SCHEDULING STATUS: S1

1 NAME OF THE MEDICINE

PHOLTEX MUCUS 200, 200 mg, effervescent tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each effervescent tablet contains 200 mg N-Acetylcysteine.

Contains sugar (sorbitol 0,28 % *m/m*) and artificial sweeteners (saccharin sodium 0,6 % *m/m* and sodium cyclamate 0,8 % *m/m*).

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent tablets

Round, flat, white or almost white tablet with orange smell.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

N-Acetylcysteine is used as a mucolytic, of non-infective secretions in cystic fibrosis and in respiratory conditions.

4.2 Posology and method of administration

Posology

As a mucolytic:

Adults: 200 mg (1 effervescent tablet) three times daily.

Paediatric population

Children:

2 – 6 years: 200 mg (1 effervescent tablet) twice daily.

Method of administration

The effervescent tablets should be dissolved in a glass of water before use.

4.3 Contraindications

Hypersensitivity to N-Acetylcysteine or any of the other ingredients (See section 6.1).

Safety during pregnancy and lactation has not been established. (See section 4.6).

It is not known whether N-Acetylcysteine is excreted in human milk. It is therefore not advised to administer **PHOLTEX MUCUS 200** to breastfeeding women. (See section 4.6).

4.4 Special warnings and precautions for use

N-Acetylcysteine should be used with caution in asthmatic patients and since mucolytics may disrupt the gastric mucosal barrier, it should be used with caution in patients with a history of peptic ulceration.

Patients with the rare hereditary condition of sorbitol intolerance should not take **PHOLTEX MUCUS 200**.

4.5 Interaction with other medicines and other forms of interaction

No data on interaction studies are available.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

It is not known whether N-Acetylcysteine is excreted in human milk. It is therefore not advised to administer **PHOLTEX MUCUS 200** to breastfeeding women. (See section 4.3).

4.7 Effects on ability to drive and use machines

PHOLTEX MUCUS 200 does not impair your ability to drive or operate machinery, however caution should be exercised if drowsiness is experienced.

4.8 Undesirable effects

Nervous system disorders:

Less frequent: Headache, drowsiness.

Gastro-intestinal disorders:

Less frequent: Nausea, vomiting, stomatitis.

Respiratory, thoracic and mediastinal disorders:

Less frequent: Bronchospasm, rhinorrhoea.

Ear and labyrinth disorders:

Less frequent: Tinnitus.

Skin and subcutaneous tissue disorders:

Less frequent: Allergic dermatitis (skin rash or hives), urticaria.

Immune system disorders:

Less frequent: Anaphylaxis.

Other:

Less frequent: Chills and fever.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

See undesirable effects (section 4.8). Treatment should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 10.2.2 Medicines acting on the respiratory system – other.

ATC code: R05CB01 Mucolytics

Mechanism of action

N-Acetylcysteine is a mucolytic agent that reduces the viscosity of secretions probably by the splitting of disulphide bonds in mucoproteins.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid anhydrous

Sodium hydrogen carbonate

Sodium carbonate anhydrous

Sorbitol

Saccharin sodium

Sodium cyclamate

Orange spray dried flavour

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at or below 25 °C in a cool dry place. Protect from light.

The container must be tightly closed.

6.5 Nature and contents of container

Two white cylindrical polypropylene tubes each containing 10 effervescent tablets sealed with a polyethylene cap containing silica gel in a unit carton.

6.6 Special precautions for disposal

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd

15E Riley Road

Bedfordview

2007

8 REGISTRATION NUMBER

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5 August 2011

10 DATE OF REVISION OF THE TEXT

4 October 2022