

MEDPURINE- medpurine tablet
PURINEPHARMA 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.

MEDPURINE

Active Ingredient (in each tablet): Aspirin 81 mg (NSAID)¹

¹ nonsteroidal anti-inflammatory drug

Purpose: Pain reliever

Uses For the temporary relief of minor aches and pains or as recommended by your doctor. Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief. Ask your doctor about other uses of aspirin.

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 asthma (wheezing) shock

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

Do not use if you are allergic to aspirin or any other pain reliever / fever reducer.

Ask a doctor before use if the stomach bleeding warning

you are taking a diuretic

you have a history of stomach problems, such as heartburn

You have high blood pressure, heart disease, liver cirrhosis, kidney disease

You have asthma

Ask a doctor or pharmacist before use if you are taking any other drugs containing an NSAID (prescription or nonprescription)

taking a blood thinning (anticoagulant) or steroid drug

taking a prescription drug for diabetes, gout or arthritis

Stop use and ask a doctor if an allergic reaction occurs. Seek medical 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, redness or swelling is present, fever gets worse or lasts more than 3 days, any new symptoms occur, ringing in the ears or a loss of hearing occurs

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 right away.

ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg
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Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
GLATIRAMER ACETATE (UNII: 5M691HL4BO)	
CLOSPIRAZINE HYDROCHLORIDE (UNII: N6B142V0U0)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TALC (UNII: 7SEV7J4R1U)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW (Yellow)	Score	no score
Shape	ROUND (ROUND)	Size	8mm
Flavor		Imprint Code	O
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58599-016-30	120 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	04/14/2015	

Labeler - PURINEPHARMA LLC (019950491)

Registrant - PURINEPHARMA LLC (019950491)

Establishment

Name	Address	ID/FEI	Business Operations
PURINEPHARMA LLC		019950491	RELABEL(58599-016)

Establishment

Name	Address	ID/FEI	Business Operations
Time-Cap Lab Inc		037052099	MANUFACTURE(58599-016)

Revised: 4/2015

PURINEPHARMA LLC