Urodoxa Tablets
P1536454

Urodoxa Tablets
P1536454

SCHEDULING STATUS

S3

PROPRIETARY NAME (and dosage form):
URODOXA 1 mg (tablet)
URODOXA 2 mg (tablet)
URODOXA 4 mg (tablet)
URODOXA 8 mg (tablet)

COMPOSITION:
URODOXA 1 mg:
Each uncoated tablet contains doxazosin mesilate equivalent to doxazosin 1 mg. Contains sugar: 24 mg lactose.

URODOXA 2 mg:
Each uncoated tablet contains doxazosin mesilate equivalent to doxazosin 2 mg. Contains sugar: 24 mg lactose.

URODOXA 4 mg:
Each uncoated tablet contains doxazosin mesilate equivalent to doxazosin 4 mg. Contains sugar: 48 mg lactose.

URODOXA 8 mg:
Each uncoated tablet contains doxazosin mesilate equivalent to doxazosin 8 mg. Contains sugar: 96 mg lactose.

The other ingredients of the formulations are cellulose microcrystalline, sodium starch glycolate and magnesium stearate.

PHARMACOLOGICAL CLASSIFICATION:
A.7.1 Vasodilators, hypotensive medicines

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties:
Doxazosin exerts a vasodilator effect via selective and competitive blockade of post-junctional alpha-1-adrenoceptors. Doxazosin has been shown to block the 1A subtype of the alpha-1-adrenoceptor which accounts for over 70 % of the subtypes in the prostate.

Pharmacokinetic properties:
Doxazosin is well absorbed after oral administration, with peak blood levels occurring at about 2 hours. The plasma elimination is biphasic with the terminal elimination half-life being 19 to 22 hours, hence providing the basis for once daily dosing. Doxazosin is extensively metabolised with less than 5 % excreted unchanged.

Maximum reduction in blood pressure normally occurs about 6 hours after dosing.

Most (98 %) of plasma doxazosin is protein bound. *In vitro* data in human plasma indicates that doxazosin has no effect on protein binding of the medicines tested (digoxin, phenytoin, warfarin or indomethacin).

INDICATIONS:
Hypertension:
URODOXA is indicated for the treatment of mild to moderate hypertension.

Benign Prostatic Hyperplasia:
URODOXA is also indicated for the treatment of the urinary outflow obstruction and symptoms associated with Benign Prostatic Hyperplasia (BPH). **URODOXA** may be used in BPH patients who are either hypertensive or normotensive.

CONTRA-INDICATIONS:
URODOXA is contra-indicated in patients with a known hypersensitivity to quinazolines or any of the ingredients of **URODOXA**.
URODOXA is contra-indicated in:
- Pregnancy and lactation (see **"PREGNANCY AND LACTATION"**).
- Patients with a history of orthostatic hypotension.
- Patients with BPH and concomitant congestion of upper urinary tract, chronic urinary tract infection or bladder stones.
- As monotherapy in patients either overflow bladder or anuria or without progressive renal insufficiency.

WARNINGS AND SPECIAL PRECAUTIONS:
URODOXA is not recommended for the treatment of heart failure caused by mechanical obstruction, for example aortic or mitral valve stenosis, pulmonary embolism, and restrictive pericardial disease. It should be used with caution is patients with angina pectoris.

Treatment with **URODOXA** should be introduced with caution due to the risk of sudden collapse after the initial dose.

Extra caution is necessary in patients with hepatic or renal impairment and in the elderly.

There is no experience with the use of **URODOXA** in children.

Patients undergoing cataract surgery: Intraoperative Floppy Iris Syndrome (IFIS) has been observed during cataract surgery in some patients on or previously treated with alpha-1 blockers. This variant of small pupil syndrome is characterised by the combination of a flaccid iris that billows in response to intraoperative irrigation currents, progressive intraoperative miosis despite preoperative dilation with standard mydriatic medicines, and potential prolapse of the iris toward the phacoemulsification incisions. The patient's surgeon should be prepared for possible modifications to their surgical technique, such as the utilisation of iris hooks, iris dilator rings, or viscoelastic substances. There does not appear to be a benefit of stopping alpha-1 blocker therapy prior to cataract surgery.

Patients taking phosphodiesterase (PDE-5) inhibitors: Concomitant administration of **URODOXA** with a PDE-5 inhibitor can result in additive blood pressure lowering effects and symptomatic hypotension.

