# ACETAMINOPHEN- acetaminophen tablet, chewable 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.

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# Acetaminophen Drug Facts

# **Active ingredient**

Acetaminophen

### **Purpose**

Pain Reliever / Fever Reducer

## Keep Out of Reach of Children

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical, even if you do not notice any signs or symptoms.

#### Uses

temporarily reduces fever and relieves minor aches and pains caused by

headache common cold flu toothache sore throat

#### Warnings

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if the 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, lasts for more than 2 days or is accompanied or fillowed 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 the child has liver disease

**Ask a doctor or pharmacist before use if the 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 redness or swelling is present any new symptoms appear

#### **Directions**

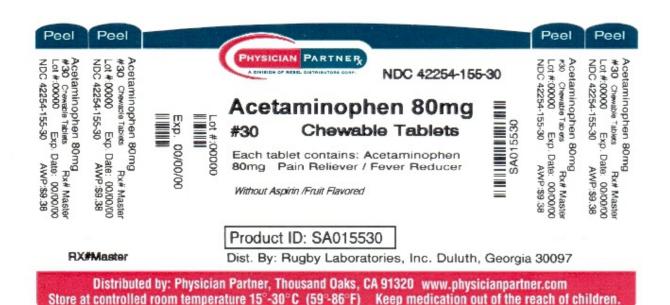
# this product does not contain directions or complete warnings for adult use

find correct does on chart below if possible, use weight to dose, otherwise use age chew tablets before swallowing give dose every 4 hours while symptoms last do not give more than 5 doses in 24 hours

Weight (pounds)	Age (years)	Dose (tablets)
72 - 95	11 - 12	4 - 6
60 - 71	9 - 10	4 - 5
48 - 59	6 - 8	4
36 - 47	4 - 5	3
24 - 35	2 - 3	2
under 24	under 2	ask a doctor

# **Inactive ingredients**

# Package/Label Principal Display Panel



# **ACETAMINOPHEN**

acetaminophen tablet, chewable

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42254-155(NDC:0536-3233)
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			

Inactive Ingredients					
Ingredient Name	Strength				
ASPARTAME (UNII: Z0H242BBR1)					
SUCROSE (UNII: C151H8M554)					
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)					
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)					
MAGNESIUM STEARATE (UNII: 70097M6I30)					
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)					
STEARIC ACID (UNII: 4ELV7Z65AP)					

Product Characteristics				
Color	PINK (Light)	Score	no score	
Shape	ROUND	Size	8 mm	
Flavor		Imprint Code	Logo;051	
Contains				

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42254-155-30	30 in 1 BOTTLE		

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part343	02/16/2012				

# **Labeler** - Rebel Distributors Corp (118802834)

# **Registrant -** PSS World Medical, Inc. (101822862)

Establishment			
Name	Address	ID/FEI	Business Operations
PSS World Medical, Inc.		791528623	REPACK(42254-155)

Establishment			
Name	Address	ID/FEI	Business Operations
STAT RX USA LLC		786036330	REPACK(42254-155)

Establishment			
Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	RELABEL(42254-155), REPACK(42254-155)

Establishmen	t		
Name	Address	ID/FEI	Business Operations
SCRIPT PAK		964420108	RELABEL(42254-155), REPACK(42254-155)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Keltman Pharmaceuticals, Inc.		362861077	REPACK(42254-155)		

Establishment			
Name	Address	ID/FEI	Business Operations
Rebel Distirbutors Corp.		118802834	RELABEL(42254-155), REPACK(42254-155)

Revised: 2/2012 Rebel Distributors Corp