

**GOODYS EXTRA STRENGTH- acetaminophen, 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.

Goodys Extra Strength Headache Powders

FAST PAIN RELIEF
Goody's®
EXTRA STRENGTH
HEADACHE POWDERS

ACETAMINOPHEN • ASPIRIN (NSAID) / CAFFEINE
PAIN RELIEVER / PAIN RELIEVER AID
24 ENVELOPES CONTAINING 6 POWDERS EACH

Drug Facts

Active ingredients

(in each powder):

Acetaminophen 260 mg
Aspirin (NSAID*) 520 mg
Caffeine 32.5 mg
*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer
Pain reliever/fever reducer
Pain reliever aid

Uses

• temporarily relieves minor aches and pains due to:

| | |
|------------------------|----------------|
| • headache | • muscle aches |
| • minor arthritis pain | • colds |

• temporarily reduces fever

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 severe allergic reaction which may include:

• hives • facial swelling • shock • asthma (wheezing).

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4 powders 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 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)
- 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 have 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 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

When using this product

limit the use of caffeine-containing drugs, food, or drinks because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat. The recommended dose of this product contains about as much caffeine as a cup of coffee.

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.

Overdose warning:

Taking more than the recommended dose can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 take more than directed (see overdose warning)
- adults and children 12 years and over: place 1 powder on tongue every 6 hours, while symptoms persist. Drink a full glass of water with each dose, or 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

- each powder contains: potassium 60 mg
- store below 25°C (77°F)

Inactive ingredients

lactose monohydrate, potassium chloride

Questions or comments?

1-866-255-5197 (English/Spanish) weekdays

PRINCIPAL DISPLAY PANEL

FAST PAIN RELIEF

Goody's®

EXTRA STRENGTH

HEADACHE POWDERS

ACETAMINOPHEN • ASPIRIN (NSAID) / CAFFEINE

PAIN RELIEVER / PAIN RELIEVER AID

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PAIN RELIEVER • FEVER REDUCER / PAIN RELIEVER AID

NO PRINT OR VARNISH
ON THIS PANEL

NO PRINT OR VARNISH
ON THIS PANEL

Drug Facts

Active ingredients (in each powder) **Purposes**
 Acetaminophen 200 mg... Pain reliever/fever reducer
 Aspirin (NSAID) 150 mg... Pain reliever/fever reducer
 Caffeine 32.5 mg... Pain reliever aid
 Nonsteroidal anti-inflammatory drug

Uses
 • temporarily relieves minor aches and pains due to:
 • headache • minor arthritis pain
 • muscular aches • colds
 • temporarily reduces fever

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.
Always alert: Aspirin may cause a serious allergic reaction which may include:
 • hives • facial swelling • shock • asthma (wheezing)
 Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:
 • more than 4 powders 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

Drug Facts (continued)

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 a longer time than directed

Do not use
 • if you have 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 disease, 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.
 When using this product limit the use of caffeine-containing drugs, food, or drinks because too much caffeine may cause nervousness,

Drug Facts (continued)

irritability, restlessness, and excessive night awakenings. Do not use caffeine-containing products if you are pregnant, nursing, or taking any medicine. See your doctor before using this product if you are pregnant, nursing, or taking any medicine. See your doctor before using this product if you are pregnant, nursing, or taking any medicine. See your doctor before using this product if you are pregnant, nursing, or taking any medicine.

Directions
 • do not use more than directed (see warning)
 • adults and children 17 years of age and over: 3 powders (or 12 envelopes) every 6 hours, with symptoms of minor to moderate pain (more than 3 days)
 • children 12 years of age and over: 2 powders (or 8 envelopes) every 6 hours, with symptoms of minor to moderate pain (more than 3 days)
 • children 6 to 11 years of age: 1 powder (or 4 envelopes) every 6 hours, with symptoms of minor to moderate pain (more than 3 days)
 • children under 6 years of age: Do not use

Other information
 • each powder contains potassium bitartrate (used as a buffer)
 • contains 20 mg caffeine
 • contains 20 mg aspirin
 • contains 32.5 mg caffeine

Inactive ingredients
 • hydroxypropyl methylcellulose
 • croscarmellose sodium
 • polyethylene glycol
 • polyvinylpyrrolidone
 • hydroxypropyl methylcellulose
 • croscarmellose sodium
 • polyethylene glycol
 • polyvinylpyrrolidone
 • hydroxypropyl methylcellulose
 • croscarmellose sodium
 • polyethylene glycol
 • polyvinylpyrrolidone

Contains 9 mg of caffeine per envelope

Drug Facts (continued)

irritability, restlessness, and excessive night awakenings. Do not use caffeine-containing products if you are pregnant, nursing, or taking any medicine. See your doctor before using this product if you are pregnant, nursing, or taking any medicine. See your doctor before using this product if you are pregnant, nursing, or taking any medicine. See your doctor before using this product if you are pregnant, nursing, or taking any medicine.