Postural hypotension with or without symptoms (e.g. dizziness) may develop within a few hours following administration of **URODOXA**. However, infrequently, symptomatic postural hypotension has also been reported later than a few hours after dosing. As with other alpha-blockers, there is a potential for syncope, especially after the initial dose or after an increase in dosage strength. Patients should be warned of the possible occurrence of such events and should avoid situations where injury could result should syncope occur. Care should be taken when **URODOXA** is administered to patients with symptomatic hypotension or patients who have had a hypotensive response to other medications.

URODOXA contains lactose and should not be given to patients with rare hereditary problems or a history of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption.

Effect on the ability to drive and use machinery:
The ability to engage in activities such as driving a motor vehicle or operating machinery may be impaired, especially when initiating therapy. **URODOXA** may cause drowsiness or dizziness therefore patients affected should not drive or operate machinery.

INTERACTIONS:
No adverse medicine interaction has been noted in clinical experience with thiazide diuretics, furosemide, beta-blocking agents, oral hypoglycaemic medicines, antibiotics, uricosuric agents or anticoagulants.

However the hypotensive effects of **URODOXA** may be enhanced by use with diuretics and other anti-hypertensives, and by alcohol and other medicines that cause hypotension.

The risk of first-dose hypotension may be particularly increased in patients receiving beta-blockers or calcium channel blockers.

Concomitant administration of **URODOXA** with a PDE-5 inhibitor can result in additive blood pressure lowering effects and symptomatic hypotension; therefore, PDE-5 inhibitor therapy should be initiated at the lowest dose in patients taking **URODOXA**.

PREGNANCY AND LACTATION:
The safety of **URODOXA** in pregnancy or lactation has not yet been established (see **"CONTRA-INDICATIONS"**).

DOSAGE AND DIRECTIONS FOR USE:
Hypertension:
The initial dosage of **URODOXA** is 1 mg given once daily. Depending on the individual patient's response, dosage may then be increased after 1 – 2 weeks of therapy to 2 mg and thereafter at similar intervals to 4 mg, 8 mg and 16 mg to achieve the desired reduction in blood pressure. **URODOXA** may be used in combination with a thiazide diuretic or a beta-blocking agent, in patients not adequately controlled on a single antihypertensive agent.

Benign Prostatic Hyperplasia:
The initial dosage of **URODOXA** is 1 mg given once daily. Depending on the individual patient's urodynamics and BPH symptomatology, dosage may then be increased to 2 mg and thereafter to 4 mg and up to the maximum recommended dose of 8 mg. The recommended titration interval is 1 - 2 weeks. The usual recommended dose is 2 - 4 mg once daily. Blood pressure should be evaluated routinely in these patients.

SIDE EFFECTS:
Blood and the lymphatic system disorders:
The following side effects have been reported and frequencies are unknown:
Thrombocytopenia, leukopenia.

Immune system disorders:
The following side effect has been reported and frequency is unknown:
Allergic medicine reactions.

Psychiatric disorders:
Less frequent:
Nervousness.

The following side effects have been reported and frequencies are unknown:
Depression, insomnia, agitation.

Nervous system disorders:
Frequent:
Dizziness, vertigo, headache.

Less frequent:
Somnolence.

The following side effects have been reported and frequencies are unknown:
Tremor, paraesthesia, postural dizziness.

Eye disorders:
The following side effects have been reported and frequencies are unknown:
Blurred vision, abnormal vision.

Cardiac disorders:
Less frequent:
Cardiac dysrhythmias, palpitations, tachycardia.

The following side effects have been reported and frequencies are unknown:
Myocardial infarction, angina pectoris.

Vascular disorders:
Less frequent:
Hypotension.

The following side effect has been reported and frequency is unknown:
Cerebrovascular accidents.

Respiratory, thoracic and mediastinal disorders:
Less frequent:
Dyspnoea, rhinitis.

The following side effect has been reported and frequency is unknown:
Epistaxis.

Gastrointestinal disorders:
Less frequent:
Nausea, abdominal pain.

The following side effects have been reported and frequencies are unknown:
Diarrhoea, dry mouth, vomiting.

Hepato-biliary disorders:
The following side effects have been reported and frequencies are unknown:
Jaundice, hepatitis, cholestasis.

Skin and subcutaneous tissue disorders:
The following side effects have been reported and frequencies are unknown:
Skin rashes, pruritus, purpura.

