APPROVED PATIENT INFORMATION LEAFLET

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URODOXA 1 mg (Tablet)

URODOXA 2 mg (Tablet)

URODOXA 4 mg (Tablet)

URODOXA 8 mg (Tablet)

Doxazosin mesilate

Read all of this leaflet carefully before you start taking URODOXA.

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

1. WHAT URODOXA CONTAINS:

The active substance is doxazosin.

URODOXA 1 mg: Each uncoated tablet contains doxazosin mesilate equivalent to doxazosin 1 mg.

URODOXA 2 mg: Each uncoated tablet contains doxazosin mesilate equivalent to doxazosin 2 mg.

URODOXA 4 mg: Each uncoated tablet contains doxazosin mesilate equivalent to doxazosin 4 mg.

URODOXA 8 mg: Each uncoated tablet contains doxazosin mesilate equivalent to doxazosin 8 mg.

The other ingredients of **URODOXA** are cellulose, microcrystalline, lactose, magnesium stearate and sodium starch glycolate.

2. WHAT URODOXA IS USED FOR:

Doxazosin is in a class of medications called alpha-blockers. **URODOXA** is a treatment for high blood pressure, or the symptoms caused by enlargement of the prostate gland in men.

3. BEFORE YOU TAKE [PRODOUCT NAME]:

Do not take [PRODOUCT NAME]:

- If you have ever had an allergic reaction in the past to **[PRODOUCT NAME]**, quinazolines or any of the ingredients of **[PRODOUCT NAME]**.
- If you are pregnant or breast-feeding.
- If you have a history of low blood pressure when you stand up from sitting or lying down.
- If you have trouble passing urine, bladder of kidney problems.
- If you have an enlarged prostate.

Take special care with [PRODOUCT NAME]:

- If you have liver or kidney disease
- If you are elderly.
- If you are undergoing eye surgery because of cataract (cloudiness of the lens of the eye) please inform your eye specialist before the operation that you are using or have previously used **[PRODOUCT NAME]**. **URODOXA** may cause complications during the surgery.
- When you start to take **URODOXA** you may experience faintness or dizziness caused by low blood pressure, when getting up from sitting or lying down. If you feel faint or dizzy, you should sit or lie down until you feel better and avoid situations where you might fall or hurt yourself. Your doctor may want to measure your blood pressure regularly at the start of therapy to reduce the possibility of these effects happening.
- If you have a condition called angina pectoris or heart failure.

Pregnancy and Breast-feeding:

Do not take **URODOXA** if you are pregnant or breast-feeding. The safety of **URODOXA** in pregnancy or breast-feeding has not been determined.

If you are pregnant or breast-feeding your, please consult your doctor, pharmacist or other health care professional for advice before taking **[PRODOUCT NAME]**.

Driving and using machinery:

Take care if you drive or operate machinery. **URODOXA** tablets may affect your ability to drive or operate machinery safely, particularly when you first start to take them. **URODOXA** may make you drowsy or dizzy. If affected, do not drive or operate machinery.

Important information about some of the ingredients of [PRODOUCT NAME]:

URODOXA contains lactose. Patients with rare hereditary problems of galactose intolerance, lapp lactase deficiency, or glucose-galactose malabsorption should not take **[PRODOUCT NAME]**.

Taking other medicines with [PRODOUCT NAME]:

- Before taking **[PRODOUCT NAME]**, tell your doctor if you have recently taken or are using any other medicines.
- If you are using any other medicines, you may not be able to take **[PRODOUCT NAME]**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side effects.
- If you are taking other medicines used to treat high blood pressure (such as PDE-5 Inhibitors) as well as alcohol it may cause a dangerous reduction in your blood pressure, especially immediately after the first dose.
- **URODOXA** may lower your blood pressure even more if you are already taking other medicines to treat your high blood pressure.

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

4. HOW TO TAKE [PRODOUCT NAME]:

- Take **URODOXA** only as directed by your doctor.
- If you are taking **URODOXA** for the first time the normal dose is 1 mg once daily. After this the usual dose is 2 mg or 4 mg daily. In some circumstances this may be increased to a maximum of 8 mg daily if you are being treated for prostate enlargement, or to a maximum of 16 mg daily if you are being treated for high blood pressure.

- Your doctor will gradually increase your dosage at intervals of 1 to 2 weeks.

Always take **URODOXA** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **URODOXA** is too strong or too weak, talk to your doctor or pharmacist.

If you take more URODOXA 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 forget to take [PRODOUCT NAME]:

If you forget to take **[PRODOUCT NAME]**, take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

5. POSSIBLE SIDE EFFECTS:

URODOXA can have side effects.

