PATIENT INFORMATION LEAFLET

for MUCATAK 200 EFFERVESCENT TABLETS

SCHEDULING STATUS: S1

MUCATAK 200 EFFERVESCENT TABLETS (200 mg, effervescent tablets)

Acetylcysteine

Contains sweetener: Each effervescent tablet contains 10 mg aspartame.

Sugar free.

Read all of this leaflet carefully because it contains important information for you

MUCATAK 200 EFFERVESCENT TABLETS is available without a doctor's prescription, for you or your child to treat a mild illness. Nevertheless, you or your child still need to use MUCATAK 200 EFFERVESCENT TABLETS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share MUCATAK 200 EFFERVESCENT TABLETS with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You or your child must see a doctor if your symptoms worsen or do not improve after 14 days.

What is in this leaflet

1. What MUCATAK 200 EFFERVESCENT TABLETS is and what it is used for
2. What you need to know before you or your child take MUCATAK 200 EFFERVESCENT TABLETS
3. How to take MUCATAK 200 EFFERVESCENT TABLETS
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5. How to store MUCATAK 200 EFFERVESCENT TABLETS
6. Contents of the pack and other information.

1. What MUCATAK 200 EFFERVESCENT TABLETS is and what it is used for

MUCATAK 200 EFFERVESCENT TABLETS is a mucolytic agent that helps to thin and loosen non-infected phlegm in the airways of patients with respiratory conditions or cystic fibrosis.

2. What you need to know before you take MUCATAK 200 EFFERVESCENT TABLETS

Do not take MUCATAK 200 EFFERVESCENT TABLETS:

- If you or your child are hypersensitive (allergic) to acetylcysteine or to any of the other ingredients of MUCATAK 200 EFFERVESCENT TABLETS (listed in section 6).
- You must not give MUCATAK 200 EFFERVESCENT TABLETS to children below the age of 2 years.
- If you are pregnant or breastfeeding.
- If you or your child have an ulcer (sore) in your stomach or intestine.

Warnings and precautions

Take special care with MUCATAK 200 EFFERVESCENT TABLETS:

Before taking MUCATAK 200 EFFERVESCENT TABLETS, tell your doctor or pharmacist:

- If you or your child are asthmatic.
- If you are an elderly person and have a respiratory disease.
- If you or your child have a history of stomach ulcers.
- If you or your child has an allergic skin reaction (symptoms include redness, inflamed or swollen skin, blisters, hives, and sometimes peeling or pain).
- If you or your child are intolerant to histamine, MUCATAK 200 EFFERVESCENT TABLETS may not be suitable for you because it affects how histamine is broken down in your body. The most common symptoms of histamine intolerance are headaches, runny nose and itching

Children

MUCATAK 200 EFFERVESCENT TABLETS must not be given to children under 2 years of age.

Other medicines and MUCATAK 200 EFFERVESCENT TABLETS

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

Tell your doctor if you or your child are taking any of the following:

- Cough relieving medicines, as suppression of the cough reflex may result in build up and congestion of phlegm which cannot be coughed up. Consult your doctor or pharmacist before using MUCATAK 200 EFFERVESCENT TABLETS with a cough relieving medicine.
- Oral antibiotics (medicines used to treat infections e.g. tetracyclines) should be taken 2 hours apart from one another.
- Nitroglycerin (used to treat angina symptoms such as chest pain).
- Activated charcoal (used in the treatment of overdose).

MUCATAK 200 EFFERVESCENT TABLETS can affect certain urine and salicylate (anti-inflammatory medicine) tests.

Pregnancy, breastfeeding and fertility

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.

You should not take MUCATAK 200 EFFERVESCENT TABLETS if you are pregnant or breastfeeding as the safety and/or efficacy of MUCATAK 200 EFFERVESCENT TABLETS during pregnancy and breastfeeding has not been established.

The effects of MUCATAK 200 EFFERVESCENT TABLETS on fertility is unknown.

Driving and using machines

MUCATAK 200 EFFERVESCENT TABLETS can cause headache, convulsions and blurred vision (see section 4) which may affect your ability to drive a vehicle or use machines.It is not always possible to predict to what extent MUCATAK 200 EFFERVESCENT TABLETS may interfere with

your daily activities. You should ensure that you do not engage in the above activities until you know how MUCATAK 200 EFFERVESCENT TABLETS affects you.

MUCATAK 200 EFFERVESCENT TABLETS contains aspartame

Aspartame is a source of phenylalanine. Aspartame may be harmful for people with phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

MUCATAK 200 EFFERVESCENT TABLETS contains sodium

This medicine contains 146,4 mg sodium (main component of cooking/table salt) in each effervescent tablet.