Renal and urinary disorders:
The following side effects have been reported and frequencies are unknown:
Haematuria. Cases of urinary incontinence were reported; this effect may be related to the pharmacological action of **URODOXA.**

Reproductive system and breast disorders:
Less frequent:
Priapism.

The following side effects have been reported and frequencies are unknown:
Sexual dysfunction, impotence.

General disorders and administrative site conditions:
Frequent:
Asthenia.

The following side effects have been reported and frequencies are unknown:
Fatigue, malaise, chest pain, oedema.

Investigations:
The following side effect has been reported and freqeuncy is unknown:
Abnormal liver function tests.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
See **"SIDE EFFECTS"**.
Dialysis is not indicated, since **URODOXA** is highly protein bound. Treatment is symptomatic and supportive.

IDENTIFICATION:
URODOXA 1 mg:
White to off-white coloured, circular, biconvex shaped uncoated tablet debossed with 'D O' on one side and '1' on other side

URODOXA 2 mg:
White to off-white coloured, caplet shaped uncoated tablet debossed with 'D O' on one side separated by break line and '2' on other side

URODOXA 4 mg:
White to off-white coloured, diamond shaped uncoated tablet debossed with 'D O' on one side separated by break line and '4' on other side

URODOXA 8 mg:
White to off-white coloured, caplet shaped uncoated tablet debossed with 'D O' on one side separated by break line and '8" on other side.

PRESENTATION:
URODOXA 1 mg:
1) Tablets are packed in white opaque 250 µm PVC film coated with 60 g/m^2 PVdc and printed 25 µm aluminium foil with 7 g/m^2 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 µm PVC film coated with 60 g/m^2 PVdc and printed 25 µm aluminium foil with 7 g/m^2 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 µm PVC film coated with 60 g/m^2 PVdc and printed 25 µm aluminium foil with 7 g/m^2 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 µm PVC film coated with 60 g/m^2 PVdc and printed 25 µm aluminium foil with 7 g/m^2 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.

STORAGE INSTRUCTIONS:
Store at or below 25 °C. Protect from light. Keep original containers well closed. Do not remove blisters from carton until required for use.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:
SOUTH AFRICA:
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

NAMIBIA:
URODOXA 1 mg: 21/7.1.3/0017
URODOXA 2 mg: 21/7.1.3/0018
URODOXA 4 mg: 21/7.1.3/0019
URODOXA 8 mg: 21/7.1.3/0020

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Aurogen South Africa (Pty) Ltd
Woodhill Office Park, Building 1, First floor,
53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12, 1448
Johannesburg
South Africa

DATE OF PUBLICATION OF THE PACKAGE INSERT:
Date of registration:
18 February 2016

Date of revision:
14 February 2024

DETACH BEFORE DISPENSING

S3

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. Contains sugar: 24 mg lactose.
URODOXA 2 mg: Each uncoated tablet contains doxazosin mesilate equivalent to doxazosin 2 mg. Contains sugar: 24 mg lactose.
URODOXA 4 mg: Each uncoated tablet contains doxazosin mesilate equivalent to doxazosin 4 mg. Contains sugar: 48 mg lactose.
URODOXA 8 mg: Each uncoated tablet contains doxazosin mesilate equivalent to doxazosin 8 mg. Contains 96 mg lactose.
The other ingredients of **URODOXA** are cellulose microcrystalline, 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 URODOXA:
Do not take URODOXA:
- If you have ever had an allergic reaction in the past to **URODOXA**, quinazolines or any of the ingredients of **URODOXA**.
- If you are pregnant or breastfeeding.
- 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 URODOXA:
- 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 **URODOXA**. **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 Breastfeeding:
Do not take **URODOXA** if you are pregnant or breastfeeding. The safety of **URODOXA** in pregnancy or breastfeeding has not been determined.

If you are pregnant or breastfeeding your, please consult your doctor, pharmacist or other healthcare professional for advice before taking **URODOXA.**

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 URODOXA
URODOXA contains lactose. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take **URODOXA**

Taking other medicines with URODOXA:
- Before taking **URODOXA**, 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 **URODOXA**, 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 URODOXA:
- 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 URODOXA:
If you forget to take **URODOXA**, 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 **URODOXA**, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF URODOXA:
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 URODOXA:
URODOXA 1 mg:
1) Tablets are packed in white opaque 250 µm PVC film coated with 60 g/m^2 PVdc and printed 25 µm aluminium foil with 7 g/m^2 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 µm PVC film coated with 60 g/m^2 PVdc and printed 25 µm aluminium foil with 7 g/m^2 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 µm PVC film coated with 60 g/m^2 PVdc and printed 25 µm aluminium foil with 7 g/m^2 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 µm PVC film coated with 60 g/m^2 PVdc and printed 25 µm aluminium foil with 7 g/m^2 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 URODOXA:
URODOXA 1 mg:
White to off-white coloured, circular, biconvex shaped uncoated tablet debossed with 'D O' on one side and '1' on other side

