

REESE HEADACHE POWDERS- aspirin and caffeine powder
Reese Pharmaceutical Co

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.

Drug Facts

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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

- temporarily relieves minor aches and pains due to:
 - headache
 - toothache
 - menstrual cramps
 - muscular 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 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 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 aspirin or 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

When using this product

limit the use of caffeine-containing drugs, foods, 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 care 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

- 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 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

- each powder contains: **potassium 55 mg**
- store below 25°C (77°F)

Inactive ingredients

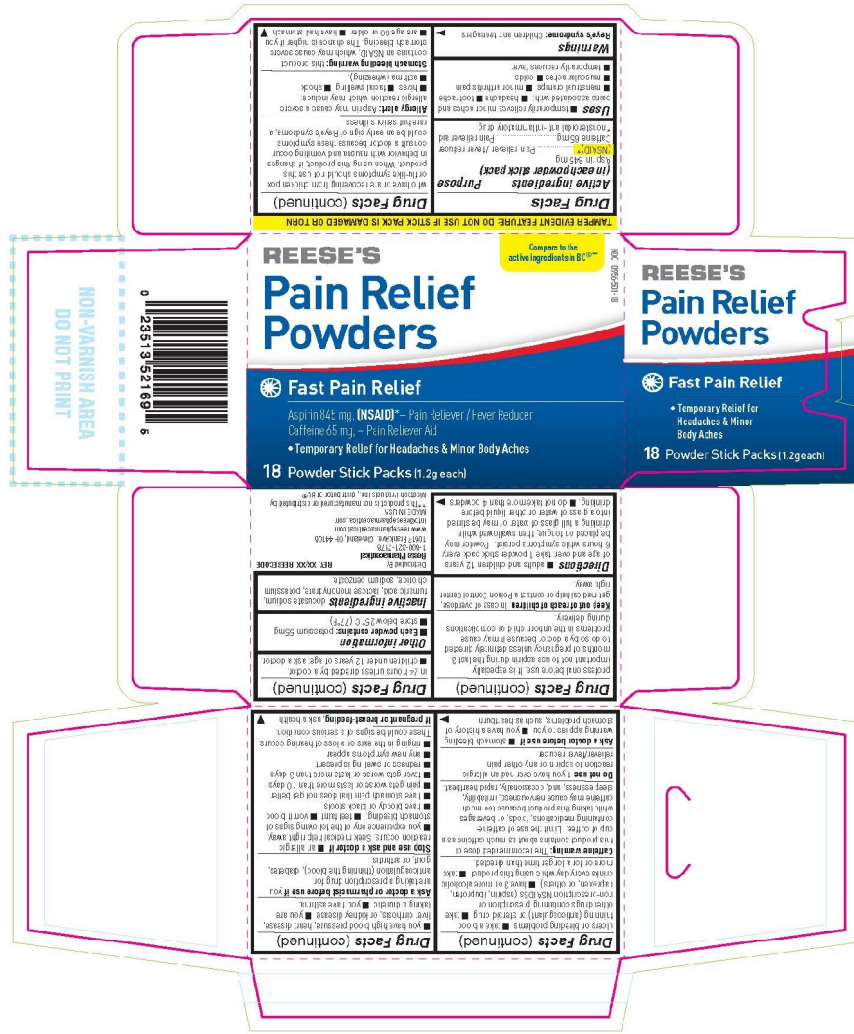
docusate sodium, fumaric acid, lactose monohydrate, potassium chloride

Questions or comments?

Reese Pharmaceutical 1-800-321-7178

PRINCIPAL DISPLAY PANEL

Headache Powders



REESE HEADACHE POWDERS

aspirin and caffeine powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10956-501
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
FUMARIC ACID (UNII: 88XHZ13131)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10956-501-18	18 in 1 CARTON	07/22/2020	
1		1 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:10956-501-24	24 in 1 CARTON	07/22/2020	
2		1 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:10956-501-50	50 in 1 CARTON	07/22/2020	
3		1 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	07/22/2020	

Labeler - Reese Pharmaceutical Co (004172052)**Registrant** - Reese Pharmaceutical Co (004172052)**Establishment**

Name	Address	ID/FEI	Business Operations
Pharbest		557054835	manufacture(10956-501)

