SCHEDULING STATUS:

S1

PHOLTEX MUCUS 200 effervescent tablets

N-Acetylcysteine 200 mg

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

Read all of this leaflet carefully before you start taking PHOLTEX MUCUS 200 effervescent tablets.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **PHOLTEX MUCUS 200** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **PHOLTEX MUCUS 200** is and what it is used for
2. What you need to know before you take **PHOLTEX MUCUS 200**
3. How to take **PHOLTEX MUCUS 200**
4. Possible side effects
5. How to store **PHOLTEX MUCUS 200**
6. Contents of the pack and other information

1. What PHOLTEX MUCUS 200 is and what it is used for

PHOLTEX MUCUS 200 belongs to a group of medicines called “Medicines acting on the respiratory system – other”.

PHOLTEX MUCUS 200 is used as mucolytic (dissolves or breaks down mucus). It is used to treat chest (respiratory) conditions involving excessive or thickened mucus secretions.

2. What you need to know before you take PHOLTEX MUCUS 200

Do not take PHOLTEX MUCUS 200:

- if you are hypersensitive (allergic) to acetylcysteine or any of the other ingredients of **PHOLTEX MUCUS 200** (listed in section 6),
- if you are pregnant or breastfeeding (see section **Pregnancy and breast-feeding**).

Warnings and precautions

Take special care with PHOLTEX MUCUS 200:

- **PHOLTEX MUCUS 200** should be used with caution if you are asthmatic or if you have a history of stomach ulcers as **PHOLTEX MUCUS 200** may cause nausea or vomiting which may result in bleeding in your stomach.
- If an allergic reaction to **PHOLTEX MUCUS 200** occurs, stop taking the medicine and contact a doctor.

Other medicines and PHOLTEX MUCUS 200

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

No data on interaction studies are available.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

The safety of **PHOLTEX MUCUS 200** during pregnancy and breastfeeding has not been established. You are advised not to take **PHOLTEX MUCUS 200** if you are pregnant or breastfeeding (see section **2. What you need to know before you take PHOLTEX MUCUS 200**).

Driving and using machines

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

It is not always possible to predict to what extent **PHOLTEX MUCUS 200** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **PHOLTEX MUCUS 200** affects them.

PHOLTEX MUCUS 200 contains sorbitol

If you have been told that you have an intolerance to some sugars, you should not take **PHOLTEX MUCUS 200**

3. How to take PHOLTEX MUCUS 200

Do not share medicines prescribed for you with any other person.

Always take **PHOLTEX MUCUS 200** exactly as described in this leaflet or as your doctor, or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is as follows:

- The effervescent tablets should be dissolved in a glass of water before use.
- Children 2 – 6 years should take 200 mg (1 effervescent tablet), twice daily.
- Adults should take 200 mg (1 effervescent tablet), three times daily.

If you take more PHOLTEX MUCUS 200 than you should

See section **4. Possible side effects**.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take PHOLTEX MUCUS 200

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

PHOLTEX MUCUS 200 can have side effects.

Not all side effects reported for **PHOLTEX MUCUS 200** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **PHOLTEX MUCUS 200**, please consult your health care provider for advice.

If any of the following happens, stop taking **PHOLTEX MUCUS 200** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- anaphylaxis (skin rash, hives, itching, difficulty swallowing, puffiness or swelling of the eyelids or around the eyes, face, lips of tongue or fast heartbeat),
- bronchospasm (narrowing of the air passages, difficulty breathing, or shortness of breath).

These are all very serious side effects. If you have them, you may have had a serious reaction to **PHOLTEX MUCUS 200**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- runny nose,
- nausea,
- vomiting,
- inflammation of the inside of the mouth,
- headache,
- drowsiness,
- ringing in the ears,
- skin rash,
- itchy skin,
- chills,
- fever.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **PHOLTEX MUCUS 200**.

5. How to store PHOLTEX MUCUS 200

Store in a cool, dry place, at or below 25 °C protected from light. The container must be tightly closed.

Store all medicines out of reach of children.

Do not use after the date, which is stamped on the pack.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicine in drains or sewage systems (e.g. toilets).

6. Contents of the pack and other information

What PHOLTEX MUCUS 200 contains

- The active substance is N-Acetylcysteine.
- The other ingredients are citric acid anhydrous, sodium hydrogen carbonate, sodium carbonate anhydrous, sorbitol, orange flavour and the sweeteners saccharin sodium and sodium cyclamate.

What PHOLTEX MUCUS 200 looks like and contents of the pack

PHOLTEX MUCUS 200 is a round, flat, white or almost white tablet with orange smell.

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

Holder of Certificate of Registration

iNova Pharmaceuticals (Pty) Ltd

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Bedfordview

2007

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Access to the corresponding Professional Information

Full professional Information can be found at www.inovapharma.co.za or can be obtained upon request from iNova Pharmaceuticals.