Applicant: Aurogen South Africa (Pty) Ltd
Product Name: UKASTYN
Dosage form and strength: Each effervescent tablet contains Acetylcysteine 200 mg and 600 mg.

Approved Patient Information Leaflet

SCHEDULING STATUS

S1

PATIENT INFORMATION LEAFLET

UKASTYN 200 mg, Effervescent tablets.

UKASTYN 600 mg, Effervescent tablets.

Acetylcysteine

Contains Sugar: Lactose 825,9 mg and 1919,5 mg

Contains Sweetener: Aspartame 3 mg and 15 mg

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

UKASTYN is available without a doctor's prescription. Nevertheless, you still need to use **UKASTYN** carefully to get the best results from it.

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

What is in this leaflet:

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1. What UKASTYN is and what it is used for

- **UKASTYN** contains the active ingredient acetylcysteine. It dissolves thick mucous (phlegm) in the respiratory tract and relieves tight chest conditions.

2. What you need to know before you take UKASTYN

Do not take UKASTYN:

- If you are hypersensitive (allergic) to acetylcysteine or to any of the other components of **UKASTYN** tablets (see "WHAT **UKASTYN** CONTAINS").
- If you are pregnant.
- Do not give **UKASTYN** effervescent tablets to children under two years of age.

Warnings and precautions with UKASTYN

Talk to your doctor before taking **UKASTYN**

- If you have asthma.
- If you have a history of stomach ulcers.

Take special care with UKASTYN tablets:

- If you have notice any changes to your skin such as those seen in Stevens-Johnson syndrome and Lyell's syndrome, which is characterised by severe blisters and bleeding in the lips, eyes, mouth, nose and genitals or fever, chills, aching muscles and generally feeling unwell. Stop treatment and seek medical advice immediately.
- If you experience difficulty breathing, stop treatment and seek medical advice.
- If you experience nausea and vomiting. Seek medical advice.
- If you have histamine intolerance. If you are not able to tolerate food and drinks that contain large amounts of histamines, **UKASTYN** may not be suitable for you, because it affects how histamines are broken down in the body. The most common symptoms of histamine intolerance are headaches, runny nose and itching.

As the thick phlegm becomes more fluid, its volume will increase, especially at the beginning of the treatment. If you are unable to efficiently cough up this fluid phlegm, you must consult a doctor so that

adequate measures can be taken to remove the phlegm.

Other medicines and UKASTYN

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

Do not take **UKASTYN** with cough suppressants (antitussives) unless under careful diagnosis and advice from your doctor, as this may cause an accumulation of mucous in the airway.

Do not take **UKASTYN** tablets together with any antibiotics, as this may alter the effectiveness of the antibiotic Allow an interval of at least two hours between the antibiotics and **UKASTYN** tablets.

Do not take **UKASTYN** with activated charcoal, as this may reduce the effects of **UKASTYN.**

Do not take **UKASTYN** with nitroglycerin (used for heart failure, high blood pressure and to treat and prevent chest pain) as it may cause your blood pressure to drop.

Consult your doctor prior to use if you are taking carbamazepine (for epilepsy) as **UKASTYN** may alter the effects of carbamazepine.

Tell your doctor prior to undergoing any laboratory tests while take **UKASTYN.**

Dissolving **UKASTYN** with other medicines is not recommended.

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. Do not take **UKASTYN** if:

- You are pregnant,
- You are breastfeeding.

Driving and using machines

UKASTYN has no known influence on the ability to drive or use machinery.

Important information about some of the ingredients of UKASTYN

UKASTYN contains lactose (some form of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

UKASTYN contains sodium, it may effect blood pressure. Before taking **UKASTYN**, please consult your doctor for advice if you have any blood pressure related issues.

