# MAPAP INFANTS CONCENTRATED- acetaminophen suspension/drops Rebel Distributors Corp

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.

-----

# Major Pharmaceuticals Infants' Mapap® Concentrated Drops Drug Facts

# Active ingredient (in each 0.8 mL)

Acetaminophen 80 mg

#### **Purpose**

Fever reducer/pain reliever

#### Uses

temporarily:

- reduces fever
- relieves minor aches and pains due to:
- the common cold
- flu
- headache
- sore throat
- toothache

#### **Warnings**

Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

#### Do not use

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 your child has

liver disease

# Ask a doctor or pharmacist before use if your child is

taking the blood thinning drug warfarin

### Stop use and ask a doctor if

- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

# Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical even if you do not notice any signs or symptoms.

#### **Directions**

- do not give more than directed (see Liver warning)
- shake well before using
- find right dose on chart. If possible, use weight to dose; otherwise use age.
- use only enclosed dropper designed for use with this product. Do not use any other dosing device.
- fill to dose level
- dispense liquid slowly into child's mouth, toward inner cheek
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give for more than 5 days unless directed by a doctor
- replace dropper tightly to maintain child resistance
- this product does not contain directions or complete warnings for adult use

Dosing Chart			
Weight(lb)	Age(yr)	Dose (mL)	
under 24	under 2 years	ask a doctor	
24-35	2–3 years	1.6 mL (0.8 + 0.8 mL)	

Attention: use only enclosed dropper specifically designed for use with this product. Do not use any other dosing device.

#### Other information

- store at 20°-25°C (68°-77°F)
- do not use if printed bottle wrap is broken or missing

#### **Inactive ingredients**

anhydrous citric acid, butylparaben, carboxymethylcellulose sodium, carrageenan, FD&C red no. 40, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol solution

#### Questions or comments?

1-800-616-2471

# **Principal Display Panel**



Store at controlled room temperature 15°-30°C (59°-86°F) Keep medication out of the reach of children.

#### MAPAP INFANTS CONCENTRATED

acetaminophen suspension/ drops

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21695-267(NDC:0904-5255)	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name Basis of Strength Strength				
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	80 mg in 0.8 mL		

Inactive Ingredients				
Ingredient Name	Strength			
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)				
BUTYLPARABEN (UNII: 3QPI1U3FV8)				
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)				
CARRAGEENAN (UNII: 5C69 YCD2YJ)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GLYCERIN (UNII: PDC6A3C0OX)				

HIGH FRUCTO SE CORN SYRUP (UNII: XY6 UN3QB6S)		
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		

Product Characteristics				
Color	RED (opaque)	Score		
Shape		Size		
Flavor	CHERRY (sweet)	Imprint Code		
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:21695-267-15	1 in 1 CARTON			
1		15 mL in 1 BOTTLE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/15/1990	

# Labeler - Rebel Distributors Corp (118802834)

Establishment				
Name	Address	ID/FEI	Business Operations	
Rebel Distributors Corp		118802834	RELABEL, REPACK	

Revised: 1/2012 Rebel Distributors Corp