URODOXA 2 mg:
White to off-white coloured, caplet shaped uncoated tablet debossed with 'D O' on one side separated by break line and '2' on other side

URODOXA 4 mg:
White to off-white coloured, diamond shaped uncoated tablet debossed with 'D O' on one side separated by break line and '4' on other side

URODOXA 8 mg:
White to off-white coloured, caplet shaped uncoated tablet debossed with 'D O' on one side separated by break line and '8" on other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER:
SOUTH AFRICA:
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

NAMIBIA:
URODOXA 1 mg: 21/7.1.3/0017
URODOXA 2 mg: 21/7.1.3/0018
URODOXA 4 mg: 21/7.1.3/0019
URODOXA 8 mg: 21/7.1.3/0020

10. NAME AND ADDRESS OF REGISTRATION HOLDER:
Aurogen South Africa (Pty) Ltd
Woodhill Office Park, Building 1, First floor
53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12, 1448
Johannesburg
South Africa

11. DATE OF PUBLICATION:
Date of registration:
18 February 2016

Date of revision:
14 February 2024

SKEDULERINGSTATUS

S3

EIENDOMSNAAM (en doseervorm):
URODOXA 1 mg (tablet)
URODOXA 2 mg (tablet)
URODOXA 4 mg (tablet)
URODOXA 8 mg (tablet)

SAMESTELLING:
URODOXA 1 mg:
Elke onbedekte tablet bevat doksasosienmesilaat ekwivalent aan doksasosien 1 mg. Bevat suiker: 24 mg laktose.

URODOXA 2 mg:
Elke onbedekte tablet bevat doksasosienmesilaat ekwivalent aan doksasosien 2 mg. Bevat suiker: 24 mg laktose.

URODOXA 4 mg:
Elke onbedekte tablet bevat doksasosienmesilaat ekwivalent aan doksasosien 4 mg. Bevat suiker: 48 mg laktose.

URODOXA 8 mg:
Elke onbedekte tablet bevat doksasosienmesilaat ekwivalent aan doksasosien 8 mg. Bevat suiker: 96 mg laktose.

Die ander bestanddele van die formulasies is mikrokristallyne sellulose, natriumstyselglikolaat en magnesiumstearaat.

FARMAKOLOGIESE KLASSIFIKASIE:
A 7.1 Vasodilatore, hipotensiewe medisyne

FARMAKOLOGIESE WERKING:
Farmakodinamiese eienskappe:
Doksasosien oefen 'n vasodilaterende effek via selektiewe en kompeterende blokkering van na-verbinding alfa-1-adrenoseptore. Daar is aangetoon dat doksasosien die 1A sub-tipe van die alfa-1-adrenoseptor, wat meer as 70 % van die sub-tipes in die prostaat verteenwoordig, blokkeer.

Farmakokinetiese eienskappe:
Doksasosien word goed na orale toediening geabsorbeer, met piek bloedvlakke wat ongeveer 2 ure later voorkom. Die plasma-eliminasie is bi-fasies met 'n terminale halfleeftyd van 19 tot 22 ure. Dit laat toe vir eenkeer daaglikse dosering. Doksasosien word uitgebreid gemetaboliseer, met minder as 5 % wat onveranderd uitgeskei word.

Die maksimum afname in bloeddruk kom gewoonlik ongeveer 6 ure na dosering voor.

Die meeste (98 %) van die doksasosien in die plasma is proteïengebonde. *In vitro* data in menslike plasma dui daarop dat doksasosien geen effek op die proteïenbinding van die medisyne wat gebruik is, het nie (digoksien, fenitoïen, warfarien of indometasien).

INDIKASIES:
Hipertensie:
URODOXA word aangedui vir die behandeling van geringe tot matige hipertensie.

Benigne Prostatiese Hiperplasie:
URODOXA word ook aangedui vir die behandeling van urienvloei-obstruksie en simptome geassosieer met Benigne Prostatiese Hiperplasie (BPH). **URODOXA** kan vir BPH in beide hiper- en normotensiewe pasiënte gebruik word.

