Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Guaifenesin 200 mg syrup in sachet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml sachet contains 200 mg guaifenesin
Excipient(s) with known effect

Ethanol	approx 400 mg/sachet
Glucose	6984 mg/sachet
Sucrose	1998 mg/sachet
Sodium benzoate	10 mg/sachet
Propylene glycol maximum	79 mg/sachet

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup in sachet

Clear yellow-brown coloured syrup.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Guaifenesin 200 mg syrup in sachet indicated for the symptomatic relief of productive cough in adults and adolescents of 12 years and above.

4.2 Posology and method of administration

Posology

Adults andadolescents of12 years andabove:

One 10ml sachet (200 mg guaifenesin) 4 times a day.
Maximum daily dose: 4 sachets (800 mg guaifenesin)

Paediatric population

The safety and efficacy of Guaifenesin 200 mg syrup in sachet in children under 12 years has not yet been established
No data are available

Elderly:
As per adults.

Hepatic/renalimpairment:
Caution should be exercised in severe hepatic and severe renal impairment (see Section 5.2).

If cough worsens or persists for more than 5 days, tends to recur, or is accompanied by a fever, rash, or persistent headache, a physician should be consulted.

Method of administration:

Oral route. Tear the sachet open and put the solution directly in the mouth.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

This product should not be used for persistent or chronic cough, such as occurs with asthma, or where cough is accompanied by excessive secretions, unless directed by a physician.

A persistent cough may be a sign of a serious condition. If cough worsens or persists for more than 5 days, tends to recur, or is accompanied by a fever, rash, or persistent headache, a physician should be consulted.

Caution should be exercised when using the product in the presence of severe renal or severe hepatic impairment (see Section 5.2). The concomitant use of cough suppressants is not recommended.

This product contains ethanol, glucose, sucrose, sodium benzoate, propylene glycol and sodium.

This medicine contains 400 mg of alcohol (ethanol) in each sachet which is equivalent to 4 g/dl (4 % w/v). The amount in each sachet of this medicine is equivalent to 10 ml beer or 4 ml wine.

The ethanol content should be taken into account in breast-feeding women and high-risk groups such as patients with liver disease, epilepsy or suffering from alcoholism.

This medicine contains 7 g glucose per sachet. This should be taken into account in patients with diabetes mellitus.
Patients with rare glucose-galactose malabsorption should not take this medicine.

This medicine contains 2 g sucrose per sachet. This should be taken into account in patients with diabetes mellitus.
Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This medicine contains 10 mg benzoate salt in each sachet which is equivalent to 1 mg/ml.

This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially 'sodium-free'.

This medicine contains 79 mg propylene glycol in each sachet which is equivalent to 7.9 mg/ml.

4.5 Interaction with other medicinal products and other forms of interactions

If urine is collected within 24 hours of a dose of this product a metabolite of guaifenesin may cause a colour interference with laboratory determinations of urinary 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).
Expectorants such as guaifenesin should not be combined with cough suppressants in the treatment of cough since the combination may counteract each other and patients may be exposed to unnecessary adverse effects.

No interaction studies have been performed showing an interaction with guaifenesin.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no or limited amount of data from the use of guaifenesin in pregnant women. Guaifenesin 200 mg syrup in sachet is not recommended during pregnancy and in women of childbearing potential not using contraception. Available data on animal study showed guaifenesin was associated with developmental toxicity (see section 5.3).

Breast-feeding
Guaifenesin is excreted in breast milk in small amounts. There is insufficient information on the effects of guaifenesin in new-borns/infants. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Guaifenesin 200 mg syrup in sachet therapy, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility

There is insufficient information available to determine whether guaifenesin has the potential to impair fertility.

4.7 Effects on ability to drive and use machines

This Product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The following side effects may be associated with the use of guaifenesin:

SOC	Frequency Category	Adverse Event Term
Immune System Disorders	Not Known	Anaphylactic reactions Hypersensitivity reactions including pruritus and urticaria
Gastrointestinal Disorders	Not Known	Abdominal pain upper, diarrhoea, nausea, vomiting
Skin and Subcutaneous Tissue Disorders	Not Known	Rash

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 via the national reporting system:
HPRA Pharmacovigilance
Website: www.hpra.ie

4.9 Overdose

Symptoms andsigns

The symptoms and signs of overdose may include abdominal pain, nausea and drowsiness.

When taken in excess, guaifenesin may cause renal calculi.

Management

Treatment should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Cough and cold preparations, Expectorants. ATC Code: R05CA03

Mechanism of action:

This Product is thought to exert its pharmacological action by stimulating receptors in the gastric mucosa. This increases the output from secretory glands of the gastrointestinal system and reflexly increases the flow of fluids from glands lining the respiratory tract. The result is an increase in volume and decrease in viscosity of bronchial secretions. Other actions may include stimulating vagal nerve endings in bronchial secretory glands and stimulating certain centres in the brain, which in turn enhance respiratory fluid flow. Guaifenesin produces its expectorant action within 24 hours.

5.2 Pharmacokinetic properties

Absorption

Guaifenesin is well absorbed from the gastro-intestinal tract following oral administration, although limited information is available on its pharmacokinetics. After the administration of 600 mg guaifenesin to healthy adult volunteers, the Cmax was approximately 1.4 ug/ml, with tmax occurring approximately 15 minutes after drug administration.

Distribution

No information is available on the distribution of guaifenesin in humans.

Biotransformation and elimination

Guaifenesin appears to undergo both oxidation and demethylation followed by excretion in the urine. Approximately 40% of a dose is excreted as the metabolite beta-2-methoxyphenoxy-lactic acid in the urine within 3 hours.

Following an oral dose of 600 mg guaifenesin to 3 healthy male volunteers, the t½ was approximately 1 hour and the drug was not detectable in the blood after approximately 8 hours.

Hepatic and renal impairment

No formal studies of guaifenesin in patients with hepatic or renal impairment have been conducted and no data are available for any grade of impairment.

5.3 Preclinical safety data

Carcinogenicity

There is insufficient information available to determine whether guaifenesin has carcinogenic potential.

Mutagenicity

There is insufficient information available to determine whether guaifenesin has mutagenic potential.

Teratogenicity

There is insufficient information available to determine whether guaifenesin has teratogenic potential. In a study with limited information guaifenesin showed developmental toxicity at therapeutic and higher doses.

Fertility

There is insufficient information available to determine whether guaifenesin has the potential to impair fertility.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium citrate (E331)
Citric acid monohydrate
Carbomer
Glycerol (E422)
Ethanol
Glucose, liquid
Sucrose
Sucralose (E955)
Sodium benzoate (E211)
Caramel (E150)
Purified water

Levomenthol flavour
Honey flavour
Lemon flavour
Cooling flavour
Tingling flavour
Bitterness blocking flavour
Hot mix flavour
Non-alcohol enhancer flavour

(Flavours contain Propylene glycol and other flavouring ingredients)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

The sachet is composed of PET, Aluminium and PE.

Available in packs of 12 or 20 sachets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Johnson & Johnson (Ireland) Limited
Airton Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0330/059/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th January 2022

10 DATE OF REVISION OF THE TEXT