

TABCIN 500- acetylsalicylic acid, phenylephrine bitartrate, chlorpheniramine maleate tablet, effervescent
Salimex, S.A.

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.

TABCIN 500

Active Ingredients
(in each tablet)

Acetylsalicylic Acid 500 mg
Phenylephrine Bitartrate 8 mg
Chlorpheniramine maleate 2 mg

Purpose

Acetylsalicylic Acid 500 mg Analgesic
Phenylephrine Bitartrate 8 mg Decongestant
Chlorpheniramine maleate 2 mg Antihistamine

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away.

Uses for the relief of:

- heartburn, acid indigestion, and sour stomach when accompanied with headache or body aches and pains
- upset stomach with headache from overindulgence in food or drink
- headache, body aches, and pain alone

Warnings

Reye's syndrome: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives
- asthma (wheezing)

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take aspirin or other pain relievers/fever reducers. Aspirin may cause stomach bleeding.

Directions

- fully dissolve 2 tablets in 4 ounces of water before taking
- adults and children 12 years and over: 2 tablets every 4 hours, or as directed by a doctor do not exceed 8 tablets in 24 hours
- adults 60 years and over 2 tablets every 4 hours, or as directed by a doctor do not exceed 4 tablets in 24 hours
- children under 12 years consult a doctor

Other information

- each tablet contains: sodium 567 mg
- store at room temperature. Avoid excessive heat.
- Tabcin 500 in water contains principally the antacid sodium citrate and the analgesic sodium acetylsalicylate

Inactive ingredients

Sodium Bicarbonate

Questions or comments?

01 800-706-0300



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Reg. No. 0119m80 55A VI	

TABCIN 500

acetylsalicylic acid, phenylephrine bitartrate, chlorpheniramine maleate tablet, effervescent

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53666-408
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	500 mg
Phenylephrine Bitartrate (UNII: 27O3Q5ML57) (PHENYLEPHRINE - UNII:1WS297W6MV)	Phenylephrine Bitartrate	8 mg
Chlorpheniramine maleate (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	Chlorpheniramine maleate	2 mg

Inactive Ingredients

Ingredient Name		Strength		
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
Product Characteristics				
Color	white	Score	no score	
Shape	ROUND	Size	14mm	
Flavor		Imprint Code	tabcin	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53666-408-15	150 in 1 CASE		
1	NDC:53666-408-12	12 in 1 BOX		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	08/21/2013		

Labeler - Salimex, S.A. (589201581)

Establishment

Name	Address	ID/FEI	Business Operations
Bayer de Mexico, S.A. de CV		588165709	manufacture(53666-408)

Revised: 9/2013

Salimex, S.A.