

BC CHERRY- aspirin and caffeine powder
Medtech Products Inc.

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.

BC Cherry Aspirin

Drug Facts

Active ingredient

(in each powder)

Aspirin (NSAID*) 845 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Active ingredient

(in each powder)

Caffeine 65 mg

Purpose

Pain reliever aid

Uses

- temporary relieves minor aches and pains due to:
 - headaches
 - minor arthritis pain
 - toothaches
 - colds
 - menstrual cramps
 - muscular aches

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
- shock
- asthma (wheezing)

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 non-prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for longer time than directed

Caffeine warning: This product contains caffeine. Limit the use of caffeine-containing medications, foods, or beverages 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.

Ask a doctor before use if

- stomach bleeding warnings 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
- you have asthma

Ask a doctor or pharmacist before use if you are

taking a prescription drug for diabetes, gout, or arthritis.

Stop use and ask a 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
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- any new symptoms appear
- ringing in the ears or a loss of hearing occurs.

These could be signs of a serious condition.

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 (1-800-222-1222) right away.

Directions

- **Adults and children 12 years of age and over:** place 1 powder on tongue every 6 hours, while symptoms persist. Drink a full glass of water or other liquid.
- Do not take more than 4 powders in 24 hours unless directed by a doctor.
- **Children under 12 years of age:** ask a doctor.

Other information

- store below 25°C (77°F)

Inactive ingredients

acesulfame potassium, colloidal silicon dioxide, flavor, guar gum, mannitol, microcrystalline cellulose, sucralose

Questions? 1-866-255-5197

PRINCIPAL DISPLAY PANEL

BC® cherry
 FAST PAIN RELIEF
 ASPIRIN (NSAID) – PAIN RELIEVER • FEVER REDUCER
 CAFFEINE – PAIN RELIEVER AID
 4 POWDERS



TO OPEN CHILD-RESISTANT PACKAGE



1. Shake pack so powder settles on bottom.



2. Pinch and tear at either arrow or use scissors.

Lift flap for Drug Facts in numerical order.



Drug Facts

1

Active ingredients (in each powder)

Purposes

Aspirin (NSAID*) 845 mg	Pain reliever
Caffeine 65 mg	Pain reliever aid
*nonsteroidal anti-inflammatory drug	

Uses

temporarily relieves minor aches and pains due to: ■ headache ■ minor arthritis pain ■ toothache ■ colds ■ menstrual cramps ■ muscular aches

Drug Facts (continued)

2

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: ■ facial swelling ■ asthma (wheezing) ■ shock ■ hives **Stomach bleeding warning:** This product contains a 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 non-prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

Drug Facts (continued)

3

- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed.

Caffeine warning: This product contains caffeine. 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 any other pain reliever/fever reducer

Ask a doctor before use if ■ 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 ■ you have asthma

Ask a doctor or pharmacist before use if you are taking a prescription drug for diabetes, gout, or arthritis

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NO COPY

Drug Facts (continued)

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Stop use and ask a 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
 - pain gets worse or lasts more than 10 days
 - fever gets worse or lasts more than 3 days
 - redness or swelling is present
 - any new symptoms appear
 - ringing in the ears or a loss of hearing occurs
- These could be signs of a serious condition.

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.

NO
COPY**Drug Facts** (continued)

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Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1800-222-1222) right away.

Directions

- **Adults and children 12 years and over:** place 1 powder on tongue every 6 hours, while symptoms last. Drink a full glass of water with each dose, or may stir powder into a glass of water or other liquid.
- do not take more than 4 powders in 24 hours unless directed by a doctor
- **children under 12 years of age:** ask a doctor

Other information

- store below 25°C (77°F)

Inactive ingredients

acesulfame potassium, colloidal silicon dioxide, flavor, guar gum, mannitol, microcrystalline cellulose, sucralose

Questions? 1-866-255-5197

NO
COPY**BC CHERRY**

aspirin and caffeine powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-200
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	845 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GUAR GUM (UNII: E89I1637KE)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-200-04	4 in 1 BOX; Type 0: Not a Combination Product	10/01/2012	
2	NDC:63029-200-22	24 in 1 BOX; Type 0: Not a Combination Product	10/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	10/01/2012	

Labeler - Medtech Products Inc. (122715688)

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Medtech Products Inc.