1.5.5.2 Proposed Annotated Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: Schedule 3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL DOSAGE FORM:

UNAT® 2,5 mg

UNAT® 5 mg

UNAT® 10 mg

1.WHAT UNAT® CONTAINS

UNAT® Tablets contains torasemide as active ingredient.

The other ingredients are colloidal anhydrous silica, magnesium stearate, maize starch, lactose monohydrate.

2. WHAT UNAT® IS USED FOR

UNAT® contains a medicine called torasemide. This belongs to a group of medicines called 'diuretics' or 'water tablets'

- UNAT® 5 mg tablets are used to treat high blood pressure (hypertension).
- UNAT 5® mg and UNAT® 10 mg tablets are used to treat swelling caused by too much water in the body (oedema).

The tablets work by making you pass more water (urine).

3. BEFORE YOU TAKE UNAT®

Do not take this medicine if you are allergic (hypersensitive) to:

- Torasemide or any of the other ingredients of UNAT®.

- Similar medicines called 'sulphonylureas'. These are used to treat diabetes (high blood sugar). These medicines include chlorpropamide, glibenclamide. Glipizide and tolbutamide.

Do not take UNAT® if any of these apply to you. If you are not sure, talk to your doctor or pharmacist before taking UNAT®.

Do not take UNAT® if:

- You have kidney problems (renal failure).
- You have kidney problems that have been caused by medicines.
- You have liver problems.
- You have a low volume of blood (hypovolaemia).
- You have low blood pressure (hypotension).
- You have heart beat problems (cardiac arrhythmia).
- You are taking an antibiotic called an "aminoglycoside' or "cephalosporin" (for an infection). These medicines include streptomycin, gentamycin, cephalexin and ceftriaxone. See the section on "Taking other medicines'.
- You are pregnant or breast-feeding a baby. See the section on "Pregnancy and breast-feeding."

Do not take UNAT® if any of these apply to you. If you are not sure, talk to your doctor or pharmacist before taking UNAT®.

Take special care with UNAT®

Check with your doctor or pharmacist before taking UNAT® if:

- You have a low levels of potassium or sodium in your blood (shown in blood tests).
- You have difficulty with micturition (passing urine) including prostatic hypertrophy.
- You have diabetes (diabetes mellitus).

If any of these apply to you, or if you are not sure, talk to your doctor or pharmacist before taking UNAT®.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because UNAT® can affect the way some other medicines work.
Also some other medicines can affect the way UNAT® works.

Do not take UNAT® if you are already taking an antibiotic called “aminoglycoside” or “cephalosporin” (for an infection).
These medicines include streptomycin, gentamycin, cephalexin and ceftriaxone. If this applies to you, ask your doctor or pharmacist for advice.
It is particularly important to **tell your doctor or pharmacist** if you are taking any of the following medicines:

- Other medicines to treat high blood pressure.
- Medicines called “ACE inhibitors” (used to treat heart disease)
- Medicines like digoxin or digitoxin (used to treat heart disease)
- Adrenaline (also called epinephrine) or noradrenaline (also called norepinephrine). These are used to treat low blood pressure.
- Cholestyramine, or other “ionexchange resins” (used to treat high levels of cholesterol in your blood).
- High doses of medicines called “salicylates’, such as aspirin.
- Medicines called ‘non-steroidal anti-inflammatory drugs’ (NSAID’s). These include indomethacin and ibuprofen.
- Laxactives.

- Steroid medicines, such as hydrocortisone, prednisolone and dexamethasone.
- Medicines to relax your muscles (muscle relaxants).
- Cisplatin (used to treat cancer).
- Lithium (used to treat mental health problems).
- Probenecid (used to treat gout).
- Theophylline (used to treat asthma).

Taking UNAT® tablets with other medicinal products:

Inform your doctor or pharmacist if you are taking or have recently taken other medicinal products, including over the counter products.

Pregnancy and breast-feeding

Do not take UNAT® if you are pregnant, might become pregnant or are breast-feeding. This is because it is not known if UNAT® will affect your baby.

Driving and using machines

You may feel dizzy while taking UNAT®. If this happens, do not drive or use any tools or machinery.

Important information about some of the ingredients of UNAT®

This medicine contains lactose, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

4. HOW TO TAKE UNAT®

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

High blood pressure

- The usual dose for adults and elderly people is between 2.5 mg and 5 mg once a day.

Water retention (oedema)

- The usual dose for adults and elderly people is 5 mg once a day.
- Your doctor may increase the dose to 20 mg a day if needed.

