of coffee. Limit the use of 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 aspirin or any other pain reliever/fever reducer or prescription. If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask doctor before use if:

- you have liver disease
- you are taking a diuretic
- you have high blood pressure
- you have asthma
- you have a kidney disease
- you are taking a blood thinner
- you have a heart condition
- you are taking a medicine for high blood pressure, heart disease, liver disease, or kidney disease
- you are taking a medicine for diabetes, gout, or arthritis

Ask a doctor or pharmacist before use:

- any other drug containing an NSAID (prescription or over-the-counter)
- a blood thinning (anticoagulant) or steroid drug
- a prescription drug for diabetes, gout, or arthritis

Drug Facts (continued)

(NSAID), which may cause stomach bleeding. The chance is highest if you:

- are age 60 or older
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Ask doctor before use if:

- you have liver disease
- you are taking a diuretic
- you have high blood pressure
- you have asthma
- you have a kidney disease
- you are taking a blood thinner
- you have a heart condition
- you are taking a medicine for high blood pressure, heart disease, liver disease, or kidney disease
- you are taking a medicine for diabetes, gout, or arthritis

Ask a doctor or pharmacist before use:

- any other drug containing an NSAID (prescription or over-the-counter)
- a blood thinning (anticoagulant) or steroid drug
- a prescription drug for diabetes, gout, or arthritis

EXTRA STRENGTH PAIN RELIEVER

acetaminophen, aspirin, and caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-1700
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL (capsule shaped, biconvex tablets)	Size	18mm
Flavor		Imprint Code	S53
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-1700-2	1 in 1 CARTON	04/10/2018	
1		24 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	04/10/2018	

Revised: 12/2023

SPIRIT PHARMACEUTICALS LLC