SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Zedex Cough Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml contains :

Bromhexine Hydrochloride BP	:	8 mg
Dextromethorphan Hydrobromide BP	:	10 mg
Ammonium Chloride BP	:	100 mg
Menthol BP	:	5 mg

QUALITATIVE AND QUANTITATIVE COMPOSITION

S. No.	Ingredients	Quality Standards	Each 10 ml contains	Function
1.	Bromhexine Hydrochloride	BP	8.0 mg	Active Ingredient
2.	Dextromethorphan Hydrobromide	BP	10 mg	Active Ingredient
3.	Ammonium Chloride	BP	100 mg	Active Ingredient
4.	Menthol	BP	5.0 mg	Active Ingredient
5.	Pharma grade Sugar	BP	5.1 g	Sweetener
6.	Liquid glucose	USNF	3.5 g	Viscoliser
7.	Benzoic acid	BP	7.0 mg	Preservative
8.	Sodium benzoate	BP	3.5 mg	Preservative
9.	Saccharin Sodium	BP	33.0 mg	Sweetener
10.	Propylene glycol	BP	0.800 g	Cosolvent
11.	Vanillin Powder BBA	BP	1.0 mg	Flavoring Agent
12.	Colour Apple Green (Bush IH – 8925)	I.H.	2.5 mg	Colouring Agent
13.	Essence Mixed fruit (IFF-VSA) S 2535	I.H.	0.012 ml	Flavoring Agent
14.	Purified water	BP	q.s. to 10 ml	Vehicle

BP: British Pharmacopeia

USNF: United States National Formulary

I.H: In-House

3. PHARMACEUTICAL FORM

Liquid Oral-GREEN COLOURED SOLUTION HAVING A MENTHOL FLAVOUR

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic treatment of irritating and hacking cough.

Cough associated with URTI, bronchitis, pulmonary congestion where retention of tenacious and viscid mucoid secretions is a problem.

4.2 Posology and method of administration

Adults : 10ml to be taken 3-4 times a day.

Children
(2-6 years) : 2.5ml to be taken 3-4 times a day.
(6-12 years) : 5ml to be taken 3-4 times a day.

or

As directed by the physician.

4.3 Contra-indications

Dextromethorphan should not be used in patients receiving monoamine oxidase (MAO) inhibitors.

Bromhexine is contraindicated in the 1 st trimester of pregnancy.

4.4 Special warnings and special precautions for use

Dextromethorphan should be used with caution in sedated patients, in the debilitated and in patients confined to the supine position.

Long term animal studies have not been performed to assess the carcinogenic potential of dextromethorphan. There is no animal or human data concerning the carcinogenic and mutagenic effect or impairment of fertility by these drugs.

Bromhexine :
Anaphylactic reactions and severe cutaneous adverse reactions (SCARs), including erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis and acute generalised exanthematous pustulosis, have been reported In patients receiving ambroxol. As ambroxol is a metabolite of bromhexine, the risk of anaphylactic and severe cutaneous reactions is considered to apply also to bromhexine. The risk of anaphylactic reactions and SCARs with ambroxol or bromhexine is low. Frequencies of these side effects are unknown. If symptoms or signs of a progressive skin rash (sometimes associated with blisters or mucosal lesions) are present, bromhexine treatment should be discontinued immediately and medical advice should be sought. Caution is advised when treating patients with haemoptysis because the constituent ingredient bromhexine can lead to rejection of fibrin clots and result in new bleeding

4.5 Interactions with other medicaments and other forms of Interaction

There are no known significant interactions with other medicines.

4.6 Pregnancy and lactation

It is not know whether dextromethorphan is excreted in human milk. Caution should be exercised when dextromethorphan is administered to a nursing woman.

4.7 Effects on ability to drive and use machines

Zedex may cause side effects which could affect your ability to drive.

4.8 Undesirable effects

Dextromethorphan hydrobromide occasionally causes slight drowsiness, dizziness and gastrointestinal disturbances. The drug is relatively well tolerated with minor and infrequent side effects Rarely it causes nausea and epigastric discomfort. It is contraindicated in patients with peptic ulceration.

Bromhexine: Gastrointestinal side effects may occur occasionally with bromhexine and a transient rise in serum aminotransferase values has been reported. Other reported adverse effects include

headache, vertigo (dizziness), sweating and allergic reactions including anaphylactic reactions and severe cutaneous adverse reactions (SCARs).

