SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Nasodyne Adult Expectorant

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL of syrup contains carbocisteine 100 mg and promethazine HCl 2.5 mg. It also contains the following excipients: Sucrose, alcohol, methyl paraben, powdered caramel colorant, liquid sorbitol, citric acid monohydrate, sodium hydroxide and purified water

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL form

Expectorant

4. Clinical particulars

4.1 Therapeutic indications

Alleviation of unproductive and irritative coughs in adults and children ≥2 years, particularly when coughing occurs at night.

4.2 Posology and method of administration

Adults: 3 to 4 spoons (15 ml to 20 ml) three times a day.
Treatment must be short (a few days) and only at times when coughing occurs.
If a dose is missed, go back to the regular dosing schedule. However, treatment must be only at times when coughing occurs. Do not take a double dose to make up for the dose missed.

Method of administration

Oral administration. This medicine should be taken by mouth.
The measuring spoon provided with the bottle of expectorant is to be used for children only.

4.3 Contraindications

Known allergy to one of the ingredients of Nasodyne and particularly to antihistamines or parabens; former or recent agranulocytosis; urination difficulties due to the prostate gland or another cause; certain forms of glaucoma. Children <2 years (due to the potential for fatal respiratory depression).
Nasodyne must generally not be used, unless otherwise indicated by the doctor, in combination with sultopride

4.4 Special warnings and precautions for use

Nasodyne contains alcohol. The alcohol content of this syrup is 3.09% i.e, 122 mg of alcohol/measuring spoon (5 mL); 366 mg of alcohol/tablespoon (15 mL).

In the event of long-standing disease of the liver or kidneys, consult the doctor for dosage adjustment.
Intake of Nasodyne requires a medical opinion: In the event of ulcer of the stomach or duodenum; serious heart disease; epilepsy; in children, in the event of asthma or gastroesophageal reflux; in the elderly, who are predisposed to constipation, dizziness or drowsiness presenting with prostatic disorders.
Inform the doctor before initiating treatment.
Refrain from alcoholic beverages or drugs containing alcohol throughout the duration of treatment.
Preferably avoid exposure to sunlight during the treatment.
In the event of diabetes mellitus or a low-sugar diet, take the sugar content of the syrup into account in the daily ration: 3 g of sugar/measuring spoon and 9 g of sugar/tablespoon.
If in doubt, do not hesitate to ask for the doctor's or pharmacist's advice.
When to Seek Medical Advice: Consult a doctor when: Experiencing long-standing disease of the liver or kidneys; experiencing one of the situations described previously; pregnant or breastfeeding; experiencing side effects of Nasodyne (see Side Effects); have taken Nasodyne for a few days in a row and the condition is not improving; if cough becomes productive or is accompanied by fever; have taken an overdose of Nasodyne.
List of excipients which must be specified for the risk-free use of Nasodyne in certain patients: Methyl parahydroxybenzoate, sucrose (3 g/measuring spoon) and alcohol (122 mg/measuring spoon).

4.5 Interaction with other medicinal products and other forms of interaction

In order to prevent possible interactions between several drugs and in particular, sultopride, systematically report any on-going treatment to the doctor or pharmacist.
Nasodyne contains promethazine (an antihistamine) and carbocisteine. Avoid other products containing these drugs so that the maximum recommended dose for each drug is not exceeded.
If you use other drugs or over the counter products at the same time, the effects Nasodyne Syrup may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that your doctor can help you prevent or manage drug interactions. Nasodyne Syrup may interact with the following drugs and products:
Acetaminophen
Aminoglycoside Antibiotics
Aminoglycosides
Amiodarone
Anagrelide
Bepridil
Bupropion
Citalopram
Colistin
Dolasetron

4.6 Pregnancy and lactation

Use in pregnancy: If the patient becomes pregnant during treatment, consult the doctor. The doctor will decide whether it is necessary to maintain treatment through the pregnancy.

Towards the end of pregnancy, misuse of Nasodyne may have adverse effects on the newborn. In consequence, always ask the doctor's or pharmacist's advice before using this drug and never exceed the prescribed dose and treatment duration.

Use in lactation: Nasodyne is excreted in breast milk. Do not take this drug if breastfeeding.

Use in children: Nasodyne should be used with caution in children ≥2 years.

4.7 Effects on ability to drive and use machines

Effects on the Ability to Drive or Operate Machinery: Attention, particularly that of drivers and machine users, is drawn to the possibility of drowsiness associated with the use of Nasodyne. This phenomenon is accentuated by consumption of alcoholic beverages.

