National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1. Name of the medicinal product
Novalyn For Children Syrup

2. Qualitative and quantitative composition
Each 5 ml contains:-

Diphenhydramine hydrochloride	B.P	7.0 mg
Sodium Citrate	B.P	28.5mg
L-menthol	B.P	0.55 mg

3. Pharmaceutical form
Syrup
A pink coloured Syrup

4. Clinical particulars
4.1 Therapeutic indications
Novalyn for children is indicated for the relief of coughs, symptoms of cold and allergic conditions including sneezing, itching and rhinitis (itchy and runny nose).

It is also useful for treatment of motion sickness.
4.2 Posology and method of administration
Posology:

Unless otherwise directed by a physician:

Children 1 – 5 years: 5ml (1 teaspoonful) every 3 to 4 hours.

Children 6 – 12 years: 10ml (2 teaspoonfuls) every 3 to 4 hours.

4.3 Contraindications
- Hypersensitivity to any of the components of the preparation.
- Neonates and premature infants owing to their increased susceptibility to the antimuscarinic effect of Diphenhydramine anti-histamine.
- Hepatic or renal impairment,
- Chronic obstructive disease,
- Narrow angle glacouma,
- Benign prostatic hypertrophy
- Acute attacks of asthma.

4.4 Special warnings and precautions for use
This product may cause drowsiness. If affected, do not drive or operate machinery. Avoid alcoholic drink.

4.5 Interaction with other medicinal products and other forms of interaction

Diphenhydramine inhibits cytochrome P450 isoenzyme CYP2D6 that is partly responsible for the metabolism of beta blockers including metoprolol and the antidepressant venlafaxine.

Diphenhydramine may enhance the sedating effects of CNS depressants including alcohol, barbiturates, hypnotics, opoid analgesics, anxiolytic sedatives and psychotics.
It has additive antimuscarinic action with other antimuscarinic drugs like atropine, tricyclic antidepressants, and MAOIs.
It has been suggested that sedating antihistamins could mask the warning signs of damage caused by ototoxic drugs such as aminoglycoside antibiotics.
Diphenhydramine may suppress cutaneous histamine response to allergen extracts. Its therapy should be stopped several days before skin testing.

Citrate salts like Sodium citrate can enhance the absorption of Aluminium from the GIT.

4.6 Fertility, pregnancy and lactation
Although diphenhydramine has been in widespread use for many years without ill consequence, it is known to cross the placenta and has been detected in breast milk. Novalyn for Children should therefore only be
used when the potential benefit of treatment to the mother exceeds any possible hazards to the developing foetus or suckling infant.

4.7 Effects on ability to drive and use machines
This product may cause drowsiness. If affected, the patient should not drive or operate machinery.

4.8 Undesirable effects
Side effects are rare and usually mild. The most reported sedation and CNS depression including dizziness, lassitude, blurred vision and incardination, which may diminish after few days of treatment. Concurrent ingestion of alcohol or other CNS depressants produce an additive effect that impairs motor skills. Other side effects include gastrointestinal disturbances which may be reduced by giving the drug with meals. Hypersensitivity reactions and rashes may also occur but are less common

4.9 Overdose
Novalyn for Children when taken in the usual recommended dose does not present with any toxicological problem but when taken in excessive dose or overdosage toxicity occurs.
Overdosage is associated with antimuscarinic, extrapyramidal and CNS effects. When CNS stimulation predominates, symptoms of toxicity include; hallucinations, excitement, ataxia, incoordination, athetosis, and convulsions. Fixed, dilated pupils with a flushed face, together with sinus tachycardia, urinary retention, dry mouth and fever. Terminally there is deepening coma with cardio-respiratory collapse and death usually within 2 to 18 hours.
Other symptoms include severe vomiting or diarrhoea

5. Pharmacological properties
5.1 Pharmacodynamic properties
Diphenhydramine:
Diphenhydramine a monoethanolamine derivative is a sedating antihistamine with antimuscarinic properties. It is a common ingredient of compound preparations for symptomatic treatment of coughs and the common cold.

The mechanism of its antitussive action is due to a central mechanism involving the medullary cough centre. A peripheral action may contribute to the drug's effectiveness.

Sodium Citrate:
Sodium citrate is a bicarbonate-producing salt and has an alkaline nature. It has expectorant action and is used as a common ingredient in cough mixtures.

Menthol:
Menthol is either extracted from peppermint oil (which contains 30-50% concentration of menthol) or prepared synthetically. It is used chiefly to relieve symptoms of bronchitis, sinusitis and similar conditions. It is also a topical antitussive. Its antitussive action is believed to occur from local anaesthetic action of the aromatic vapour.

5.2 Pharmacokinetic properties
Diphenhydramine
Diphenhydramine is well absorbed from the GIT although first pass metabolism appears to affect systemic availability. Peak plasma concentrations achieved about 1 – 4 hours after oral administration.

It is widely distributed throughout the body including the CNS. It crosses the placenta and has been detected in breast milk.

Metabolism is extensive. It is excreted mainly in the urine as metabolites; little is excreted as unchanged drug.

Elimination ranges from 2.4 – 9.3 hours.

Sodium Citrate:
Sodium Citrate is metabolised after absorption to bicarbonate. In the absence of a deficit of bicarbonate in the plasma, bicarbonate ions are excreted in the urine, which is rendered alkaline, and there is an accompanying diuresis.

Menthol:
After absorption, menthol is excreted in the urine and bile as a glucuronide.

6. Pharmaceutical particulars

6.1 List of excipients

Sucrose B.P
Sodium Benzoate B.P
Sorbitol Solution (70%) B.P
Sodium Carboxymethyl Cellulose B.P
Carmoisine B.P
Strawberry
Flavour Deionised
water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life

Three Years

6.4 Special precautions for storage

Product should be stored below 30^{o}C and protected from light.

6.5 Nature and contents of container

Novalyn for Children is presented in a 100ml amber pet bottle, enclosed a printed cardboard catorn with a 10ml measuring cup.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT/MANUFACTURER

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