

# Details for: TEMPRA INFANT DROPS

## Company: PALADIN LABS INC

DIN	Active Ingredient(s)	Strength	Dosage Form	Route of Administration
00875988	ACETAMINOPHEN	80 MG / ML	Drops	ORAL

[Report a Side Effect](#)    [View Reported Side Effects](#)

### Summary Reports

- [Summary Safety Review - Phenylephrine and acetaminophen - Drug-drug interaction](#)
- [Summary Safety Review - Acetaminophen - Liver Injury](#)

### Drug Facts Table

- ▼ Active ingredient (in each dosage unit)  
Acetaminophen 80MG/ML
- ▼ Purpose  
Pain reliever or fever reducer
- ▼ Uses
  - Reduces fever
  - Temporarily relieves mild to moderate aches and pain due to
  - headache
  - backache
  - migraine
  - sore throat
  - arthritis or rheumatism
  - pre-menstrual/menstrual cramps
  - muscle sprains and strains
  - toothache / teething pain
  - common cold and flu
  - immunization
- ▼ Warnings
  - ▼ Liver warning:  
Acetaminophen may cause **severe or possibly fatal liver damage** if you take
    - more than the recommended dose in 24 hours
    - with other drugs containing acetaminophen
    - while drinking 3 or more alcoholic drinks every day (adult products only) Symptoms of liver damage may include
    - yellow skin or eyes
    - dark urine
    - sweating
    - nausea
    - vomiting
    - stomach pain
    - unusual tiredness
    - loss of appetite
  - ▼ Allergy alert:  
Acetaminophen may cause serious skin reactions. Symptoms may include
    - skin reddening

- blisters
- rash **If any of the above noted symptoms occur, stop use and seek medical help right away.**

▼ Do not use

- with any other drug containing **acetaminophen**
- if you are allergic to acetaminophen or any other ingredient in this product. 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 or kidney disease.

▼ Ask a doctor or pharmacist before use if

your child takes the blood thinning drug warfarin.

▼ Stop use and ask a doctor if

- pain lasts for more than 5 days
- fever lasts more than 3 days.

▼ Keep out of reach of children

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

▼ Directions

- Do not give your child more than directed (see liver warnings)

Infants:

- Administer single dose orally, every 4-6 hours
- Dose by body weight, otherwise use age
- Do not take more than 5 doses in 24 hours
- Use only the dropper provided

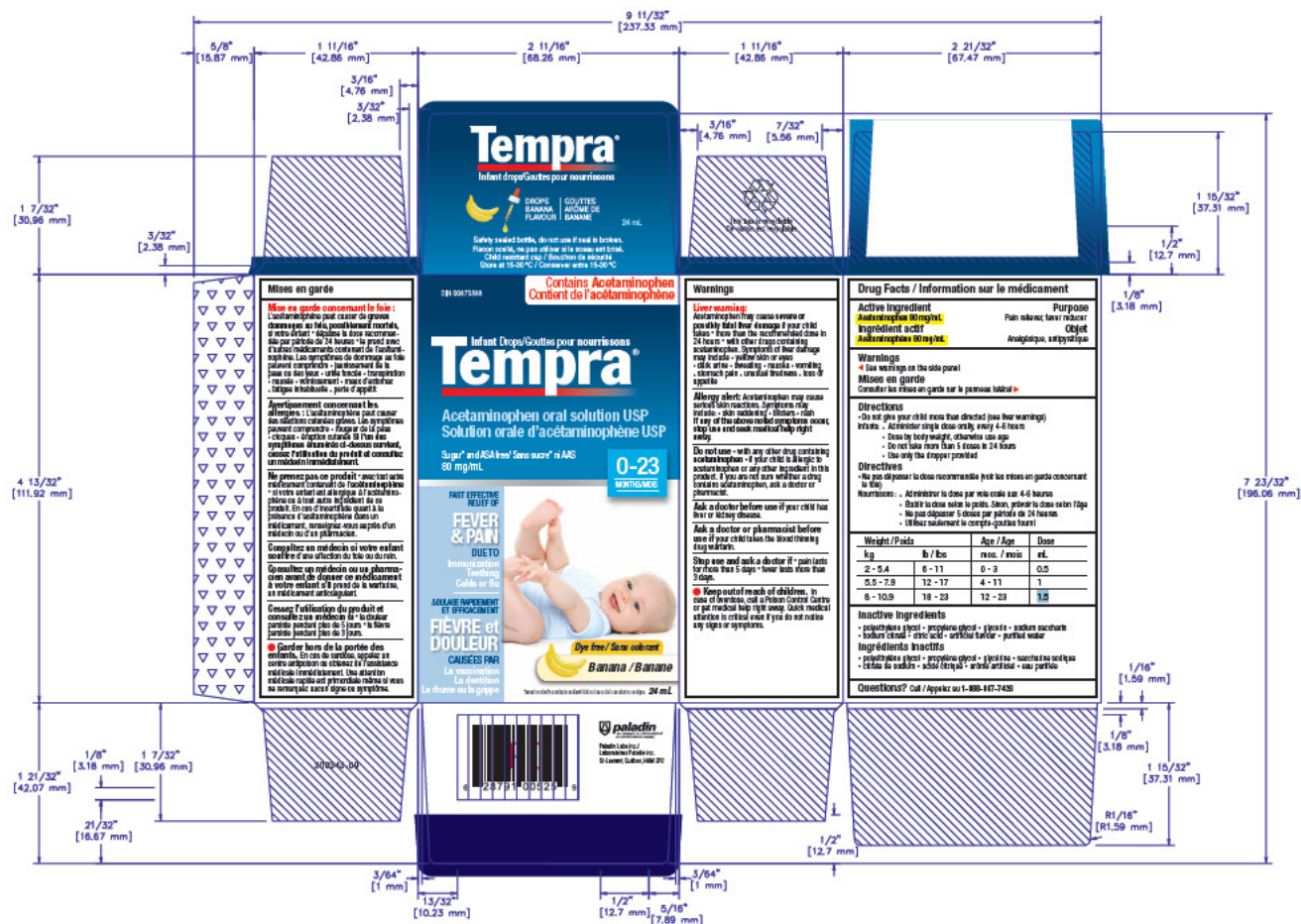
Weight		Age	Dose
kg	lb/lbs	mos.	mL
2 - 5.4	6 - 11	0 - 3	0.5
5.5 - 7.9	12 - 17	4 - 11	1
8 - 10.9	18 - 23	12 - 23	1.5

