PATIENT INFORMATION LEAFLET FOR MUCATAK® 200 EFFERVESCENT TABLETS

Scheduling Status: **S1**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

MUCATAK® 200 Effervescent Tablets

Acetylcysteine 200 mg per effervescent tablet

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

MUCATAK 200 is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you 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** with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

WHAT MUCATAK 200 CONTAINS:

The active substance is acetylcysteine. Each **MUCATAK 200** Effervescent Tablet contains 200 mg acetylcysteine.

The other ingredients are: Sodium hydrogencarbonate, citric acid (anhydrous) lemon aroma, liquid paraffin, magnesium stearate and purified water.

Contains aspartame as sweetening agent.

Sugar free.

WHAT MUCATAK 200 IS USED FOR:

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

BEFORE YOU TAKE MUCATAK 200:

Do not take MUCATAK 200:

- If you are hypersensitive (allergic) to acetylcysteine or to any of the other ingredients of **MUCATAK 200**.
- Do not give **MUCATAK 200** to children below the age of 2 years.

Take special care with MUCATAK 200:

Before taking **MUCATAK 200**, tell your doctor or pharmacist:

- If you are asthmatic.
- If you are an elderly person and have a respiratory disease.
- If you have a metabolic disorder known as phenylketonuria. **MUCATAK 200** contains aspartame as a sweetening agent. Aspartame may be harmful for people with phenylketonuria.
- If you have a history of, or are suffering from a stomach/intestinal ulcer.

Taking MUCATAK 200 with food and drink:
MUCATAK 200 should be taken after mealtimes.

Pregnancy and Breastfeeding:
The safety and/or efficacy of **MUCATAK 200** during pregnancy and breastfeeding has not been established.
You should not breastfeed your baby if you are taking **MUCATAK 200.**
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery:
MUCATAK 200 may affect your ability to drive or use machinery (see "Side effects").

Important information about some of the ingredients of MUCATAK 200:
MUCATAK 200 is sugar free. It contains aspartame as a sweetening agent. Aspartame may be harmful for people with phenylketonuria.

Taking other medicines with MUCATAK 200:
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
MUCATAK 200 should not be taken together with a cough relieving medicine, 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** with a cough relieving medicine.
MUCATAK 200 and oral antibiotics e.g. tetracyclines should be taken 2 hours apart from one another.

HOW TO TAKE MUCATAK 200:
Always take **MUCATAK 200** exactly as your doctor has instructed you.
You should always check with your doctor or pharmacist if you are unsure.
If you have the impression that the effect of **MUCATAK 200** is too strong or too weak, talk to your doctor or pharmacist.

Before taking **MUCATAK 200**, 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:
As a mucolytic:
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) for a maximum treatment period of 14 days.
Children from 6 to 14 years of age: 1 effervescent tablet twice daily (equivalent to 400 mg N-acetylcysteine/day) for a maximum treatment period of 14 days.
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) for a maximum treatment period of 14 days.

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

If you take more MUCATAK 200 than you should:
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take MUCATAK 200:
If you miss a dose, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS:
MUCATAK 200 can have side effects.
Not all side effects reported for **MUCATAK 200** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **MUCATAK 200**, please consult your doctor, pharmacist or other healthcare professional for advice.

Stop taking **MUCATAK 200** and tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
Allergic reactions such as skin rash, itching, swelling of the lips, tongue and throat, breathing difficulty and dizziness.
These are all serious side effects. You may need urgent medical attention.

Tell your doctor immediately if you notice any of the following:

Headache, fever, chills, a ringing sensation in the ears, blurred vision, fits, loss of consciousness (fainting/syncope), coughing up blood, runny nose, nausea, vomiting, mouth sores, abdominal pain and diarrhoea.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF MUCATAK 200:
Store all medicines out of reach of children.
Store at or below 25 °C in the original container and protect from light.
To protect the tablets from moisture, please keep the tube closed.
Do not use this medicine 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).

PRESENTATION OF MUCATAK 200:
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 25 effervescent tablets.

IDENTIFICATION OF MUCATAK 200:
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.

REGISTRATION NUMBER:
44/10.1/0927

NAME AND ADDRESS OF REGISTRATION HOLDER:
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DATE OF PUBLICATION:
26 October 2012.
20 April 2017.

® – **MUCATAK** is a registered trademark of Actor Pharma (Pty) Ltd

[1] Company Registration No: 2008/008787/07

Namibia:	
Registration number:	12/10.1/0285
Scheduling status:	NS1

MUC200_PIL_02_11.2017