4.8 Undesirable effects

Like all active products, Nasodyne may induce more or less unpleasant effects. Some of these effects require immediate discontinuation of treatment and consultation with a doctor.
Allergic Reactions: Skin rash type (erythema, eczema, purpura, urticaria); asthma attacks; Quincke's edema; anaphylactic shock; phenomena of sensitization of the skin under the action of sunlight; marked reduction in the white blood cells which give rise to development or recurrence of fever whether or not accompanied by signs of infection; abnormal decrease in the platelets in the blood which may give rise to bleeding from the nose or gums.
Other adverse effects are more frequent: Drowsiness, reduced alertness more marked at the start of treatment; memory or concentration disorders, dizziness (more frequent in elderly subjects): Motor incoordination, tremor; confusion, hallucinations, dry mouth, visual disorders, urinary retention, constipation, palpitations, fall in blood pressure.
Possibility of gastrointestinal intolerance phenomena (stomach pains, nausea, diarrhea). If these occur, a reduction of dosage is recommended.
More rarely, but particularly in infants, abnormal excited behaviour is observed including agitation, nervousness, insomnia.
Inform the doctor or pharmacist of any unwanted and unpleasant effect not indicated previously.

4.9 Overdose

In case of accidental overdosage, stop the treatment and consult the doctor immediately.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Carbocisteine (Nasodyne), a derivative of acetylcysteine, is a mucoregulating agent. Its major action is thought to be on the metabolism of mucus-producing cells. The mucus produced under the influence of Carbocisteine (Nasodyne) has an increased content of the less viscous sialomucin and a reduced content of the highly viscous fucomucin. Sialomucins influence the rheological properties of mucus and may also, through the inhibition of kinins, reduce or prevent bronchial inflammation and bronchospasm.
Carbocisteine (Nasodyne) is rapidly and well-absorbed after oral administration. Following oral administration of 1.5 g Carbocisteine (Nasodyne), peak serum concentration of 13-16 mg/L was reached in 1-2 hrs. Plasma t½ was 1.5-2 hrs. Carbocisteine (Nasodyne) penetrates well into lung tissues and respiratory mucus suggesting local action. Carbocisteine (Nasodyne) undergoes acetylation, decarboxylation and sulfoxidation. Majority of Carbocisteine (Nasodyne) is excreted unchanged in the urine.

5.2 Pharmacokinetic properties

Pharmacokinetics of a drug can be defined as what body does to the drug after it is taken. The therapeutic result of the medicine depends upon the Pharmacokinetics of the drug. It deals with the time taken for the drug to be absorbed, metabolized, the process and chemical reactions involved in metabolism and about the excretion of the drug. All these factors are essential to deciding on the efficacy of the drug. Based on these pharmacokinetic principles, the ingredients, the Pharmaceutical company decides dose and route of administration. The concentration of the drug at the site of action which is proportional to therapeutic result inside the body depends on various pharmacokinetic reactions that occur in the body.
Carbocisteine (Nasodyne) enhances respiration by acting as an agonist of peripheral chemoreceptors located on the carotid bodies.

Absorption: Well absorbed after oral or IM dose. Time to peak plasma concentration: 2-3 hr.

Distribution: Crosses the blood-brain barrier and the placenta, and enters breast milk. Plasma protein binding: 76-93%.

Metabolism: Extensive; mainly to Promethazine (Rhinathiol Promethazine) sulfoxide and also to *N*-desmethylpromethazine.

Excretion: Via urine and bile, as metabolites. Elimination half-life: 5-14 hr.

5.3 Preclinical safety data

No additional data of relevance to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Each 5 mL of syrup contains:
Carbocisteine 100mg
Promethazine HCl 2.5mg
Granulated sugar 3000mg
Methyl hydroxyl benzoate 7.5mg
Liquid sorbitol (non-crystallizing) 1000mg
Sodium hydroxide 24mg
Citric acid monohydrate 1mg
Caramel 2.5mg
Ethanol 96% 200mg

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

6.6 Special precautions for disposal <and other handling>

To be destroyed by NAFDAC enforcement unit.

7. <APPLICANT/SUPPLIER>

May & Baker Nigeria Plc.
1 May & Baker Avenue, Off Idiroko, Opposite covenant University
Ota, Ogun State

8. WHO PREQUALIFICATION REFERENCE NUMBER

9. DATE OF REVISION OF THE TEXT

19/11/2019