
**XYZ PHARMACEUTICALS LTD.
PRODUCT DOSSIER**

PRODUCT INFORMATION

Product Name	RespiRease Cough Syrup
Dosage Form	Oral Liquid Syrup
Manufacturer	XYZ Pharmaceuticals Ltd.
Strength	15 mg/5 mL Dextromethorphan HBr, 100 mg/5 mL Guaifenesin
Therapeutic Category	Antitussive and Expectorant
Regulatory Status	Over-the-Counter (OTC)

COMPOSITION

Each 5 mL contains:

Active Ingredient	Amount
Dextromethorphan Hydrobromide USP	15 mg
Guaifenesin USP	100 mg

Excipients: Sucrose, Glycerin, Sodium Benzoate, Natural Cherry Flavor, Citric Acid, Purified Water

INDICATIONS

- Temporary relief of cough caused by minor throat and bronchial irritation associated with common cold.
- Helps loosen phlegm and thin bronchial secretions to make cough more productive.

DOSAGE AND ADMINISTRATION

Age Group	Dose	Frequency	Maximum Daily Dose
Adults and children \geq 12 years	10 mL (2 teaspoons)	Every 4 hours	60 mL (6 doses) in 24 hrs
Children 6 to <12 years	5 mL (1 teaspoon)	Every 4 hours	30 mL (6 doses) in 24 hrs
Children under 6 years	Not recommended	-	-

CONTRAINDICATIONS

- Hypersensitivity to any component of the product
- Patients taking MAO inhibitors or within 14 days of stopping such therapy
- Patients with chronic productive cough

WARNINGS AND PRECAUTIONS

- Drowsiness
- Dizziness
- Mild stomach discomfort

STORAGE CONDITIONS AND SHELF LIFE

Storage	Store at room temperature (15–30°C) in a tightly closed container, protected from light.
Shelf Life	24 months from the date of manufacture

MANUFACTURING INFORMATION

Batch Number	123456
Manufacture Date	20/05/2025
Expiration Date	22/09/2027

Note:

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