Get emergency medical help if you have any of these signs of an allergic reaction:

- Difficulty breathing.
- Swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have any of these serious side effects:

- Chest pain
- Angina
- Irregular heart beat
- Palpitations (rapid irregular action of heart)
- Increased rate of heart beat
- Heart attack
- Stroke

- Shortness of breath
- Painful erection of the penis that lasts for hours

Other side effects include:

Frequent: dizziness, vertigo (feeling of spinning or rotation of surroundings), headache and weakness.

Less frequent: nervousness, difficulty sleeping, low blood pressure, runny nose, nausea and stomach pain.

Unknown frequency: depression, inability to sleep, agitation, tremor (shake), numbness, tingling, pins and needles, abnormal vision; blurred vision, nose bleeds, diarrhoea; dry mouth, vomiting, yellow pigmentation of skin and eyes, skin rash, itching, red or purple patches on the skin and urinary incontinence.

Tell your doctor if any of the above side effects are severe, bothersome or do not go away.

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

6. STORING AND DISPOSING OF [PRODOUCT NAME]:

Store at or below 25 °C (room temperature). Protect from light. Keep original containers well closed. Do not remove blisters from carton until required for use.

Store 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).

7. PRESENTATION OF [PRODOUCT NAME]:

URODOXA 1 mg:

1) Tablets are packed in white opaque 250 micron PVC film coated with 60 gsm PVdC and printed 25 micron aluminium foil with 7 gsm heat seal lacquer. Each blister contains 10 tablets.

Pack size: 30's – Each carton contains 3 blister strips of 10 tablets each.

2) Tablets are packed in 40 ml HDPE container of 33 mm neck finish (OFC 51 ml) with 33 mm - 400 RS closure with TEKNIPLEX HS-123 induction sealing wad with rayon coil. The HDPE container is stored in a carton. Each container contains 30 tablets.

Pack size: 30's – One HDPE container contains 30 tablets.

URODOXA 2 mg:

1) Tablets are packed in white opaque 250 micron PVC film coated with 60 gsm PVdC and printed 25 micron aluminium foil with 7 gsm heat seal lacquer. Each blister contains 10 tablets.

Pack size: 30's – Each carton contains 3 blister strips of 10 tablets each.

2) Tablets are packed in 40 ml HDPE container of 33 mm neck finish (OFC 51 ml) with 33 mm – 400 RS closure with TEKNIPLEX HS-123 induction sealing wad with rayon coil. The HDPE container is stored in a carton. Each container contains 30 tablets.

Pack size: 30's - One HDPE container contains 30 tablets.

URODOXA 4 mg:

1) Tablets are packed in white opaque 250 micron PVC film coated with 60 gsm PVdC and printed 25 micron aluminium foil with 7 gsm heat seal lacquer. Each blister contains 10 tablets.

Pack size: 30's – Each carton contains 3 blister strips of 10 tablets each.

2) Tablets are packed in 40 ml HDPE container of 33 mm neck finish (OFC 51 ml) with 33 mm – 400 RS closure with TEKNIPLEX HS-123 induction sealing wad with rayon coil. The HDPE container is stored in a carton. Each container contains 30 tablets.

Pack size: 30's - One HDPE container contains 30 tablets.

URODOXA 8 mg:

1) Tablets are packed in white opaque 250 micron PVC film coated with 60 gsm PVdC and printed 25 micron aluminium foil with 7 gsm heat seal lacquer. Each blister contains 10 tablets.

Pack size: 30's – Each carton contains 3 blister strips of 10 tablets each.

2) Tablets are packed in 40 ml HDPE container of 33 mm neck finish (OFC 51 ml) with 33 mm - 400 RS closure with TEKNIPLEX HS-123 induction sealing wad with rayon coil. The HDPE container is stored in a carton. Each container contains 30 tablets.

Pack size: 30's - One HDPE container contains 30 tablets.

8. IDENTIFICATION OF [PRODOUCT NAME]:

URODOXA 1 mg:

White to off-white, coloured, circular, biconvex shaped uncoated tablets debossed with 'H' on one side and '01' on other side.

URODOXA 2 mg:

White to off-white, coloured, caplet shaped uncoated tablets debossed with 'H02' on one side and breakline on other side.

URODOXA 4 mg:

White to off-white, coloured, diamond shaped uncoated tablets debossed with 'H03' on one side and breakline on other side.

URODOXA 8 mg:

White to off-white, coloured, caplet shaped uncoated tablets debossed with 'H04' on one side and breakline on other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER:

URODOXA 1 **mg:** 45/7.1/0150

URODOXA 2 mg: 45/7.1/0151

URODOXA 4 mg: 45/7.1/0152

URODOXA 8 mg: 45/7.1/0153

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

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11. DATE OF PUBLICATION

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