

DIRECT SAFETY 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 Aspirin Free

Drug Facts

Active ingredient (in each tablet)

Acetaminophen 325 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 12 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 12 tablets in 24 hours.

Children under 12 years: Do not give to children under 12 years of age.

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

Direct Safety Aspirin Free Label

Direct Safety®

Aspirin-Free

Pain Reliever/Fever Reducer

Acetaminophen 325 mg.

Acetaminofeno 325 mg.

Pull to Open

Tire Para Abrir

Industrial Pack 500

(250 Packets of 2 Tablets)

DIRECT SAFETY

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For the temporary relief of minor aches and pains associated with:
 ■ headache ■ muscular aches ■ minor arthritis pain
 ■ common cold ■ toothache ■ menstrual cramps

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 ■ more than 12 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 redness ■ hives ■ 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
 ■ you are taking the blood thinning drug warfarin

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DIRECT SAFETY

ASPIRIN-FREE

**Pain Reliever/
Fever Reducer**

Acetaminophen 325 mg.
Acetaminofeno 325 mg.

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Tire Para Abrir

Industrial Pack 500
(250 Packets of 2 Tablets)

DIRECT SAFETY

Información del Medicamento

Ingrediente activo (en cada tableta)
Acetaminofeno, 325mg.

Propiedad
Alivia el dolor/ablanda la fiebre

Usos
Para el alivio temporal de leve dolor y malestares asociados con:
 ■ dolor de cabeza ■ dolores musculares
 ■ dolores leves de la artritis ■ resaca común
 ■ dolor de dientes ■ cólicos de la menstruación
Para reducir la fiebre.

Advertencias
Advertencia con respecto al hígado: Este producto contiene acetaminofeno. Daño grave al hígado puede ocurrir si usted consume:
 ■ más de 12 tabletas en 24 horas, lo cual es la máxima dosis recomendada
 ■ este producto con cualquier otro medicamento que contenga acetaminofeno
 ■ 3 o más bebidas alcohólicas diariamente mientras toma este producto
Alerta a las alergias: El acetaminofeno puede causar severas reacciones alérgicas en la piel. Las cuales pueden incluir:
 ■ enrojecimiento de la piel ■ ampollas ■ erupción
 Si se presenta una reacción alérgica en la piel, suspenda su consumo de inmediato y obtenga atención médica.

No se administre
 ■ con ningún otro producto que contenga acetaminofeno (recetado o sin receta), si no está seguro si su medicamento contiene acetaminofeno consulte con un médico o farmacéutico
 ■ por más de 10 días para el dolor o fiebre a menos que lo indique el médico
 ■ por más de 3 días para la fiebre a menos que lo indique el médico

Consulte a un médico antes de administrarlo si usted tiene:
 ■ la enfermedad del hígado

Consulte con un médico o farmacéutico antes de administrarlo si:
 ■ toma el medicamento warfarin para el ablandamiento de la sangre

Conservar la caja para obtener la información completa del producto

ASPIRIN-FREE

Pain Reliever

Acetaminophen 325 mg.

NO ASPIRINA

Alivia El Dolor

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

Reorder No. 23580
Reorder: 800-356-9100
conney.com

DISTRIBUTED BY:
CONNEY SAFETY PRODUCTS
MADISON, WI 53744-4190

PAQUETES CON SELLADO EVIDENTE.
NO USE NINGÚN PAQUETE
ABIERTO O ROTO.

Reorder No. 23580
Reorder: 800-356-9100
conney.com

146 Direct Safety Aspirin Free Label

Direct Safety®

Aspirin-Free

Pain Reliever/Fever Reducer

Acetaminophen 325 mg.

Acetaminofeno 325 mg.

Pull to Open

Tire Para Abrir

Industrial Pack 500 (250 Packets of 2 Tablets)

DIRECT SAFETY

ASPIRIN-FREE

**Pain Reliever/
Fever Reducer**

Acetaminophen 325 mg.
Acetaminofeno 325 mg.

Retain carton for complete product information

ASPIRIN-FREE
Pain Reliever
Acetaminophen 325 mg.

INDUSTRIAL PACK 500
DO NOT USE IF OPENED OR DAMAGED

Product No. 23580
Revised: 08/25/16-17/18
csespx-001

DISTRIBUIDO POR:
COMBET SAFETY PRODUCTS
MADISON, WI 53744-1176

Industrial Pack 500
(250 Packets of 2 Tablets)

DIRECT SAFETY

ASPIRIN-FREE

**Pain Reliever/
Fever Reducer**

Acetaminophen 325 mg.
Acetaminofeno 325 mg.

Retain carton for complete product information

NO ASPIRINA
Alivia El Dolor

INDUSTRIAL PACK 500
NO USE NUNCA PAQUETE
ABIERTO O ROTO.

Product No. 23580
Revised: 08/25/16-17/18
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DISTRIBUIDO POR:
COMBET SAFETY PRODUCTS
MADISON, WI 53744-1176

Industrial Pack 500
(250 Packets of 2 Tablets)

DIRECT SAFETY ASPIRIN FREE acetaminophen tablet, film coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61245-145
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	325 mg
Inactive Ingredients			
Ingredient Name		Strength	
HYPROMELLOSES (UNII: 3NXW29V3WO)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDWL1A)			
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)			
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)			
STARCH, CORN (UNII: O8232NY3SJ)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
Product Characteristics			
Color	white (white)	Score	no score
Shape	ROUND (ROUND)	Size	10mm
Flavor		Imprint Code	AZ;234
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61245-145-13	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 ASPIRIN FREE

acetaminophen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61245-146
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (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	11mm
Flavor		Imprint Code	FR;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61245-146-13	250 in 1 BOX	05/31/2013	06/01/2023
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	06/01/2023

Labeler - Conney Safety Products, LLC (023316151)

Revised: 3/2023

Conney Safety Products, LLC