KONTRA-INDIKASIES:
URODOXA word teenaangedui in pasiënte met 'n bekende hipersensitiwiteit teen kinasoliene of enige van die bestanddele van **URODOXA**.

URODOXA word teenaangedui in:
- Swangerskap en laktasie (sien "**SWANGERSKAP EN LAKTASIE**").
- Pasiënte met 'n geskiedenis van ortostatiese hipotensie.
- Pasiënte met BPH en meegaande kongestie van boonste urienweg-, chroniese urienweginfeksie of blaasstene.
- As monoterapie in pasiënte met oorvloeiing van die blaas of anurie, met of sonder progressiewe nierontoereikendheid.

WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS:
URODOXA word nie vir die behandeling van hartversaking wat deur meganiese obstruksie veroorsaak word, bv. aorta- of mitralisklepstenose, pulmonêre embolisme en beperkende perikardiese siekte, aanbeveel nie. Dit behoort met sorg in pasiënte met angina pectoris gebruik te word.

Weens die risiko van skielike insinking na die aanvanklike dosis, behoort die behandeling met **URODOXA** met sorg ingestel te word.

Bykomende sorg behoort aan die dag gelê te word in pasiënte ontoereikende lewer- en nier funksie, asook in bejaardes.

Daar bestaan geen ondervinding met die gebruik van **URODOXA** in kinders nie.

Pasiënte wat katarakchirurgie ondergaan: Intra-operatiewe slapirissindroom (ISIS) is gedurende katarakchirurgie waargeneem in sommige pasiënte wat met alfa-1-blokkeerders behandel word of voorheen met alfa-1-blokkeerders behandel is. Hierdie variant van kleinpupilsindroom word deur die kombinasie van 'n slap iris as respons tot intra-operatiewe spoeling, progressiewe intra-operatiewe miose, ongeag pre-operatiewe verdunning met standaard midriatiese medisyne, en die potensiële prolaps van die iris na die fako-emulsifiseringsinsnydings gekenmerk. Die pasiënt se chirurg behoort voorbereid te wees vir moontlike modifikasies van sy/haar chirurgiese tegniek, soos die gebruikmaking van irishake, irisverwydingsringe of viskoëlastiese middels. Dit wil voorkom asof die staking van alfa-1-blokkeringsterapie voor katarakchirurgie nie van enige voordeel is nie.

Pasiënte wat phosfodiesterase (PDE-5) inhibeerder gebruik: Die gelyktydige toediening van **URODOXA** saam met 'n PDE-5 inhibeerder kan tot bykomende bloeddrukverlagende effekte en simptomatiese hipotensie lei.

Posturale hipotensie met of sonder simptome (bv. duiseligheid) kan binne 'n paar ure na die toediening van **URODOXA** ontwikkel. Simptomatiese posturale hipotensie is egter af en toe later as 'n paar ure na dosering aangemeld. Soos met ander alfablokkeerders, bestaan daar 'n potensiaal vir sinkopee, veral na die aanvanklike dosis of na 'n toename in dosissterkte. Pasiënte behoort oor die moontlike voorkoms van sulke episodes ingelig te word en behoort situasies waar 'n besering moontlik tot sinkopee kan lei, te vermy. Sorg behoort aan die dag gelê te word wanneer **URODOXA** aan pasiënte met simptomatiese hipotensie toegedien word, of in pasiënte in wie 'n hipotensiewe respons tot ander medikasies voorgekom het.

URODOXA bevat laktose en behoort nie aan pasiënte met selde voorkomende probleme of 'n geskiedenis van galaktoseïntoleransie, die Lapp-laktasetekort of met glukose-galaktase wanabsorpsie toegedien te word nie.

Effek op die vermoë om te bestuur en met masjinerie te werk:
Die vermoë om aan aktiwiteite soos die bestuur van 'n motor of die werk met masjinerie kan ingekort word, veral wanneer daar met terapie begin word. **URODOXA** kan lomerigheid of duiseligheid veroorsaak en daarom behoort pasiënte wat só geaffekteer word nie motor te bestuur of met masjinerie te werk nie.

INTERAKSIES:
Geen nadelige middelinteraksies is in kliniese ondervinding met tiasieddiuretika, furosemied, betablokkerende middels, orale hipoglukemiese medisyne, antibiotika, urikosuriese middels of antikoagulante aangemeld nie.

