Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine 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.

SCHEDULNG STATUS **S4**

NAME, STRENGTH AND DOSAGE FORM:

BETAROXIME T 250 (Tablets)

BETAROXIME T 500 (Tablets)

1. WHAT BETAROXIME T CONTAINS?

BETAROXIME T 250: The active substance is cefuroxime 250 mg (as cefuroxime axetil) per tablet

BETAROXIME T 500: The active substance is cefuroxime 500 mg (as cefuroxime axetil) per tablet

The other ingredients are:

Hydrogenated Vegetable Oil, Cellulose, Microcrystalline (Avicel pH 102), Colloidal silicon dioxide (Aerosil 200), Croscarmellose Sodium, Sodium Lauril Sulfate

2. WHAT BETAROXIME T IS USED FOR?

BETAROXIME T belongs to a group of medicines known as cephalosporins which help the body fight infections by destroying certain bacteria that cause infection.

BETAROXIME T is used for the treatment of bacterial infections. These include infections of:

- throat and/or tonsils
- middle ear
- sinuses
- lower airways (bronchitis)
- urinary bladder
- In Lyme's disease (tick-borne disease caused by bacteria of class borrelia and characterized by fever, headache, fatigue and depression).

3. BEFORE YOU TAKE BETAROXIME T

Do not take BETAROXIME T

- You are hypersensitive (allergic) to cefuroxime axetil, other cephalosporin antibiotics or any of the other ingredients of **BETAROXIME T** listed at the end of the leaflet.

You have previously had an allergic reaction to penicillin

antibiotics (such as piperacillin, ticarcillin, ampicillin, amoxicillin, oxacillin, cloxacillin, flucloxacillin, nafcillin etc.); you may also be allergic to efuroxime axetil. You should be strictly monitored while taking this medicine.

TAKE SPECIAL CARE WITH BETAROXIME T

Please tell your doctor if you have any medical problems, especially if

- You have a history of gastro-intestinal (stomach-intestinal areas), especially ulcerative colitis (ulceration of the colon), or regional enteritis (inflammation of the intestine) or pseudomembranous ('false membrane') colitis
- Renal impairment – a smaller dose may be needed
- Porphyria – safety has not yet been evaluated.

Please inform your doctor before taking this medicine, even if these statements were applicable to you at any time in the past.

Laboratory Tests

It is recommended that either glucose oxidase or hexokinase methods be used to determine blood/plasma glucose levels in patients receiving **BETAROXIME T**.

This medicine may give false-negative test results with ferricyanide blood glucose test.

BETAROXIME T does not interfere in the alkaline picrate assay for creatinine. A false-positive Coombs reaction may appear in patients who receive large doses of **BETAROXIME T**.

TAKING BETAROXIME T WITH FOOD OR DRINK

BETAROXIME T should be taken half an hour after food for optimum absorption.

Pregnancy and breast-feeding

Safety and effectiveness of this medicine has not been evaluated in pregnant and nursing mothers. If you are pregnant or breast feeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional advice.

Be sure to tell your doctor immediately if you are pregnant, think you may be pregnant, or if you are planning to become pregnant. If you are pregnant or breast-feeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Be sure to tell your doctor immediately if you are breast-feeding.

Taking other medicines with BETAROXIME T

If you are also taking Probenecid, this may increase the levels of **BETAROXIME T** in the blood.

If you are taking other medicines on a regular basis including complementary or traditional medicines, the use of

BETAROXIME T with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

If you are taking medicines on a regular basis, concomitant use of the medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional, for advice.

If you are pregnant or breast feeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

4. HOW TO TAKE BETAROXIME T

Always take **BETAROXIME T** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults:

- ***Infections of the sinuses and/or lower airways (bronchitis)*: The usual dose is 250mg to be taken twice a day for 7 days**
- ***Infection of the urinary bladder*: The usual dose is 125mg to be taken twice a day for 7 days**
- ***Lyme's disease*: The usual dose is 500 mg to be taken twice a day for 20 days**

Children:

Cefuroxime axetil has not been studied in children less than 3 months of age.

