SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Prinalyn Paediatric Cough Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains: -

Diphenhydramine hydrochloride 7.0mg

Excipient of safety concern

Sodium Benzoate 25mg

For full excipients, see section 6.1

3. PHARMACEUTICAL FORM

Syrup

A clear red syrup with pleasant aroma

4. CLINICAL PARTICULARS

4.1.Therapeutic indications

Prinalyn Paediatric Cough Syrup is indicated for the relief of cough and associated congestive symptoms.

4.2.Posology and method of administration

For oral use.

Age	Dose
6 to 12 Years	Take two 5ml spoonful every 6 hours.

Not more than four doses should be given in any 24 hours.
Not to be used for more than five days without the advice of a pharmacist or Doctor.
Parents or carers should seek medical attention if the child's condition deteriorates during treatment.

Hepatic dysfunction

Caution should be exercised if moderate to severe hepatic dysfunction is present (see Pharmacokinetics - Hepatic dysfunction).

Renal dysfunction
It may be prudent to increase the dosage interval in subjects with moderate to severe renal failure (see Pharmacokinetics - Renal dysfunction).
Do not exceed the stated dose.
Keep out of the reach and sight of children.

4.3.**Contraindications**

Prinalyn Paediatric Cough Syrup is contraindicated in individuals with known hypersensitivity to the product or any of its constituents. Prinalyn Paediatric Cough Syrup is contraindicated in individuals with chronic or persistent cough, such as occurs with asthma, or where cough is accompanied by excessive secretions, unless directed by the physician. Prinalyn Paediatric t Cough Syrup should not be administered to patients currently receiving monoamine oxidase inhibitors (MAOI) or those patients who have received treatment with MAOIs within the last two weeks.

4.4.Special warnings and precautions for use

This product may cause drowsiness. If affected individuals should not drive or operate machinery. Subjects with moderate to severe renal or hepatic dysfunction or urinary retention should exercise caution when using this product (see Pharmacokinetics - Renal/Hepatic Dysfunction). This product contains diphenhydramine and therefore should not be taken by individuals with narrow-angle glaucoma or symptomatic prostatic hypertrophy. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine

4.5.Interaction with other medicinal products and other forms of interaction

This product contains diphenhydramine and therefore may potentiate the effects alcohol, codeine, antihistamines and other CNS depressants. As diphenhydramine possesses some anticholinergic activity, the effects of anticholinergics (e.g., some psychotropic drugs and atropine) may be potentiated by this product. This may result in tachycardia, dry mouth, gastrointestinal disturbances (e.g., colic), urinary retention and headache.

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. Prinalyn Paediatric Syrup 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 associated with the use of Prinalyn Paediatric Syrup are uncommon. Diphenhydramine may cause drowsiness; dizziness; gastrointestinal disturbance; dry mouth; nose and throat; difficulty in urination or blurred vision.

Less frequently it may cause palpitations, tremor, convulsions or paresthesia. Hypersensitivity reactions have been reported, in particular, skin rashes, erythema, urticaria and angioedema.

Adverse reactions to menthol at the low concentration present in Prinalyn Paediatric Syrup are not anticipated.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product, Healthcare professionals are asked to report any suspected adverse reactions to **TMDA**

4.9. Overdose

Symptoms and signs

The symptoms and signs of Prinalyn Paediatric Syrup overdose may include drowsiness, hyperpyrexia and anticholinergic effects. With higher doses, and particularly in children, symptoms of CNS excitation including hallucinations and convulsions may appear; with massive doses, coma or cardiovascular collapse may follow.

Treatment

Treatment of overdose should be symptomatic and supportive. Measures to promote rapid gastric emptying (with Syrup of Ipecac-induced emesis or gastric lavage) and, in cases of acute poisoning, the use of activated charcoal may be useful. Seizures may be controlled with Diazepam or Thiopental Sodium. The intravenous use of Physostigmine may be efficacious in antagonizing severe anticholinergic symptoms.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamine

ATC Code: R06AA02

Diphenhydramine possesses antitussive, antihistaminic and anticholinergic properties. Experiments have shown that the antitussive effect (resulting from an action on the brainstem) is discrete from its antihistaminic effect.

The duration of activity of diphenhydramine is between 4 and 8 hours.

5.2. Pharmacokinetic properties

Absorption

Diphenhydramine is well absorbed from the gut following oral administration. Peak serum levels of diphenhydramine following a 50 mg oral dose are reached at between 2 and 2.5 hours.

Distribution
Diphenhydramine is widely distributed throughout the body, including the CNS. Following a 50 mg oral dose of diphenhydramine, the volume of distribution is in the range 3.3 - 6.8 l/kg, and it is some 78% bound to plasma proteins.

Metabolism and Elimination
Diphenhydramine undergoes extensive first pass metabolism. Two successive N-demethylations occur, with the resultant amine being oxidized to a carboxylic acid. Values for plasma clearance of a 50 mg oral dose of diphenhydramine lie in the range 600-1300 ml/min and the terminal elimination half-life lies in the range 3.4 - 9.3 hours. Little unchanged drug is excreted in the urine. Menthol is hydroxylated in the liver by microsomal enzymes to p-methane-3,8 diol. This is then conjugated with glucuronide and excreted both in urine and bile as the Glucuronide.
The Elderly
Pharmacokinetic studies indicate no major differences in distribution or elimination of Diphenhydramine compared to younger adults.

Renal Dysfunction
The results of a review on the use of Diphenhydramine in renal failure suggest that in moderate to severe renal failure, the dose interval should be extended by a period dependent on Glomerular filtration rate (GFR).

Hepatic Dysfunction
After intravenous administration of 0.8 mg/kg Diphenhydramine, a prolonged half-life was noted in patients with chronic liver disease which correlated with the severity of the disease. However, the mean plasma clearance and apparent volume of distribution were not significantly affected.

5.3.Preclinical safety data

Mutagenicity
The results of a range of tests suggest that neither diphenhydramine nor menthol have mutagenic potential.

Carcinogenicity
There is insufficient information to determine the carcinogenic potential of diphenhydramine, although such effects have not been associated with these drugs in animal studies.

Teratogenicity
The results of a number of studies suggest that the administration of either diphenhydramine does not produce any statistically significant teratogenic effects in rats, rabbits and mice.

Fertility

There is insufficient information to determine whether diphenhydramine has the potential to impair fertility, although a diminished fertility rate has been observed in mice in one study.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Menthol crystals, Sodium Carboxyl Methyl Cellulose 1000cps, Rectified Spirit (90% Alcohol), Saccharin sodium, anhydrous citric acid, Sodium benzoate, Sunset yellow and Strawberry flavour

6.2. Incompatibilities

None known

6.3. Shelf life

24 months from the date of Manufacture.

6.4. Special precautions for storage

Do not store above 30°C, Store in a cool and dry place. Protect from light.

6.5. Nature and contents of container

Amber glass bottle containing 100ml Prinalyn Paediatric Syrup in a unit box. Supplied with insert and a measuring transparent cup.

6.6. Special precautions for disposal and other handling

Keep the medicine out of reach of children.

7. MARKETING AUTHORIZATION HOLDER

PRINCE PHARMACEUTICALS CO. LTD,
PLOT NO. 4/1, BUHONGWA INDUSTRIAL AREA,
P.O.BOX 11415,
MWANZA, TANZANIA.
TEL: +255713226969/+255786759635
EMAIL: hetalvithlani@hotmail.com
OR info@princepharmatz.com

8. MARKETING AUTHORIZATION NUMBER (S)

TAN 22 HM 0441

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

07th October, 2022

10. DATE OF REVISION OF THE TEXT