

XESSO NEO- benzocaine spray
PREMIUM NATURAL COSMETICS INC

Xesso Neo 5% Benzocaine Oral Spray

Warning

- **METHEMOGLOBINEMIA WARNING:** Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in the blood. Stop use and seek immediate medical attention if you or a child in your care develops: pale, gray, or blue-colored skin (cyanosis), headache, rapid heart rate, shortness of breath, dizziness or lightheadedness, fatigue, or lack of energy.
- **Sore Throat Warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea or vomiting, consult a doctor promptly. For adult use only.
- Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other 'caine' anesthetics.
- Keep this and all drugs out of reach of children. In case of accidental overdose, seek medical help or call a Poison Control Center right away.
- As with any drug, consult a health care professional if you are pregnant or nursing. Ask a health care professional before using this product.
- Stop use and consult a doctor if difficulty in breathing occurs, swelling or fever develops, or if sore mouth or throat symptoms do not improve within 7 days.
- Do not exceed the recommended dosage.
- Keep away from fire or flames.

Keep out of reach of children section

Keep this and all drugs out of reach of children. In case of accidental overdose, seek medical help or call a Poison Control Center right away.

Directions

Apply to the affected area (one spray).

Allow to remain in place for at least 15 seconds then spit out.

May be repeated every two hours as needed or as directed by a health care professional.

Inactive Ingredients

Alcohol, FD&C RED NO. 40, Glycerin, Natural Flavors, PEG-40 Hydrogenated Castor Oil, Polyvinylpyrrolidone (PVP), Sucralose, Water.

Use Section

For temporary relief of minor throat irritation, pain, and sore throat.

XESSO NEO

benzocaine spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81777-106
Route of Administration	ORAL, TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
POLYOXYL 40 CASTOR OIL (UNII: 4ERD2076EF)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL 95% (UNII: 7528N5H79B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81777-106-04	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/16/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	04/16/2024	

Labeler - PREMIUM NATURAL COSMETICS INC (051403646)

Registrant - Creative Essences Inc (079120182)

Establishment

Name	Address	ID/FEI	Business Operations
Creative Essences Inc		079120182	manufacture(81777-106)