- ***3 months to 2 years of age:* The usual dose is 125mg twice in a day.**
- ***Over 2 years of age:* The usual dose is 250mg twice a day.**

***Lyme's disease*: The usual dose for children over 12 years of age is 500 mg to be taken twice a day.**

BETAROXIME T **should be taken in 2 daily doses.**

Because of the bitter taste of cefuroxime axetil, the tablets should not be crushed.

BETAROXIME T **should be taken half an hour after food for optimum absorption.**

Duration of treatment

The usual course of treatment is 7 days, ranging from 5 to 10 days.

In case of Lyme's disease, the course of treatment is for 20 days.

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

Do not open the blister until ready to administer. For single tablet removal, open the package and peel back the foil on the blister to expose the tablet. Do not push the tablet through the foil because this could damage the tablet.

Even if you feel better, do not alter or discontinue the daily dose of **BETAROXIME T** without first consulting your doctor.

If you take more BETAROXIME T than you should

If you have taken more of cefuroxime axetil suspension than you should have, then you may experience fits. Treatment is symptomatic and supportive. The levels of BETAROXIME T in the blood may be reduced by dialysis.

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

If you cannot reach your doctor, go to the nearest hospital and take the pack with you.

If you forget to take BETAROXIME T

If you forget to take a dose, take it as soon as you remember, unless it is almost time for your next dose. Do not take a double dose to make up for forgotten individual doses. If you miss several doses, contact your doctor.

Never stop taking **BETAROXIME T** unless on your doctor's advice

If you have any further questions on the use of this product, ask your doctor or pharmacist.

Do not share medicines prescribed for you with others.

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

5. WHICH ARE THE POSSIBLE SIDE EFFECTS?

Like all medicines, **BETAROXIME T** can cause side effects, although not everybody gets them. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, **please tell your doctor or pharmacist.**

Frequent side effects: Eosinophilia (Condition in which the number of eosinophils in the blood is abnormally high), headache, Nausea (Uncomfortable sensation in the stomach along with an urge to vomit), diarrhoea (loose or watery stools), stomach cramps

Less frequent side effects: Vomiting, Hypersensitivity reactions (An excessive response by the body to a foreign substance) such as; skin rashes hives, itching, Severe skin reactions such as blisters, sores or ulceration. Pseudomembranous colitis (stomach cramps or pain, diarrhoea (watery and severe, which may also be bloody, fever).

The following side effects have been reported but its **frequency is unknown:** bronchospasm (constriction of the chest),

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

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF BETAROXIME T

Keep all medicines out of the reach and sight of children.

Store in the original package in order to protect from moisture.

Store in a cool (below 30 °C), dry place in original container. Protect from moisture.

Do not use BETAROXIME T after the expiry date which is stated on the blister and on the carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

7. PRESENTATION:

BETAROXIME T 250:

10's: Printed unit carton containing 1 blister pack (composed of either clear PVC / Aclar and silver coloured aluminium foil backing or silver coloured cold form laminate and silver coloured aluminium foil backing) of 10 tablets each.

BETAROXIME T 500:

10's: Printed unit carton containing 1 blister pack (composed of either clear PVC / Aclar and silver coloured aluminium foil backing or silver coloured cold form laminate and silver coloured aluminium foil backing) of 10 tablets each.

8. IDENTIFICATION:

BETAROXIME T 250:

A white to off white, uncoated, capsule shaped tablet, with “A33” debossed on one side and plain on the other side.

BETAROXIME T 500:

A white to off white, uncoated, capsule shaped tablet, with “A34” debossed on one side and plain on the other side.

9. REGISTRATION NUMBER

BETAROXIME T 250: 41/20.1.1/0138

BETAROXIME T 500: 41/20.1.1/0139

10. NAME AND BUSINESS ADDRESS OF APPLICANT:

UNICORN PHARMACEUTICALS (PTY) LTD
CORNER OF SEARLE & PONTAC STREETS
CAPE TOWN
SOUTH AFRICA

11. DATE OF PUBLICATION