



BRAND NAME:	BABY GREENLIN
GENERIC NAME:	Dilute Acetic Acid Syrup

1.3 PRODUCT INFORMATION

1.3.1 Summary of Product Characteristics (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

1.1 Name of the Medicinal Product

BABY GREENLIN

(Dilute Acetic Acid Syrup)

1.2 Strength

100 ml Bottle

1.3 Pharmaceutical Form

Oral liquid dosage form

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml Contains:-

Dilute Acetic Acid BP.....0.42 ml

Colour- Erythrosine

Black current flavour

Flavour Syrupy base.....q.s.

3. PHARMACEUTICAL FORM

Oral liquid dosage form

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the symptomatic relief of the irritating and distressing coughs which often accompany colds..

4.2. Posology and method of administration

Oral. To be given slowly. Children 3 months to 1 year: half a 5ml spoonful. Over 1 year: one 5ml spoonful. Over 2½ years: two 5ml spoonfuls. Repeat as needed every 2 or 3 hours. Not appropriate for adults or the elderly

4.3. Contra-indications

None stated.

4.4. Special warnings and special precautions for use

Keep out of the reach of children.

4.5. Interactions with other Drug products and other forms of interaction

None stated.



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4.6. Pregnancy and lactation

Not applicable.

4.7. Effects on Ability to Drive and Use Machines

Not applicable.

4.8. Adverse Reactions

None stated.

4.9 Over Dose

None stated.



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5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamics properties

Baby Greenlin contains dilute acetic acid (a mild expectorant) in a sugar free blackcurrant flavoured demulcent base.

5.2 Pharmacokinetic Properties

None stated.

5.3. Preclinical safety data

Not Further data

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6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Glycerin	BP
Sorbitol 70% Soln.	BP
Sodium Benzoate	BP
Propylene Glycol	BP
Black Current Flavour	IH
Erythrosine Supra Colour	IH
Purified Water	BP/IH

6.2. Incompatibilities

None

6.3. Shelf life

36 Months.

6.4 Special precautions for storage

Store below above 30 °C.

Store in the original package, in order to protect from moisture.

6.5. Nature and contents of container

Each unit carton contains one 100 ml amber coloured plastic Bottle with Package insert.

6.6. Instruction for use and handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

MAXHEAL PHARMACEUTICALS (INDIA) LTD
J-7, M.I.D.C., TARAPUR INDUSTRIAL AREA,
BOISAR-401506, DIST. PALGHAR, INDIA

8. MARKETING AUTHORISATION NUMBER

Not Applicable.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Not Applicable.

10. DATE OF REVISION OF THE TEXT

Not Applicable.