Die hipotensiewe effekte van **URODOXA** kan egter deur die gebruik van diuretika en ander antihipertensiewe middels, alkohol en ander middels wat hipotensie veroorsaak, versterk word.

Die risiko van eerste-dosis hipotensie kan veral in pasiënte wat betablokkeerders of kalsiumkanaalblokkeerders ontvang, toeneem.

Die gelyktydige toediening van **URODOXA** saam met 'n PDE-5 inhibeerder kan tot bykomende bloeddrukverlagende effekte en simptomatiese hipotensie lei. PDE-5 inhibeerder terapie behoort daarom teen die laagste dosis in pasiënte wat **URODOXA** neem, begin te word.

SWAGERSKAP EN LAKTASIE:
Die veiligheid van **URODOXA** gedurende swangerskap en laktasie is nog nie vasgestel nie (sien "**KONTRA-INDIKASIES**").

DOSIS EN GEBRUIKSAANWYSINGS:
Hipertensie:
Die aanvanklike dosis **URODOXA** is 1 mg toegedien een keer per dag. Afhangende van die indiwiduele pasiënt se respons kan die dosis na 1 - 2 weke van terapie na 2 mg, en daarna met soortgelyke tussenposes na 4 mg, 8 mg en 16 mg verhoog word om die gewenste verlaging van bloeddruk te bereik. **URODOXA** kan in kombinasie met 'n tiasieddiuretika of 'n betablokkerende middel gebruik word in pasiënte wat nie voldoende op 'n enkel antihipertensiewe middel beheer word nie.

Benigne Prostatiese Hiperplasie:
Die aanvanklike dosis **URODOXA** is 1 mg toegedien een keer per dag. Afhangende van die indiwiduele pasiënte se urodinamika en simptomatologie van BPH, kan die dosis daarna na 2 mg en later na 4mg tot op 'n maksimum aanbevole dosis van 8 mg per dag verhoog word. Die aanbevole titreringsinterval is 1 - 2 weke. Die normale aanbevole dosis is 2 - 4 mg een keer per dag. Die bloeddruk behoort op 'n roetinebasis in hierdie pasiënte nagegaan te word.

NEWE EFFEKTE:
Afwykings van die bloed- en limfsisteem:
Die volgende newe effekte is aangemeld en die frekwensies is onbekend:
Trombositopenie, leukopenie.

Afwykings van die immuunstelsel:
Die volgende newe effek is aangemeld en die frekwensie is onbekend:
Allergiese middelinteraksies.

Psigiatriese afwykings:
Minder dikwels:
Senuweeagtigheid.

Die volgende newe effekte is aangemeld en die frekwensies is onbekend:
Depressie, slaaploosheid, agitasie.

Afwykings van die senuweestelsel:
Dikwels:
Duiseligheid, vertigo, hoofpyn.

Minder dikwels:
Slaapsug.

Die volgende newe effekte is aangemeld en die frekwensies is onbekend:
Bewerasie, parestesie, posturale duiseligheid.

Oogafwykings:
Die volgende newe effekte is aangemeld en die frekwensies is onbekend:
Onduidelike gesig, abnormale gesig.

Hartafwykings:
Minder dikwels:
Hartdisritmieë, hartkloppings, tagikardie.

Die volgende newe effekte is aangemeld en die frekwensies is onbekend:
Miokardiese infarksie, angina pectoris.

Vaskulêre afwykings:
Minder dikwels:
Hipotensie.

Die volgende newe effek is aangemeld en die frekwensie is onbekend:
Serebrovaskulêre ongelukke.

Respiratoriese, bors- en mediastinale afwykings:
Minder dikwels:
Dispnee, rinitis.

Die volgende newe effek is aangemeld en die frekwensie is onbekend:
Epistakse.

Gastroïntestinale afwykings:
Minder dikwels:
Naarheid, buikpyn.

Die volgende newe effekte is aangemeld en die frekwensies is onbekend:
Diarree, droë mond, braking.

Hepatobileêre afwykings:
Die volgende newe effekte is aangemeld en die frekwensies is onbekend:
Geelsug, hepatitis, cholestase.

Afwykings van die vel en subkutane weefsel:
Die volgende newe effekte is aangemeld en die frekwensies is onbekend:
Veluitslag, pruritus, purpura.

Nier- en urienafwykings:
Die volgende newe effekte is aangemeld en die frekwensies is onbekend:
Hematurie. Gevalle van urienretensie is aangemeld; hierdie effek mag verband hou met die farmakologiese werking van **URODOXA**.