4.9 Overdose

Dextromethorphan may produce central excitement and mental confusion Very high doses may produce respiratory depression. One case of toxic psychosis (hyperactivity, marked visual and auditory hallucination) after ingestion of a single dose of 20 tablets (300 mg of dextromethorphan has been reported.

Bromhexine treatment above 60 mg / day may cause gastric irritation.

Treatment of overdosage with dextromethorphan is essentially symptomatic and supportive. Only in cases of extreme overdosage or individual sensitivity do vital signs including respiration, pulse, blood pressure, temperature and ECG need to be monitored. Activated charcoal orally or by lavage may be given or sodium / magnesium sulfate orally can be used as a cathartic. Attention should be given to the re-establishment of adequate respiratory exchange through provision of a patient airway and institution of assisted or controlled ventilation. Diazepam may be used to control convulsion. Acidosis and electrolyte losses should be corrected.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties :

Pharmacotherapeutic group: Antitussives, Antihistamines

ATC code of Dextromethorphan Hydrobromide : R05DA09.

ATC code of Bromhexine Hydrochloride: R05CB06

Dextromethrophan is an antitussive agent and unlike it's isomer levorphanol, it has no analgesic or addictive properties. The drug acts centrally and elevates the threshold for coughing, it is about equal to codeine in depressing the cough reflex. In therapeutic dose dextromethorphan does not inhibit ciliary activity. Bromhexine increases the expectoration of sputum in bronchitis patients, increases the output of water into respiratory tract fluid and depolymerises the mucopolysaccharides in the mucous. It is also claimed to act on bronchial glands, to liberate lysosomal enzymes from the mucous secreting cells which digest the mucopolysaccharide fibers. Thus bromhexine is extremely useful in restoring the mucociliary equilibrium. Besides this, it has been attributed to have mild anti tussive effect. Bromhexine increases sputum volume by stimulating the mucous gland of the respiratory tract and promoting ciliary clearance of sputum. Bromhexine further reduces sputum viscosity by breaking down the tenacious network of mucopolysaccharide fibres in mucoid sputum which are mainly responsible for sputum stickiness.

Bromhexine creates an environment in the bronchial tree conducive to the removal of sticky mucus thus promoting expectoration without excessive straining.

Ammonium chloride produces mild irritation of the mucous lining of the stomach and this gastorvagal reflex increases the respiratory tract fluid, relieving dryness and soreness of the respiratory passage.

5.2 Pharmacokinetics properties :

Dextromethorphan is rapidly absorbed from the gastrointestinal tract and exerts its effect in 15 to 30 minutes. The duration of action after oral administration is approximately 3-6 hours. Dextromethorphan is metabolized primarily by live enzymes undergoing O-demethylation, N-demethylation and partial conjugation with glucuronic acid and sulfate.

Bromhexine hydrochloride is rapidly absorbed from the gastrointestinal tract and about 85 to 90 % of the dose is excreted in urine mainly as metabolite. Bromhexine is highly bound to plasma proteins.

Administration of bromhexine hydrochloride by mouth to healthy subjects produced peak plasma concentations after about 1 hour. Only small amounts were excreted unchanged in the urine with a half life of about 6.5 hours.

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sr No	Excipients	Specification
1	Pharma grade sugar	As per BP
2	Liquid Glucose	As per USP
3	Benzoic Acid	As per BP
4	Sodium benzoate	As per BP
5	Sodium Saccharin	As per BP
6	Propylene Glycol	As per BP
7	Vanillin Powder BBA	As per BP
8	Brilliant Blue	As per IH
9	Essence Mixed fruit (IFF-VSA) (S-2535)	As per IH
10	Purified water	As per BP

BP: British Pharmacopoeia
USP: United States national formulary
IH: IN- House Specification

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

24 months from the date of manufacture.

6.4 Special precautions for storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container

100 ml packed in an amber PET bottle with R.O.P.P. Cap with logo and measuring cup and pasted with printed label. One bottle is packed in a printed carton with package insert.

6.6 Special precautions for disposal

No special requirements.

7. Applicant/ Manufacturer

Name and address of Manufacturer
Naxpar Pharma Pvt. Ltd. 182, Village, Gurumajra, Kishanpura, Tehsil Nalagarh, Baddi, Dist. Solan (HP) 174101, India.

Name and address of Applicant
Wockhardt Limited ,
Wockhardt Towers, Bandra Kurla Complex, Bandra East ,Mumbai 400051.

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