

THRULIFE EXTRA STRENGTH HEADACHE RELIEF - acetaminophen, aspirin, caffeine tablet

Polygen 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.

THRULIFE EXTRA STRENGTH HEADACHE RELIEF

**Active ingredient(s)
(in each caplet)**

Acetaminophen 250 mg

Aspirin 250 mg (NSAID)*

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Pain reliever

Pain reliever aid

Use(s)

temporarily relieves minor headaches and pains due to: •headache • muscular aches • premenstrual & menstrual cramps • cold• sinusitis • arthritis • toothache

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

Liver Warning: This product contains acetaminophen.

Severe liver damage may occur if you take · more than 8 tablets 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 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 ·take other drugs containing prescription or nonprescription NSAIDs (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 heartbeat.

Do not use

- if you have ever had an allergic reaction to acetaminophen, 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 heart burn ·you have high blood pressure, heart disease, liver cirrhosis, or kidney disease ·you are taking a diuretic ·you have asthma

Ask a doctor or pharmacist before use if

- a prescription drug for diabetes, gout, arthritis
- any other drug containing an NSAID (prescription or nonprescription) · a blood thinning (anticoagulant) or steroid drug ·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.
 - painful area is red or swollen
 - any few 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 for more than 3 days

Pregnancy/Breastfeeding

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 caplets every 6 hours: not more than 8 caplets in 24 hours ·
- children under 12 years of age: ask a doctor.

Other information

- store at controlled room temperature 20°-25°C (68°-77°F)
- read all product information before using.
- use by expiration date on package

Inactive ingredients

Microcrystalline cellulose, Croscarmellose sodium, Stearic acid, Hypromellose, Traicetin, Titanium

dioxide & Talc

Dosage & Administration section

- 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

OTC - Questions section

1-888-291-7337

Principal Display Panel Bottle label PDP

EXTRA STRENGTH HEADACHE RELIEF

ThruLife NDC 52605-014-01

Compare to the active ingredients in **EXTRA STRENGTH EXCEDRIN[®]**

EXTRA STRENGTH HEADACHE RELIEF

ACETAMINOPHEN 250 mg, ASPIRIN 250 mg (NSAID) AND CAFFEINE 65 mg

PAIN RELIEVER / PAIN RELIEVER AID

SEE NEW WARNINGS INFORMATION

100 CAPLETS**
**capsule-shaped tablets

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

Drug Facts

Active ingredients (in each caplet)

Active ingredient	Purpose
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 ■ arthritis ■ sinusitis ■ cold ■ toothache
■ menstrual and menstrual cramps ■ muscular aches

Warnings See carton for complete 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

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 ■ 3 or more alcoholic drinks every day while using this product ■ with other drugs containing acetaminophen. **Stomach bleeding 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 ■ take other drugs containing prescription or nonprescription NSAIDs (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. **Do not use** ■ if you ever had an allergic reaction to acetaminophen, 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.

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.

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 caplets every 6 hours; not more than 8 caplets in 24 hours ■ children under 12 years: ask a doctor

Other information ■ TAMPER-EVIDENT BOTTLE: DO NOT USE IF INNER FOIL SEAL UNDER CAP IS BROKEN OR MISSING
■ Store at controlled room temperature 20°-25°C (68°-77°F)

*This product is not manufactured or distributed by Novartis Consumer Health, Inc., owner of the registered trademark Extra Strength Excedrin[®]. Distributed By: PolyGen Pharmaceuticals LLC, Edgewood, NY 11717, USA

LOT NO.:
EXP. DATE:

R105/12
LBS0022

Carton label PDP

EXTRA STRENGTH HEADACHE RELIEF



THRULIFE EXTRA STRENGTH HEADACHE RELIEF

acetaminophen, aspirin, caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52605-014
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	P14
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52605-014-01	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part343	01/31/2013	

Labeler - Polygen Pharmaceuticals LLC (962415720)**Establishment**

Name	Address	ID/FEI	Business Operations
Polygen Pharmaceuticals LLC		962415720	RELABEL(52605-014) , REPACK(52605-014) , MANUFACTURE(52605-014) , PACK(52605-014)