Reproduksiesisteem- en borsafwykings:
Minder dikwels:
Priapisme.

Die volgende newe effekte is aangemeld en die frekwensies is onbekend:
Seksuele disfunksie, impotensie.

Algemene afwykings en kondisies by die plek van toediening:
Dikwels:
Astenie.

Die volgende newe effekte is aangemeld en die frekwensies is onbekend:
Moegheid, malaise, borspyn, edeem.

Ondersoeke:
Die volgende newe effek is aangemeld en die frekwensies is onbekend:
Abnormale lewerfunksietoetse.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Sien "**NEWE EFFEKTE**".

Aangesien **URODOXA** hoogs proteïengebonde is, word dialise nie aangedui nie. Die behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:
URODOXA 1 mg:
Wit tot naaswit, ronde, bikonvekse, onbedekte tablet, met "D O" aan die een kant en "1" aan die ander kant ingepers.

URODOXA 2 mg:
Wit tot naaswit, kapletvormige, onbedekte tablet, met "D O" aan die een kant met n breeklyn tussenin, en "2" aan die ander kant ingepers.

URODOXA 4 mg:
Wit tot naaswit, diamantvormige, onbedekte tablet, met "D O" aan die een kant met n breeklyn tussenin, en "4" aan die ander kant ingepers.

URODOXA 8 mg:
Wit tot naaswit, kapletvormige, onbedekte tablet, met "D O" aan die een kant met n breeklyn tussenin, en "8" aan die ander kant ingepers.

AANBIEDING:
URODOXA 1 mg:
1) Tablette word in wit, ondeursigtige 250 µm PVC film, bedek met 60 g/m^2 PVdc en gedrukte 25 µm aluminiumfoelie, bedek met 7 g/m^2 hitteseëllak verpak. Elke strokie bevat 10 tablette.

Pakgrootte: 30's - Elke karton bevat 3 stolpstrokies met 10 tablette elk.

2) Tablette word in 40 ml HDPE met 'n 33 mm nek (OFC 51 ml) en 33 mm - 400 RS deksel met TEKNIPLEX HS-123 induksie seëlprop met rayon spiraal verpak. Die HDPE houer word in 'n karton verpak. Elke houer bevat 30 tablette.

Pakgrootte: 30's - Een HDPE houer bevat 30 tablette.

URODOXA 2 mg:
1) Tablette word in wit, ondeursigtige 250 µm PVC film, bedek met 60 g/m^2 PVdc en gedrukte 25 µm aluminiumfoelie, bedek met 7 g/m^2 hitteseëllak verpak. Elke strokie bevat 10 tablette.

Pakgrootte: 30's - Elke karton bevat 3 stolpstrokies met 10 tablette elk.

2) Tablette word in 40 ml HDPE met 'n 33 mm nek (OFC 51 ml) en 33 mm - 400 RS deksel met TEKNIPLEX HS-123 induksie seëlprop met rayon spiraal verpak. Die HDPE houer word in 'n karton verpak. Elke houer bevat 30 tablette.

Pakgrootte: 30's - Een HDPE houer bevat 30 tablette.

URODOXA 4 mg:
1) Tablette word in wit, ondeursigtige 250 µm PVC film, bedek met 60 g/m^2 PVdc en gedrukte 25 µm aluminiumfoelie, bedek met 7 g/m^2 hitteseëllak verpak. Elke strokie bevat 10 tablette.

Pakgrootte: 30's - Elke karton bevat 3 stolpstrokies met 10 tablette elk.

2) Tablette word in 40 ml HDPE met 'n 33 mm nek (OFC 51 ml) en 33 mm - 400 RS deksel met TEKNIPLEX HS-123 induksie seëlprop met rayon spiraal verpak. Die HDPE houer word in 'n karton verpak. Elke houer bevat 30 tablette.

Pakgrootte: 30's - Een HDPE houer bevat 30 tablette.

URODOXA 8 mg:
1) Tablette word in wit, ondeursigtige 250 µm PVC film, bedek met 60 g/m^2 PVdc en gedrukte 25 µm aluminiumfoelie, bedek met 7 g/m^2 hitteseëllak verpak. Elke strokie bevat 10 tablette.

Pakgrootte: 30's - Elke karton bevat 3 stolpstrokies met 10 tablette elk.

