1.3.2 Patient Information Leaflet (clean)

Please read this leaflet carefully, before you start using this medicine

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm then, even if their symptoms are the same as yours.

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Uricon® tablets

WHAT URICON® CONTAINS

The active substance in one tablet is:

Trospium chloride 20 mg

Other ingredients are:

Calcium carbonate (E170), carmellous sodium, carnauba wax, croscarmellose sodium, iron oxide hydrate (E172), lactose monohydrate, macrogol 8000, microcrystalline cellulose, povidone, silica colloidal anhydrous, stearic acid, sucrose, talc, titanium dioxide (E171), wheat starch and white bees wax.

WHAT URICON® IS USED FOR

Uricon® tablets are used to treat the symptoms of overactive bladder conditions. For example, needing to go to the toilet frequently, needing to suddenly rush to the toilet and/or having difficulty getting there in time and wetting yourself.

BEFORE YOU TAKE URICON®

Do not take Uricon®:

- if you have ever had allergic reactions to any of the ingredients listed above – this can be a rash, itchiness or shortness of breath.
- if you suffer from any of the following:
- urinary retention i.e. urination occurs less frequently than before;
- an eye condition: glaucoma;
- abnormal/faster than normal heartbeats;
- myasthenia gravis (a disorder which causes muscle fatigue);
- A severe gastro-intestinal condition, such as toxic megacolon.

Do **NOT** give this product to children under the age of 12 years of age.

You should speak to your Healthcare Professional before takins **Uricon®** if you:

Suffer from any of the following:

- any type of stomach or bowel obstruction;
- a blockage of the urinary tract;
- neuropathy i.e. nerve damage;
- a hiatus hernia associated with reflux oesophagitis. This is usually associated with heartburn which worsens on bending or lying down;

- an overactive thyroid.
- any heart conditions, such as coronary artery disease or congestive heart failure.
- any liver problems.
- any kidney problems

Take SPECIAL CARE in the following cases:

Uricon® tablets contain wheat starch.

If you suffer from wheat allergy (different from coeliac disease) you should not take this product. **Uricon®** is suitable for patients with coeliac disease.

Uricon® contains sucrose and lactose. If you have been told by your doctor that you have intolerance to some sugars, please contact your healthcare professional before taking **Uricon®**.

Pregnancy or lactation:

If you are pregnant or breastfeeding your baby while taking this medicine please consult your doctor, pharmacist or other healthcare professional.

Using other medicines at the same time:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **Uricon®** with these medicines may cause undesirable interactions.

Please consult your doctor, pharmacist or other healthcare professional for advice before taking any of the following medicines:

- amantadine (used in the treatment of Parkinson's disease or as protection against influenza)
- tricyclic antidepressants.
- A 'sympathomimetic' (one of a class of drugs which can increase the heart rate).
- Metoclopramide (a drug which increases the rate of movement of digested food through your gastro-intestinal system).
- Guar gum (sometimes used in a type of diabetes).
- Cholestyramine or colestipol (drugs used to reduce the levels of certain fats in your bloodstream).

If you are unsure of the types of medicines you are taking, ask your doctor or pharmacist.

HOW TO TAKE URICON®

Always take **Uricon®** tablets exactly as your doctor has instructed you. You should confirm with your doctor or pharmacist if you are unsure.

The usual dose of adults is one tablet twice a day, taken by mouth. Doctors may prescribe different doses to this. For example, patients with kidney problems may take a reduced dose of one tablet per day or one tablet every second day.

The tablets should be swallowed whole with a glass of water, before meals on an empty stomach. If you have the impression that the effect of **Uricon®** is too strong or too weak, talk to your doctor or pharmacist.

This product should not be taken by children under 12 years of age

What should you do if you forget to take a dose?

If you miss a dose, take it as soon as you remember and then carry on as before. Do not take a double dose.

What should you do if you take too many?

It is always important to follow the recommended dose on the label. If too many tablets are taken by accident, contact your healthcare professional immediately.

POSSIBLE SIDE EFFECTS

Along with its desirable effects, a medicine may have some unwanted effects. This product may cause a dry mouth, indigestion, constipation, abdominal pain, nausea and/or flatulence. Other effects known to occur rarely include urinary disorders, and increased heart rate, eye disorders (especially in patients with uncorrected farsightedness), diarrhoea, difficulty breathing, skin rashes, weakness, chest pain, muscle pain, joint pain, skin swelling, an increase in liver enzyme levels, an acute allergic reaction (rash, itchiness or shortness of breath), headache or dizziness.

Contact your doctor or pharmacist immediately if you experience a rash, itchiness of difficulty in breathing as these may indicate an allergy to the product. If you suffer from these or any other problems and think your medicine may be causing them, tell your healthcare professional.

STORAGE AND DISPOSAL OF AGIOBULK®

How **Uricon®** tablets should be stored:

KEEP THIS AND ALL MEDICINES OUT OF THE REACH OF CHILDREN.

Do not use this medicine after the expiry date printed on the container.

Do not share medicines prescribed for you with others.

Store below 25 ºC.

Disposal of this medicine:

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems.

PRESENTATION OF URICON®

Packs of 30, 60 and 120 blister packed tablets.

PRODUCT APPEARANCE OF URICON®

Brownish-yellow, polished, sugar-coated tablets.

REGISTRATION NUMBER

35/18/0406

NAME AND ADDRESS OF REGISTRATION HOLDER

XIXIA PHARMACEUTICALS (PTY) LTD

Building 6

Greenstone Hill Office Park

143 Emerald Boulevard

144 Modderfontein

145 1645

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147 **DATE OF PUBLICATION**

148 To follow