



Handout 1.5

PACKAGE INSERT

brand name →

generic name →

generic name →

drug interactions →

NEW LABEL INFORMATION NDC 50580-186-15

Concentrated TYLENOL®

Infants' Drops

CONTAINS
Acetaminophen
Fever Reducer Pain Reliever

Pediatricians' First Choice

Use ONLY enclosed dropper

Cherry FLAVOR

1/2 FL OZ (15mL) 80 mg per 0.8 mL

Concentrated TYLENOL®
A TYLENOL® product for every age.

Concentrated Tylenol® Infants' Drops:
Less liquid for your infant to swallow

Children's Liquids:
For ages 2+ years

Children's Soft-Chews:
For ages 3+ years

IMPORTANT:
Concentrated Tylenol® Infants' Drops contains more medicine per drop than Children's Tylenol® Liquid.

Use enclosed dropper ONLY.
DO NOT USE other cups or spoons.

Drug Facts

Active ingredient (in each 0.8 mL) Purposes
Acetaminophen 80 mg.....Fever reducer/pain reliever

Uses temporarily:
 ■ reduces fever
 ■ relieves minor aches and pains due to:
 ■ the common cold ■ flu ■ headaches
 ■ sore throat ■ immunizations ■ toothaches

Warnings
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 product containing acetaminophen

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

Stop use and ask a doctor if
 ■ new symptoms occur
 ■ redness or swelling is present
 ■ pain gets worse or lasts for more than 5 days
 ■ fever gets worse or lasts for more than 3 days

Keep out of reach of children.
Overdose warning: Taking more than the recommended dose (overdose) could cause serious health problems. 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
 ■ shake well before using
 ■ find right dose on chart below. If possible, use weight to dose; otherwise, use age.
 ■ fill to dose level. Do not use any other dosing device.
 ■ dispense liquid slowly into child's mouth, toward inner cheek
 ■ if needed, repeat dose every 4 hours
 ■ do not use more than 5 times in 24 hours
 ■ replace dropper tightly to maintain child resistance
 ■ use only with enclosed dropper

Drug Facts (continued)

Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)
under 24	under 2	call a doctor
24-35	2-3	1.6 mL (0.8 + 0.8 mL)

Attention: Specifically designed for use with enclosed dropper. Use only enclosed dropper to dose this product. Do not use any other dosing device.

Other information
 ■ do not use if plastic carton wrap or bottle wrap imprinted "Safety Seal®" is broken or missing
 ■ store at room temperature
 ■ see bottom panel of carton for expiration date and lot number

Inactive ingredients
 butylparaben, cellulose, citric acid, corn syrup, FD&C Red #40, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sorbitol, xanthan gum

Questions or comments?
 call toll-free 1-877-TYLENOL (1-877-895-3665)

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 Visit us at www.tylenol.com
 U.S. Patent Nos. 5,272,137 and 5,409,907