This is equivalent to 7,3 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take MUCATAK 200 EFFERVESCENT TABLETS

Do not share medicines prescribed for you or your child with any other person. Always take MUCATAK 200 EFFERVESCENT TABLETS exactly as described in this leaflet or as your doctor or pharmacist has told you.

You should always check with your doctor or pharmacist if you are unsure.

If you or your child has the impression that the effect of MUCATAK 200 EFFERVESCENT TABLETS is too strong or too weak, talk to your doctor or pharmacist.

Before or your child takes MUCATAK 200 EFFERVESCENT TABLETS, dissolve the effervescent tablet in one glass of water. Then drink the whole contents of the glass.

Unless otherwise prescribed by your doctor, the usual dose is:

Adults and adolescents from 14 years of age:

1 effervescent tablet 2 to 3 times daily (equivalent to 400 to 600 mg N-acetylcysteine/day).

Children from 6 to 14 years of age:

1 effervescent tablet twice daily (equivalent to 400 mg N-acetylcysteine/day).

Children from 2 to 5 years of age:

½ effervescent tablet 2 to 3 times daily (equivalent to 200 to 300 mg N-acetylcysteine/day).

Do not mix MUCATAK 200 EFFERVESCENT TABLETS with other medicines.

If you or your child takes more MUCATAK 200 EFFERVESCENT TABLETS than you should

Symptoms of an overdose include nausea, vomiting, diarrhoea (see section 4). Small children are at risk of increased mucus secretions. In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you or your child forgets to take MUCATAK 200 EFFERVESCENT TABLETS

If you or your child misses a dose, take it as soon as possible. However, if it is almost time for your or your child's next dose, skip the missed dose and go back to your or your child's regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

MUCATAK 200 EFFERVESCENT TABLETS can have side effects. Not all side effects reported for MUCATAK 200 EFFERVESCENT TABLETS are included in this leaflet. Should your or your child's general health worsen or if you or your child experience any untoward effects while taking MUCATAK 200 EFFERVESCENT TABLETS, please consult your health care provider for advice.

If any of the following happens, stop taking or giving MUCATAK 200 EFFERVESCENT TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, tongue, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you or your child has them, you or your child may have

had a serious reaction to MUCATAK 200 EFFERVESCENT TABLETS. You or your child may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Skin reactions such as toxic epidermal necrolysis (TEN) and Stevens-Johnson syndrome (SJS).These reactions can be life-threatening and are characterised by redness, inflamed or swollen skin, blisters, hives, and sometimes peeling or pain.
- Convulsions (fits).
- Cardiac arrest (your heart stops beating).
- Changes in the way your or your child's heart beats, for example if you notice it beating faster.
- Coughing up of blood
- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

These are all serious side effects. You or your child may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Hives, swelling below the surface of the skin.
- Headache, weakness, confusion.
- Buzzing, roaring, clicking hissing or humming sound in the ears.
- Runny nose.
- Nausea (feeling sick) vomiting (being sick), diarrhoea (frequent, loose, watery stools), stomach pain.
- Heartburn, indigestion, pain and swelling inside the mouth.
- Fever, chills.
- *Side effects with frequency unknown*
- Blurred vision.
- Reddening of skin, sweating.

- Joint pain.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of MUCATAK 200 EFFERVESCENT TABLETS.

5. How to store MUCATAK 200 EFFERVESCENT TABLETS

- Store all medicines out of the reach of children.
- Store at or below 30 °C.
- Store in the original container and protect from light.
- To protect the effervescent tablets from moisture, keep the tube closed.
- Do not use MUCATAK 200 EFFERVESCENT TABLETS after the expiry date stated on the carton and tube.
- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MUCATAK 200 EFFERVESCENT TABLETS contains

The active substance is acetylcysteine. Each MUCATAK 200 EFFERVESCENT TABLETS effervescent tablet contains 200mg acetylcysteine.

The other ingredients are citric acid anhydrous, lemon aroma, liquid paraffin or magnesium stearate and sodium hydrogen carbonate.

What MUCATAK 200 EFFERVESCENT TABLETS looks like and contents of the pack

White, flat, round tablets, break-line on one side, characteristic odour of acetylcysteine and lemon

aroma. Diameter: 18 mm; Height: 4,1 – 4,5 mm.

White aluminium or polypropylene (plastic) tubes with an inner white lining. Each tube is sealed with a white polyethylene (plastic) stopper which has an integrated silica gel adsorbent (integrated into the stopper). Each tube is contained in an outer cardboard carton and contains either 10, 15, 20 or 25 effervescent tablets.

Holder of certificate of registration

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