

TEMPRA- acetaminophen syrup
Bristol-Myers Squibb de Mexico, S. de R.L. de C.V.

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.

Temptra® for Children
Acetaminophen 160 mg/5 mL
Pain Reliever/Fever Reducer

2-11 years

Strawberry Flavor Syrup

4 fl oz (120 mL)

NDC64613-5800-2

See New Warnings Information and New Dosage Directions

Active Ingredient

Acetaminophen 160 mg/5 mL

Purpose

Pain reliever/Fever reducer

Uses

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

KEEP OUT OF REACH OF CHILDREN

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.

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

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

· 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 the 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: Taking 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 for adults as well as for children even if you do not notice any signs or symptoms.

Directions:

- **This product does not contain directions or complete warnings for adult use.**
- **do not give more than directed (see Overdose warning)**
- **Shake well before using**
- mL = milliliter
- find the correct dose on the chart below. if possible, use weight to dose; otherwise use age.
- if needed, repeat dose every 4 hours
- do not give more than 5 times in 24 hours.

Weight (lb)	Age (yr)	Dose (mL)*
under 24 lbs	under 2 years	ask a doctor
24-35 lbs	2-3 years	5 mL
36-47 lbs	4-5 years	7.5 mL
48-59 lbs	6-8 years	10 mL
60-71 lbs	9-10 years	12.5 mL
72-95 lbs	11 years	15mL

*or as directed by your doctor

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

Other Information

- each 5 mL contains: **sodium 4 mg**
- store below 30°C (86°F)
- avoid high humidity
- tamper evident: do not use if cap seal is torn or broken
- product color may vary slightly over time from pink violet to wine red.

Inactive Ingredients

Butylated Hydroxyanisole, Citric Acid, D&C Red No. 33, Polyethylene Glycol, Purified Water, Sodium Chloride, Sodium Citrate, Strawberry and other flavors, Sucrose.

Questions or Comments? call **1-800-721-5072**. You may also report side effects to this phone number.

Keep carton for full directions for use.

Manufactured by Bristol-Myers Squibb de Mexico, S de R.L. de C.V. Calzada de Tlalpan No. 2996, Col. Ejido Santa Ursula Coapa, 04870 Mexico D.F.

MADE IN MEXICO.

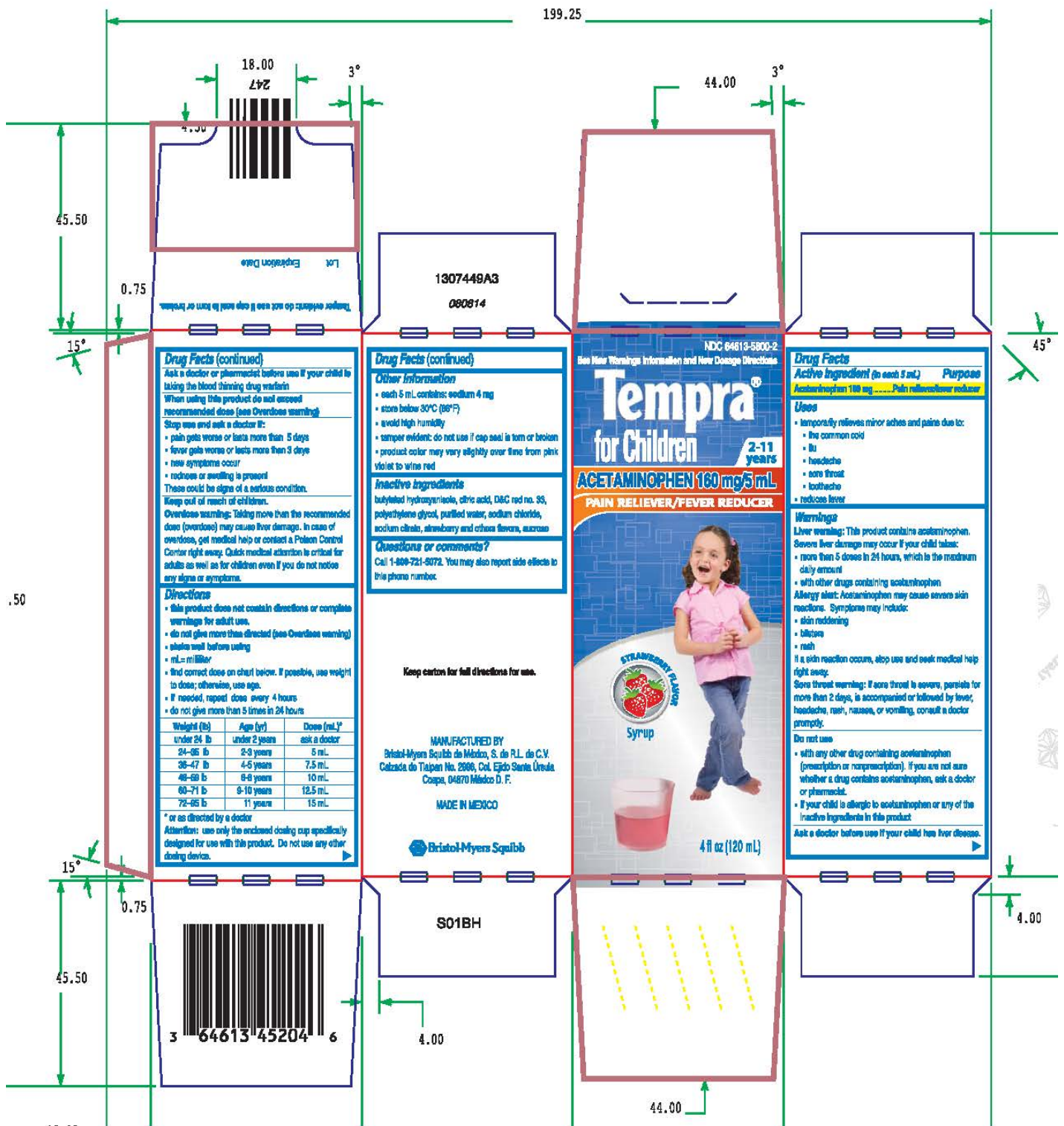
Tamper evident: do not use if cap seal is torn or broken.

Lot

Expiration Date

Bristol-Myers Squibb

Package Label



acetaminophen syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64613-5800
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
POLYETHYLENE GLYCOL 1450 (UNII: OJ4Z5Z32L4)	
WATER (UNII: 059QF0K00R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
STRAWBERRY (UNII: 4J2TY8Y81V)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	STRAWBERRY (Strawberry Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64613-5800-2	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/10/2011	10/31/2017

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	05/10/2011	10/31/2017

Labeler - Bristol-Myers Squibb de Mexico, S. de R.L. de C.V. (823646211)

Establishment

Name	Address	ID/FEI	Business Operations
Bristol-Myers Squibb de Mexico, S. de R.L. de C.V.		823646211	manufacture(646 13-5800)

Revised: 5/2016

Bristol-Myers Squibb de Mexico, S. de R.L. de C.V.