

## **NEO-LUBRINA- acetaminophen suspension**

### **OPMX Chula Vista**

*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.*

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### **Neo-Lubrina**

#### **Active Ingredient(in each 5 mL) Purpose**

Acetaminophen 160 mg..... Pain reliever/fever reducer

Pain Reliever & Fever Reducer

#### **Uses**

temporarily:

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

#### **Warnings**

**Liver warning:** This product contains acetaminophen.

Severe liver damage may occur if your child takes takes

- more than 5 doses in 24 hours. which is the maximum daily amount.
- with other drugs containing acetaminophen.

**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**

- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days

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. Shake well before using
- mL= millilitar
- find right dose on chart below, if possible, use weight to dose; otherwise, use age
- repeat dose every 4 hours while symptoms last
- only use enclosed measuring syringe
- do not give more than 5 times in 24 hours
- do not give more than 5 days unless directed by a doctor

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

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\*always check with your doctor before administering medicine to your infant/child

### **Other information**

- Each teaspoon (5 mL) contains: sodium 3 mg
- Store between 15°-30°C (59°-86°F)
- Protect from freezing. Protect from light

### **Inactive ingredients**

acesulfame potassium, citric acid, FD&C red no. 40, flavor, glycerine, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, polysorbate, propylene glycol, prosweet N&AK, purified water, sodium benzoate, sucralose, sorbitol, xanthan gum.

**Questions or comments?**

Call toll free 619-600-5632

Monday through Friday 9AM - 5PM EST

**PRINCIPAL DISPLAY PANEL**

NDC 69729-118-04 Neo-Lubrina



**NEO-LUBRINA**  
acetaminophen suspension

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:69729-118

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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

### Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-118-04	1 in 1 CARTON	06/02/2023	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	06/02/2023	

**Labeler** - OPMX Chula Vista (029918743)

## Establishment

Name	Address	ID/FEI	Business Operations
Bajaj Medical, LLC		078774921	manufacture(69729-118) , pack(69729-118) , label(69729-118)

Revised: 6/2023

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