1.3.1.2 PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

URTON EXTENDED RELEASE TABLETS

Mirabegron 25 mg AND 50 mg

Sugar free

Read all of this leaflet carefully before you start using URTON.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other health care provider.
- **URTON** 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.

What is in this leaflet

1. What URTON is and what it is used for

The active substance is mirabegron.

URTON contains the active substance mirabegron. It is a bladder muscle relaxant (also called beta 3-adrenoceptor agonist), which reduces the activity of an overactive bladder and treats the related symptoms.

URTON is used to treat the symptoms of an overactive bladder in adults such as:

- suddenly needing to empty your bladder (called urgency)
- having to empty your bladder more than usual (called increased urinary frequency)

not being able to control when to empty your bladder (called urgency incontinence).

2. What you need to know before you take URTON

Do not take URTON:

- if you are allergic to mirabegron or any of the other ingredients of this medicine,
- if you have severe kidney disease (severe end-stage renal impairment),
- if you have severe liver disease (severe hepatic impairment),
- if you have very high uncontrolled blood pressure.

Warnings and precautions:

Take special care with URTON:

- if you have kidney or liver problems. Your doctor may need to reduce your dose.
- if you have an ECG (heart tracing) abnormality known as QT prolongation or you are taking any medicine known to cause this.

URTON may cause your blood pressure to increase or make your blood pressure worse if you have a history of high blood pressure. It is recommended that your doctor check your blood pressure while you are taking **URTON**.

Other medicines and URTON:

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

Tell your doctor if you:

- use thioridazine (a medicine for mental illness), propafenone or flecainide (medicines for abnormal heart rhythm),
- use digoxin (a medicine for heart failure or abnormal heart rhythm). Blood levels of **URTON** are measured by your doctor. If the blood level is out of range, your doctor may adjust the dose of digoxin.
- Ketoconazole (a medicine used for fungal infections like ring worm or athlete's foot)
- Use URTON together with medicines for incontinence because using these medicines at the same time may cause difficulty when urinating and completely emptying the bladder.

Taking URTON with food and drink:

URTON can be taken with or without food.

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 URTON.

If you are breastfeeding, ask your doctor or pharmacist for advice before taking **URTON**. It is likely that this medicine passes into your breast milk. You and your doctor should decide if you should take **URTON** or breastfeed. You should not do both.

Driving and using machines:

URTON may affect your ability to drive or use machinery.

3. How to take URTON

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

Always take **URTON** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is one 50 mg tablet by mouth once daily.

If you have kidney or liver problems, your doctor may need to reduce your dose to one 25 mg tablet by mouth once daily.

You should take this medicine with liquids and swallow the tablet whole.

Do not crush or chew the tablet. **URTON** can be taken with or without food.

Your doctor will tell you how long your treatment with **URTON** will last.

Do not stop treatment with **URTON** early if you do not see an immediate effect. Your bladder might need some time to adapt. You should continue taking your tablets. Do not stop taking them when your bladder condition improves. Stopping treatment may result in the recurrence of symptoms of overactive bladder.

If you have the impression that the effect of **URTON** is too strong or too weak, tell your doctor or pharmacist.

If you take more URTON than you should:

If you have taken more tablets than you have been told to take, or if someone else accidentally takes your tablets, contact your doctor, pharmacist or hospital for advice immediately.

Symptoms of overdose may include a forceful beating of the heart, an increased pulse rate or an increased blood pressure.
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 / missed a dose of URTON:

If you forget to take your medicine, take the missed dose as soon as you remember. If it is less than 6 hours before your next scheduled dose, skip the dose and continue to take your medicine at the usual time.

Do not take a double dose to make up for a forgotten dose. If you miss several doses, tell your doctor and follow the advice given to you.

Effects when treatment with URTON is stopped:

Do not stop taking **URTON** without talking to your doctor first, as your overactive bladder symptoms may come back.

4. Possible side effects

URTON can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching,
- Fainting,
- Yellowing of the skin and eyes, also called jaundice.

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

- Swelling of the deeper layers of the skin caused by a build-up of fluid, which can affect any part of the body including the face, tongue or throat and may cause difficulty in breathing (angioedema),
- Irregular heartbeat (atrial fibrillation),
- Increased heart rate (tachycardia),
- If you get headaches, especially sudden, migraine-like (throbbing) headaches. These may be a sign of severely elevated blood pressure (hypertensive crisis).

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

Tell your doctor if you notice any of the following:

Frequent side effects

- Urinary tract infections
- Nausea
- Constipation
- Headache
- Diarrhoea
- Dizziness
- Increased heart rate

Less frequent side effects

- Increased blood pressure
- Bladder infection (cystitis)
- Feeling your heartbeat (palpitations)
- Vaginal infection
- Indigestion (dyspepsia)
- Infection of the stomach (gastritis)
- Swelling of the joints
- Itching of the vulva or vagina (vulvovaginal pruritus)
- Increase in liver enzymes (GGT, AST and ALT)
- Itching, rash or hives (urticaria, rash, macular rash, papular rash, pruritus)
- Swelling of the eyelid (eyelid oedema)
- Small purple spots on the skin (purpura)

- Inflammation of small blood vessels mainly affecting the skin (leucocytoclastic vasculitis)
- Inability to completely empty the bladder (urinary retention)
- Insomnia

If you notice any side effects not mentioned 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. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free) . By reporting side effects, you can help provide more information on the safety of [URTON].

5. How to store URTON

Store all medicines out of reach of children.

Keep the HDPE bottle tightly closed.

Do not use **URTON** after the expiry date which is stated on the carton, blister or bottle.

Do not remove the tablet from the blister until required for use.

Keep the blisters in the outer carton until required for use.

Store at or below 25 °C.

Return all unused medicines to your pharmacist.

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

6. Contents of the pack and other information

What URTON contains:

The active substance is mirabegron 25 mg and 50 mg.

The other ingredients are polyethylene oxide, polyethylene glycol, hydroxypropyl cellulose, butylated hydroxytoluene, magnesium stearate, hypromellose 2910 6 cp, titanium dioxide, macrogol.

What URTON looks like and contents of the pack

URTON 25 mg extended release tablets are oval, white to slightly yellowish white, film coated tablet debossed with ‘WM2’ on one side.

URTON 50 mg extended release tablets are oval, white to slightly yellowish white, film coated tablet debossed with ‘WM5’ on one side.

The tablets are packaged in 30, 90 and 500s into cartons and each carton has tablets packaged into blisters. The blisters are made of plain aluminum foil and cold forming foil.

The tablets are also packaged in 30, 90 or 500s in HDPE bottles with child-resistant closure of polypropylene (PP) and a silica gel desiccant.

Not all pack sizes may be marketed

Holder of Certificate of registration

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

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URTON 50 mg – 54/18.10/0031

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.