

INFANT AND CHILDREN NOVEX ACETAMINOPHEN- acetaminophen suspension
Herbion Pakistan (Pvt.) Ltd

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.

Active ingredient

(in each 5 mL)

Acetaminophen 160 mg

Purpose:

fever reducer / Pain reliever

Uses:

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

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 vomiting, consult a doctor promptly.

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.

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

Overdose warning:

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) 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; tsp = teaspoonful
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- remove the child protective cap and use the dosing vial / measuring cup provided
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

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

*or as directed by a doctor

Attention: use only enclosed dosing devices provided, specifically designed for use with this product.

Other Information

- **each 5 mL (1 tsp) contains:** sodium 1.2 mg
- store between 20-25⁰C (68-77⁰F)
- **do not use if bottle cap seal is broken**

Inactive Ingredients:

Sucrose, Sorbitol, Glycerin, Flavor, Xanthan Gum, Sodium Benzoate, Potassium Sorbate, FD&C RED NO. 40, Purified Water

Questions or Comments?

Call **1-888-(OK-HERBION) 654-3724**, Monday through Friday 9am - 5pm EST

Fever & Pain
Fast & Effective Relief of

Acetaminophen oral suspension
Novex
Infant & Children

NDC

Infant & Children
Novex
Acetaminophen
Acetaminophen oral suspension

**Fast & Effective Relief of
Fever & Pain**

- Ibuprofen Free
- Alcohol Free
- Aspirin Free



**Ages:
2-11**

4 fl oz (120 mL)
160 mg per 5 mL



Strawberry Flavor

NDC

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Strawberry Flavor

Drug Facts

Active ingredient Purpose
(in each 5 mL) **Acetaminophen 160 mg** Fever Reducer / Pain Reliever

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■ skin reddening ■ blisters ■ rash
If a skin reaction occurs, stop use and seek medical help right away.

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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 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: In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Drug Facts (continued)

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Questions or comments?
call 1-888-(OK-HERBION) 654-3724, Monday through Friday, 9am - 5pm EST

Herbion
PHARMA

Manufactured for:
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Hicksville, NY 11801
1-888-(OK-HERBION) 654-3724
info@herbion.us
www.herbion.us

Lot No.
Exp.



INFANT AND CHILDREN NOVEX ACETAMINOPHEN

acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44237-040	
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	
SUCROSE (UNII: C151H8M554)				
SORBITOL (UNII: 506T60A25R)				
GLYCERIN (UNII: PDC6A3C0OX)				
XANTHAN GUM (UNII: TTV12P4NEE)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)				
WATER (UNII: 059QF0KO0R)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
Product Characteristics				
Color	pink	Score		
Shape		Size		
Flavor	STRAWBERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44237-040-01	1 in 1 CARTON	03/09/2020	
1		120 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 not final	part343	03/09/2020		

Labeler - Herbion Pakistan (Pvt.) Ltd (645482936)

Registrant - Herbion Pakistan (Pvt.) Ltd (645482936)

Establishment

Name	Address	ID/FEI	Business Operations
Herbion Pakistan (Pvt.) Ltd		645482936	manufacture(44237-040)

Revised: 3/2020

Herbion Pakistan (Pvt.) Ltd