If you take more UNAT® than you should

If you take more UNAT than you should, talk to your doctor or go to a hospital straight away.

Take the medicine pack with you.

If you take too many tablets, you may pass a lot of urine, become sleepy, or feel confused, faint or dizzy. You may also have stomach upset.

If you forget to take UNAT®

If you forget to take a dose, take it as soon as you remember it.

However, if it is nearly time for the next dose, skip the missed dose.

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

If someone else takes your UNAT® tablets by mistake, they should talk to a doctor or go to a Hospital straight away.

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

5. POSSiBLE SIDE EFFECTS

UNAT® can cause side effects.

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

The following undesirable effects were observed whereas the frequency of undesirable effect is not known:

See your doctor as soon as possible if you get the following side effects:

Blood and lymphatic system disorders

Frequency not known: Thrombocytopenia, Leukopenia, Anaemia

Immune system disorders:

Very rare: Allergic skin reactions (e.g. Pruritus, Exanthema), Photosensitivity reaction

Frequency not known: Serious skin reactions (e.g. Stevens-Johnson syndrome, Toxic epidermal necrolysis)

Metabolism and nutrition disorders:

Common: Metabolic alkalosis, Fluid and electrolyte imbalance (e.g. Hypovolaemia, Hyponatraemia)

Nervous system disorders:

Common: Headache, Dizziness

Frequency not known: Cerebral ischaemia, Parenthesia, Confusional state

Eye disorders:

Frequency not known: Visual impairment

Ear and labyrinth disorders:

Frequency not known: Tinnitus, Deafness

Cardiac disorders:

Frequency not known: Acute myocardial infarction, Myocardial ischaemia, Angina pectoris, Syncope, Hypotension

Vascular disorders:

Frequency not known: Embolism

Gastrointestinal disorders:

Common: Gastrointestinal disorder (e.g. Loss of appetite, Abdominal pain upper, Nausea, Vomiting, Diarrhoea, Constipation)

Frequency not known: Dry mouth, Pancreatitis

Hepatobiliary disorders:

Uncommon: Hepatic enzyme increased (e.g. Gamma-glutamyltransferase increased)

Skin and subcutaneous tissue disorders

Very rare: Allergic skin reactions (e.g. Pruritus, Exanthema), Photosensitivity reaction

Frequency not known: Serious skin reactions (e.g. Stevens-Johnson syndrome, Toxic epidermal necrolysis)

Musculuskeletal and connective tissue disorders:

Common: muscle spasms

Renal and urinary disorders:

Uncommon: Urinary retention, Bladder dilatation

Rare: Blood urea increased, Blood creatinine increased

General disorders and administration site conditions:

Common: Fatigue, Asthenia

Investigations:

Uncommon: Blood uric acid increased,

Blood glucose increased, Lipids increased (e.g. Blood triglycerides increased, Blood cholesterol increased)

Other possible side effects:

Blood

- An increase in the levels of certain substances in your blood, including sugar, uric acid and fats (lipids).
- Your doctor may do blood tests from time to time to make sure that UNAT® is working safely.

Stomach and gut

- Stomach upset.
- Inflammation of the pancreas causing pain in the stomach (pancreatitis).
- Changes in how your liver is working (shown by blood tests).

Skin

- Skin rashes and itchy skin.
- Skin being more sensitive to the sun (photo-sensitivity).

Eyes and ears

- Blurred eyesight.
- Ringing in the ears (tinnitus) and loss of hearing.

Other

- Feeling numb or tingling in the legs or arms.
- Dry mouth.
- Some people may have difficulty passing water (urinating).

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

6. STORING AND DISPOSING OF THIS MEDICINE

Store at or below 25 °C.

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

Return all unused medicine to your pharmacist.

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

UNAT® tablets do not need special storage conditions.

7. PRESENTATION OF UNAT®

Blister packs of 30’s.

8. IDENTIFICATION OF UNAT®

UNAT 2.5 : White to off-white round tablet, embossed with T2.5 on one side.

UNAT 5: White to off-white round tablet, T-break embossed with T5 on one side.

UNAT 10: White to off-white round tablet, T-break embossed with T10 on one side.

9. REGISTRATION NUMBERS

UNAT 2.5 mg: A28/18.1/0292

UNAT 5 mg: A28/18.1/0293

UNAT 10 mg: A28/18.1/0294

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Viatris South Africa (Pty) Ltd

4 Brewery Street

Isando, Johannesburg

1609

11. DATE OF PUBLICATION

12 June 1998