EXTRA STRENGTH PAIN RELIEVER- acetaminophen, aspirin and caffeine capsule, gelatin coated
Rite Aid

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.

Rite Aid 44-571

Active ingredients (in each gelcap)

Acetaminophen 250 mg
Aspirin 250 mg (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
  - sinusitis
  - toothache
  - muscular aches
  - premenstrual and 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. 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
- shock
- asthma (wheezing)

Liver 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
- have 3 or more alcoholic drinks every day while using this product
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen,

or others]
- 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, occassionally, rapid heartbeat.

Do not use
- if you 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 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 have asthma
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are
- taking a prescription drug for diabetes, gout, or arthritis
- taking any other drug or are under a doctor's care for any serious condition

Stop use and ask a doctor if
- you experience any of the following signs of stomach bleeding:
  - feel faint
  - have bloody or black stools
  - vomit blood
  - have stomach pain that does not get better
- an allergic reaction occurs. Seek medical help right away.
- any new symptoms appear
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts more than 3 days
- painful area is red or swollen

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.

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**
- drink a full glass of water with each dose
- adults and children 12 years and over

  - take 2 gelcaps every 6 hours
  - do not take more than 8 gelcaps in 24 hours
- children under 12 years: do not use unless directed by a doctor

Other information

- store at controlled room temperature 15º-30ºC (59º-86ºF)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, D&C yellow #10, FD&C blue #1, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, microcyrstalline cellulose, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, simethicone, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

Questions?

1-800-901-5874

Principal display panel

RITE AID®
PHARMACY

**Compare to the active ingredients in Excedrin®

EXTRA STRENGTH
pain reliever
acetaminophen 250 mg
pain reliever • pain reliever aid

80 QUICK RELEASE GELCAPS

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

50844 ORG011057131

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

Rite Aid 44-571

EXTRA STRENGTH PAIN RELIEVER

acetaminophen, aspirin, caffeine capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:11822-0751
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (ACETAMINOPHEN)	ACETAMINOPHEN	250 mg
ASPIRIN (ASPIRIN)	ASPIRIN	250 mg

CAFFEINE (CAFFEINE)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10	
FD&C BLUE NO. 1	
FD&C YELLOW NO. 6	
HYPROMELLOSES	
TITANIUM DIOXIDE	

Product Characteristics

Color	GREEN	**Score**	no score
Shape	CAPSULE	**Size**	21mm
Flavor		**Imprint Code**	L;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0751-3	1 in 1 CARTON		
1		80 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	01/09/2009	

Labeler - Rite Aid (014578892)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(11822-0751)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(11822-0751)