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 MedTech Products Inc.
 QD015011



FAST PAIN RELIEF
Goody's
EXTRA STRENGTH
HEADACHE POWDERS
ACETAMINOPHEN • ASPIRIN (NSAID) / CAFFEINE
PAIN RELIEVER • FEVER REDUCER / PAIN RELIEVER AID

24 ENVELOPES CONTAINING 9 POWDERS EACH

Goody's
EXTRA STRENGTH
HEADACHE POWDERS
ACETAMINOPHEN • ASPIRIN (NSAID) / CAFFEINE
PAIN RELIEVER • FEVER REDUCER / PAIN RELIEVER AID

24 ENVELOPES CONTAINING 6 POWDERS EACH

NO PRINT OR VARNISH
ON THIS PANEL

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ON THIS PANEL





PRINCIPAL DISPLAY PANEL

FAST PAIN RELIEF

Goody's®

EXTRA STRENGTH

HEADACHE POWDERS

ACETAMINOPHEN • ASPIRIN (NSAID) / CAFFEINE

PAIN RELIEVER / PAIN RELIEVER AID

18 Powders

100591

SOLID COLOR BAND FOR LOT NO AND EXP IMPRINT

TAMPER EVIDENT FEATURE: DO NOT USE IF SAFETY OVERWRAP OR "S" TEAR-TAPE IS MISSING OR TORN.
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FAST PAIN RELIEF

Goody's®

EXTRA STRENGTH HEADACHE POWDERS

ACETAMINOPHEN • ASPIRIN (NSAID) / CAFFEINE
PAIN RELIEVER • FEVER REDUCER / PAIN RELIEVER AID

18 POWDERS

Read and keep leaflet for complete directions, warnings and ingredients

Drug Facts
Active ingredients (in each powder) Purposes
Acetaminophen 260 mg.....Pain reliever/fever reducer
Aspirin (NSAID)* 520 mg.....Pain reliever/fever reducer
Caffeine 32.5 mg.....Pain reliever aid
*nonsteroidal anti-inflammatory drug

Drug Facts (continued)
Uses
temporarily relieves minor aches and pains due to:
• headache
• minor arthritis pain
• muscle aches
• colds
temporarily reduces fever
Warnings
Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, it 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

Drug Facts (continued)
place 1 powder on tongue every 6 hours, while symptoms persist. 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.
Drug Facts (continued)
Questions or comments? 1-866-255-5197
(English/Spanish) weekdays
0 42037 10294 4

Drug Facts (continued)
reaction which may include:
• hives
• facial swelling
• shock
• asthma (wheezing)
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 4 powders 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 have had stomach ulcers or bleeding problems or 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.
Drug Facts (continued)
using this product
• take more or for a longer time than directed
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 because it may cause problems in the unborn child or complications during delivery.
Keep out of reach of children.
recommended dose can cause serious health problems. Overdose warning: Taking more than the
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 take more than directed (see overdose warning)
• adults and children 12 years of age and over:
• Take 3 or more alcoholic drinks every day while using this product.

NO PRINT OR VARNISH ON THIS PANEL

PRINCIPAL DISPLAY PANEL
FAST PAIN RELIEF
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EXTRA STRENGTH
HEADACHE POWDERS

ACETAMINOPHEN • ASPIRIN (NSAID) / CAFFEINE
PAIN RELIEVER / PAIN RELIEVER AID
 24 Powders



PRINCIPAL DISPLAY PANEL
FAST PAIN RELIEF

Goody's®
EXTRA STRENGTH
HEADACHE POWDERS
ACETAMINOPHEN • ASPIRIN (NSAID) / CAFFEINE
PAIN RELIEVER / PAIN RELIEVER AID
 50 Powders



GOODYS EXTRA STRENGTH
 acetaminophen, aspirin, and caffeine powder

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:630 29-662 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 260 mg |
| ASPIRIN (UNII: R16C05Y76E) (ASPIRIN - UNII:R16C05Y76E) | ASPIRIN | 520 mg |
| CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E) | CAFFEINE | 32.5 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| POTASSIUM (UNII: RWP5GA015D) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q815X) | |

Product Characteristics

| | | | |
|----------|-------|--------------|--|
| Color | WHITE | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:63029-662-01 | 6 in 1 BOX; Type 0: Not a Combination Product | 11/01/2013 | 11/30/2023 |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC MONOGRAPH NOT FINAL | part343 | 11/01/2013 | 11/30/2023 |

GOODYS EXTRA STRENGTH

acetaminophen, aspirin, and caffeine powder

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63029-655 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 260 mg |
| ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN | 520 mg |
| CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E) | CAFFEINE | 32.5 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| POTASSIUM (UNII: RWP5GA015D) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |

Product Characteristics

| | | | |
|----------|-------|--------------|--|
| Color | WHITE | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:63029-655-01 | 18 in 1 BOX; Type 0: Not a Combination Product | 11/01/2013 | 11/30/2023 |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC MONOGRAPH NOT FINAL | part343 | 11/01/2013 | 11/30/2023 |

GOODYS EXTRA STRENGTH

acetaminophen, aspirin, and caffeine powder

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63029-633 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 260 mg |
| ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN | 520 mg |
| CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E) | CAFFEINE | 32.5 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| POTASSIUM (UNII: RWP5GA015D) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |

Product Characteristics

| | | | |
|----------|-------|--------------|--|
| Color | WHITE | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:63029-633-01 | 24 in 1 BOX; Type 0: Not a Combination Product | 11/01/2013 | 11/30/2023 |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
|--------------------|--|----------------------|--------------------|

| | | |
|---------------------------------|------------|------------|
| OTC MONOGRAPH NOT FINAL part343 | 11/01/2013 | 11/30/2023 |
|---------------------------------|------------|------------|

GOODYS EXTRA STRENGTH

acetaminophen, aspirin, and caffeine powder

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63029-644 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | |
|--|-------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 260 mg | |
| ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN | 520 mg | |
| CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E) | CAFFEINE | 32.5 mg | |

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| POTASSIUM (UNII: RWP5GA015D) | | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | | |

| Product Characteristics | | | |
|-------------------------|-------|--------------|--|
| Color | WHITE | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:63029-644-01 | 50 in 1 BOX; Type 0: Not a Combination Product | 11/01/2013 | |

| Marketing Information | | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC MONOGRAPH NOT FINAL | part343 | 11/01/2013 | |

Labeler - Medtech Products Inc. (122715688)