PAROX- children pain and fever acetaminophen 160 mg per 5ml suspension
SJ INCORPORATION LTD

INFAN'S PAROX FOR CHILDREN
ACETAMINOPHEN 160 MG PER 5 ML ORAL SUSPENSION
PAIN RELIEVE/FEVER REDUCER

Active Ingredient (in each 5mL)

Acetaminophen, 160mg

Inactive Ingredients

Anhydrous citric acid, cherry flavor, glycerin,microcrystalline cellulose,carboxymethylcellulose sodium, potassium sorbate, purified water, sorbitol solution, sucralose, sucrose, xanthan gum

Purpose

Pain reliever/fever reducer

Uses

Temporarily: • Reduces fever
Relieves minor aches and pains due to: • the common cold • flu • headache • sore throat • toothache

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 for this product
- With other drugs containing acetaminophen

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

- skin reddening
- blisters
- rash.

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 drug containing acetaminophen(prescription or non-prescription). 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 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

Keep out of reach of children

Do not use

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

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 right dose on chart below. If possible, use weight to confirm, otherwise use age
- Remove the child protective cap and squeeze your child's dose in to the dosing cup
- Repeat dose every 4 hours while symptoms last
- Do not give more than 5 times in 24 hours or as directed by a doctor

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

Dosing Chart

Weight (lbs)	**Age (Years)**	**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	15 mL

Other information

- Each 5 ml contains Potassium 5 mg
- Store between 20-25ºC (68-77ºF)
- Do not use if carton tape or bottle wrap imprinted with "PAROX" is broken or missing

Questions ?

Call +1-800-587-4041

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

INFANT'S PARXO FOR CHILDREN

ACETAMINOPHEN 160 MG PER 5 ML ORAL SUSPENSION

PAIN RELIVER/FEVER REDUCER

DYE-FREE

NDC-83658-016-01

100 ML

CHERRY FLAVOR

PAROX

children pain and fever acetaminophen 160 mg per 5ml suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83658-016
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

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM (0.7 CARBOXYMETHYL SUBSTITUTION PER SACCHARIDE; 150 MPA.S AT 1%) (UNII: 99H65D77XY)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83658-016-01	1 in 1 CARTON	05/25/2024	
1		100 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	05/25/2024	

Labeler - SJ INCORPORATION LTD (119051828)

Registrant - SJ INCORPORATION LTD (119051828)

Establishment

Name	Address	ID/FEI	Business Operations
WESTCOAST PHARMACEUTICAL WORKS LIMITED		960107292	manufacture(83658-016)

Revised: 5/2024 SJ INCORPORATION LTD