

**DIRECT SAFETY EXTRA STRENGTH ASPIRIN FREE- acetaminophen tablet, film coated**

**Conney Safety Products, 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.*

-----

**Direct Safety XS Aspirin Free**

***Drug Facts***

***Active ingredient (in each tablet)***

Acetaminophen 500 mg

***Purpose***

Pain reliever/fever reducer

***Uses***

**For the temporary relief of minor aches and pains associated with**

- headache
- muscular aches
- minor arthritis pain
- common cold
- toothache
- menstrual cramps

**For the reduction of fever.**

**Warnings**

**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

**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.

**Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor

**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 using and ask a doctor if**

- symptoms do not improve
- new symptoms occur
- pain or fever persists or gets worse
- redness or swelling is present

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

**Keep out of reach of children.** In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt 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 older)** Take 2 tablets every 4 to 6 hours as needed. Do not take more than 8 tablets in 24 hours.

**Children under 12 years:** Do not give this adult strength product to children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage.

**Other information**

- store at room temperature 59°-86°F (15°-30°C)
- tamper-evident sealed packets
- do not use any opened or torn packets

**Inactive ingredients**

corn starch, hypromellose, maltodextrin\*, microcrystalline cellulose\*, polyethylene glycol, povidone\*, pregelatinized starch\*, sodium starch glycolate\*, stearic acid, titanium dioxide\*.

\* may contain

Questions or comments? 1-800-356-9100

### 175 Direct Safety XS Aspirin Free

Direct Safety®

Extra Strength

Aspirin-Free

Pain Reliever/Fever Reducer

Acetaminophen 500 mg.

Acetaminofeno 500 mg.

Industrial Pack 500

(250 Packets of 2 Tablets)

**DIRECT SAFETY. EXTRA-STRENGTH ASPIRIN-FREE Pain Reliever/Fever Reducer**  
Acetaminophen 500 mg. Acetaminofeno 500 mg.

**DIRECT SAFETY. EXTRA-STRENGTH ASPIRIN-FREE Pain Reliever/Fever Reducer**  
Acetaminophen 500 mg. Acetaminofeno 500 mg.

**EXTRA FUERTE NO ASPIRINA**

Retain carton for complete product information

TAMPER EVIDENT FACETS. DO NOT USE IF OPEN OR TORN.

PROFETES CON SELLADO EVIDENTE. NO USE SI EL PAQUETE ABRIERTO O ROTO.

DISTRIBUCION POR: CONSUMERS FIRST PRODUCTS, MADISON, WI 53744-4110

### 176 Direct Safety XS Aspirin Free Label

Direct Safety®

Extra Strength Aspirin Free

Aspirin-Free

Pain Reliever/Fever Reducer

Acetaminophen 500 mg.

Acetaminofeno 500 mg.

Industrial Pack 500

(250 Packets of 2 Tablets)



1	NDC:61245-176-13	250 in 1 BOX	05/31/2013	
1		2 in 1 PACKET; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	05/31/2013	

## DIRECT SAFETY EXTRA STRENGTH ASPIRIN FREE

acetaminophen tablet, film coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61245-176
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

### Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

### Product Characteristics

Color	white (white)	Score	no score
Shape	ROUND (ROUND)	Size	12mm
Flavor		Imprint Code	FR;33
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:61245-176-13	250 in 1 BOX	05/31/2013	11/01/2023
1		2 in 1 PACKET; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	05/31/2013	11/01/2023

**Labeler** - Conney Safety Products, LLC (023316151)

Revised: 3/2023

Conney Safety Products, LLC