▼ Inactive ingredients

- polyethylene glycol
- propylene glycol
- glycerin
- sodium saccharin
- sodium citrate
- citric acid
- artificial flavour
- purified water

▼ Labels

## Outer Label



UPC CODE AREA 1-1/4" x 7/8"

NO VARNISH AREA

LASER BATCH LOT/EXP AREA  
NOTE TO DESIGNER: ADD  
COLORED BOX TO LASER  
BATCH CODE AREA

GLUE AREA

XXXXXXXX = SAP CODE FOR VISION SYSTEM INSPECTION

Project:
Client:
Product:
Item Number:
UPC Code:
Size:
Color:
Date:

B-MS DRAWING #: 10000010389

Inner Label

Contains **Acetaminophen**  
Contient de l'**acétaminophène**

DIN 00875988

**Tempra**

Infant Drops/Gouttes pour nourrissons

Acetaminophen oral solution USP  
Solution orale d'acétaminophène USP

**0-23**  
MONTHS/MOIS



80 mg/mL

24 mL

Weight/Poids kg lb/lbs	Age/Âge mos./mois	Dose mL
2-5.4 6-11	0-3	0.5
5.5-7.9 12-17	4-11	1
8-10.9 18-23	12-23	1.5

● **KEEP OUT OF THE REACH OF CHILDREN.**  
**GARDER HORS DE LA PORTÉE DES ENFANTS.**

◀ **Peel off this label for important safety information before use. Avant usage, soulever l'étiquette pour des renseignements de sécurité importants.**

Store at 15-30 °C. / Conserver entre 15-30 °C.  
Safety sealed bottle. Do not use if seal is broken.  
Flacon scellé. Ne pas utiliser si le sceau est brisé.  
Paladin Labs Inc. / Laboratoires Paladin Inc.  
St-Laurent, Québec, H4M 2P2 1-888-867-7426

**Medicinal Ingredient:** 80 mg/mL acetaminophen (analgesic/antipyretic) **Indications:** Infants: Fever reducer, pain reliever **Dosage:** Administer single dose orally, every 4-6 hours. Do not give more than 5 doses in 24 hours. Dose by body weight, otherwise use age. Use only the dropper provided. **See Insert for detailed information.**

**Ingédient médicamenteux:** 80 mg/mL d'acétaminophène (analgésique/antipyrétique) **Indications:** Nourrissons: Diminution de la fièvre, soulagement de la douleur **Posologie:** Administrer la dose par voie orale aux 4-6 heures. Ne pas dépasser 5 doses par période de 24 heures. Établir la dose selon le poids. Sinon, prévoir la dose selon l'âge. Utilisez seulement le compte-gouttes fourni. **Pour plus de détails, consulter la notice.**

YYY

MM

EXP:

LOT

300341-07

**WARNINGS**  
**DO NOT USE** • with other drugs containing acetaminophen • If your child is allergic to acetaminophen  
**Liver warning:** Severe or possibly fatal liver damage may occur if your child takes: • more than five (5) doses in 24 hours • other drugs containing acetaminophen. **Stop use and seek medical help right away if** • the following symptoms of liver damage are noticed: • yellow of the skin/eyes, dark urine • sweating, nausea, vomiting, stomach pain • unusual tiredness, and/or loss of appetite **Serious allergy skin reactions** can occur (skin reddening, blisters or rash). **Stop use and ask a doctor if:** • pain lasts for more than five (5) days • fever lasts for more than three (3) days **In case of overdose:** Call a poison Control Center or get medical help right away.

**MISES EN GARDE**  
**NE PAS UTILISER** • avec d'autres médicaments contenant de l'acétaminophène • en cas d'allergie à l'acétaminophène  
**Mise en garde liée au foie :** Des lésions du foie graves pouvant causer la mort peuvent survenir si votre enfant : • dépasse cinq (5) doses en 24 heures • le prend avec d'autres médicaments contenant de l'acétaminophène. **Cesser d'utiliser le médicament et consulter un médecin immédiatement si :** • vous remarquez des symptômes de lésions du foie : • jaunissement de la peau et des yeux, urine foncée • transpiration, nausées, vomissements, maux d'estomac • fatigue inhabituelle et/ou perte d'appétit **De graves réactions cutanées** peuvent survenir (des rougeurs, cloques ou éruptions cutanées). **Cesser d'utiliser le médicament et consulter un médecin si :** • la douleur persiste plus de cinq (5) jours • la fièvre persiste plus de trois (3) jours. **En cas de surdose :** Appelez un centre antipoison ou obtenez de l'assistance médicale immédiatement.

▼ Questions?

Call 1-888-867-7426

Date modified:

2015-10-19