SUNMARK JUNIOR RAPID MELTS- acetaminophen tablet, chewable Mckesson

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.

junior rapid melts

Active ingredient (in each tablet)

Acetaminophen 160 mg

Purpose

Pain reliever/ fever reducer

Uses

temporarily relieves minor aches and pains due to:

- the common cold
- flu
- headache
- temporarily reduces fever

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.

Do not use

- with any other product containing acetaminophen (prescription or nonprescription). Ask a doctor or pharmacist before using with other drugs if you are not sure.
- if your child is allergic to acetaminophen or any of the inactive ingredients in this product.

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

When using this product do not exceed recommended dose (see overdose warning)

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.

Overdose warning: Thaking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a poison control center right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions

- this product does not contain directions or complete warnings for adult dose
- do not give more than directed (see overdose warning)
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- dissolve in mouth, or chew before swallowing
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give more than 5 days unless directed by a doctor.

Weight (lb)	Age (yr)	Tablets	
under 48 lbs	under 6 years	ask a doctor	
48-59 lbs	6-8 years	2	
60-71 lbs	9-10 years	2 1/2	
72-95 lbs	11 years	3	

Other information

- store at controlled room temperature betweeen 20-25°C(68-77°F)
- see end flap for expiration date and lot number

Inactive ingredients

acesulfame pottasium, citric acid, D&C red 27 aluminum lake, dextrose, FD&C blue 1 aluminum lake, flavors, magnesium stearate, maltodextrin, mannitol, microcrystalline cellulose powder, polyplasdone, sorbitol, sucralose.

May contain ethylcellulose, gelatin, sodium polyphosphate, silicon dioxide.

PDP

Sunmark

Junior Rapid Melts

Compare to JR. Tylenol Meltaways active ingredient

Pain reliever

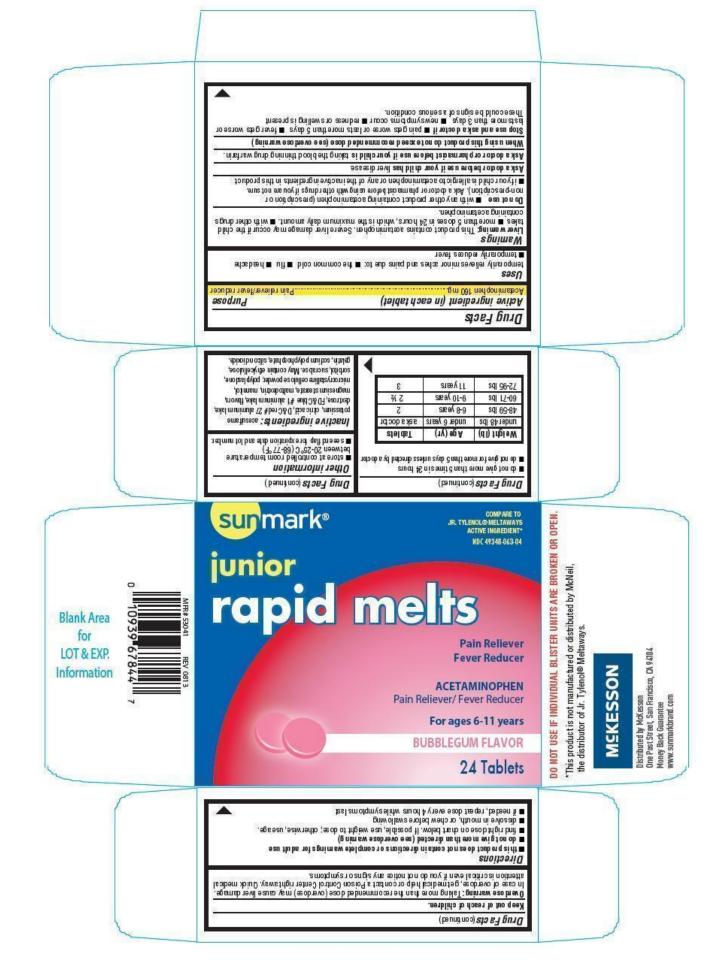
Fever reducer

Acetaminophen

Pain reliever/Fever Reducer

For ages 6-11 years

Bubblegum Flavor



SUNMARK JUNIOR RAPID MELTS

acetaminophen tablet, chewable

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:49348-063

Route of Administration ORAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	160 mg	

Inactive Ingredients				
Ingredient Name	Strength			
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)				
D&C RED NO. 27 (UNII: 2LRS 185U6K)				
DEXTROSE (UNII: IY9 XDZ35W2)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MALTO DEXTRIN (UNII: 7CVR7L4A2D)				
MANNITOL (UNII: 3OWL53L36A)				
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)				
CROSPOVIDONE (UNII: 6840 1960 MK)				
SORBITOL (UNII: 506T60A25R)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				
SODIUM POLYMETAPHOSPHATE (UNII: P1BM4ZH95L)				

Product Characteristics			
Color	pink	Score	no score
Shape	ROUND	Size	16 mm
Flavor	BUBBLE GUM	Imprint Code	G220
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:49348-063-04	4 in 1 CARTON		
1	6 in 1 BLISTER PACK		

Marketing	Information
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OTC monograph not final	part343	08/01/2013	

Labeler - Mckesson (177667227)

Registrant - Guardian Drug Company (119210276)

Establishment			
Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	manufacture(49348-063)

Revised: 4/2014 Mckesson