UKASTYN contains aspartame per effervescent tablet.
Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take UKASTYN

Do not share medicines prescribed for you with any other person. Always take **UKASTYN** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Before taking **UKASTYN** tablets dissolve the effervescent tablet in one glass of water and drink the whole contents of the glass.
You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of **UKASTYN** tablets is too strong or too weak, talk to your doctor or pharmacist.

Do not use **UKASTYN** tablets continuously for more than 14 days without consulting a doctor.

The usual doses are:

Children 2 to 5 years:

UKASTYN 200 mg: ½ (half) an effervescent tablet 2 to 3 times daily (equivalent to 200 to 300 mg acetylcysteine/day).

Children 6 to 14 years:

UKASTYN 200 mg: 1 effervescent tablet twice daily (equivalent to 400 mg acetylcysteine/day).

Adults and children older than 14 years:

UKASTYN 200 mg: 1 effervescent tablet 2 to 3 times daily (equivalent to 400 to 600 mg acetylcysteine/day).

UKASTYN 600 mg: ½ effervescent tablet twice daily or 1 effervescent tablet once daily (equivalent to 600 mg acetylcysteine per day).

Do not use **UKASTYN** tablets continuously for more than 14 days without consulting a doctor.

If you take more UKASTYN 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 missed a dose of UKASTYN

If you forget to take **UKASTYN**, take it as soon as you remember.

Do not take a double or larger dose to make up or the forgotten individual doses.

4. Possible side effects

UKASTYN can have side effects.

Not all side effects reported for **UKASTYN** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **UKASTYN**, please consult your doctor, pharmacist or other healthcare professional for advice.

Stop taking UKASTYN and seek medical help immediately if you have any of the following allergic reactions:

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

- Allergic reaction causing swelling of the face, lips, mouth, tongue or throat which may cause

difficulty in swallowing or breathing, rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **UKASTYN** tablets. You 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:

- Changes in the way your heart beats, for example, if you notice it beating faster.
- Low blood pressure.
- Difficulty breathing or fast breathing.

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Rash, itching, hives or swelling of the skin.
- Headache, convulsions (fits) or fainting.
- Buzzing, hissing, whistling, ringing or other persistent noise in the ears.
- Blurred vision.
- Increase in heart rate.
- Bleeding or increase in blood pressure.
- Stomach pain.
- Sores inside your mouth.
- Diarrhoea.
- Vomiting.
- Heartburn.
- Nausea.
- Skin reactions.
- Fever.

Side effects of unknown frequency:

- Indigestion.

If any of the side effects get serious, or if you experience one of the above –mentioned serious side effects, call the nearest doctor immediately. If you experience any side effects not listed 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. This includes any possible side effects not listed in this leaflet. You can also report side effects 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 this medicine.

5. How to store UKASTYN

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Store at or below 25 °C (room temperature).
- Do not remove blisters from the original carton until required for use.
- Keep HDPE containers tightly closed.
- Keep all medicines out of the reach and sight of children.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What UKASTYN contains

Acetylcysteine

Ascorbic acid

Citric acid

Sodium bicarbonate

Crospovidone

Lactose

Orange flavour

Peppermint flavour

Aspartame

Leucine

UKASTYN 200 mg are proposed to be marketed in the Polypropylene tube with moisture-proof LDPE assembling lid as a closure, will be further packed in preprinted cartons with package leaflet according to the approved pack size.

UKASTYN 600 mg are proposed to be marketed in the Blister pack will be further packed in preprinted cartons with package leaflet according to the approved pack size.

UKASTYN 600 mg are proposed to be marketed in the Polypropylene tube with moisture-proof LDPE assembling lid as a closure, will be further packed in preprinted cartons with package leaflet according to the approved pack size.

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Aurogen South Africa (Pty) Ltd

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53 Phillip Engelbrecht Avenue

Meyersdal, Ext. 12, 1448

Johannesburg

South Africa

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Registration number:

UKASTYN 200 mg: 56/10.3/0141.139

UKASTYN 400 mg: 56/10.3/0142.140

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