2) Tablette word in 40 ml HDPE met 'n 33 mm nek (OFC 51 ml) en 33 mm - 400 RS deksel met TEKNIPLEX HS-123 induksie seëlprop met rayon spiraal verpak. Die HDPE houer word in 'n karton verpak. Elke houer bevat 30 tablette.

Pakgrootte: 30's - Een HDPE houer bevat 30 tablette.

BERGINGSINSTRUKSIES:
Bewaar teen of benede 25 °C. Beskerm teen lig. Hou die oorspronklike houers dig toe. Moenie die stolpstrokies tot voor gebruik uit die karton verwyder nie.

HOU BUITE BEREIK VAN KINDERS

REGISTRASIENOMMERS:
SUID AFRIKA:
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

NAMIBIË:
URODOXA 1 mg: 21/7.1.3/0017
URODOXA 2 mg: 21/7.1.3/0018
URODOXA 4 mg: 21/7.1.3/0019
URODOXA 8 mg: 21/7.1.3/0020

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:
Aurogen South Africa (Edms.) Bpk.
Woodhill Kantoorpark, Gebou 1, Eerste vloer
Phillip Engelbrechtlaan 53
Meyersdal Uitbr. 12,1448
Johannesburg
Suid Afrika

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
Datum van registrasie:
18 Februarie 2016

Datum van hersiening:
14 Februarie 2024

P1536454

DETACH BEFORE DISPENSING

S3

URODOXA 1 mg (tablet)
URODOXA 2 mg (tablet)
URODOXA 4 mg (tablet)
URODOXA 8 mg (tablet)
Doksasosienmesilaat

Lees die hele brosjure sorgvuldig voordat u begin om URODOXA te neem.
- Hou hierdie blaadjie. U mag dit moontlik weer wil lees.
- Indien u enige verdere vrae het, moet u asseblief u dokter of apteker raadpleeg.
- **URODOXA** is vir u persoonlik voorgeskryf en u behoort nie u medisyne met ander mense te deel nie. Dit mag hulle skade aandoen, ookal het hulle dieselfde simptome as u.

1. WAT URODOXA BEVAT:
Die aktiewe bestanddeel is doksasosien.

URODOXA 1 mg: Elke onbedekte tablet bevat doksasosienmesilaat ekwivalent aan doksasosien 1 mg. Bevat suiker: 24 mg laktose.
URODOXA 2 mg: Elke onbedekte tablet bevat doksasosienmesilaat ekwivalent aan doksasosien 2 mg. Bevat suiker: 24 mg laktose.
URODOXA 4 mg: Elke onbedekte tablet bevat doksasosienmesilaat ekwivalent aan doksasosien 4 mg. Bevat suiker: 48 mg laktose.
URODOXA 8 mg: Elke onbedekte tablet bevat doksasosienmesilaat ekwivalent aan doksasosien 8 mg. Bevat 96 mg laktose.

Die ander bestanddele van **URODOXA** is mikrokristallyne sellulose, natriumstyselglikolaat en magnesiumstearaat.

2. WAARVOOR URODOXA GEBRUIK WORD:
Doksasosien is in 'n klas van medisyne wat alfablokkeerders genoem word. **URODOXA** is 'n behandeling vir hoë bloeddruk, of die simptome wat veroorsaak word deur 'n vergroting van die prostaatklier in mans.

3. VOORDAT U URODOXA ONTVANG:
Moenie URODOXA gebruik nie:
- As u ooit 'n allergiese reaksie teen **URODOXA** kinasoliene of enige ander bestanddele van **URODOXA** gehad het.
- As u swanger is of borsvoed.
- As u 'n geskiedenis van lae bloeddruk het wanneer u van 'n lêende of sittende posisie opstaan.
- As u probleme het om te urineer of aan blaas- of nierprobleme ly.
- As u aan 'n vergrootte prostaat ly.

Neem spesiale sorg met URODOXA
- As u aan 'n lewer- of niersiekte ly.
- As u bejaard is.
- As u oogchirurgie weens 'n katarak (troebelheid van die ooglens) ondergaan, moet u asseblief u oogspesialis voor die operasie in kennis stel dat u **URODOXA** gebruik of voorheen gebruik het. **URODOXA** kan komplikasies gedurende die operasie veroorsaak.
- Wanneer u begin om **URODOXA** te neem, mag u floute of duiseligheid weens 'n lae bloeddruk ondervind wanneer u van 'n lêende of sittende posisie opstaan. As u flou of duiselig voel, behoort u te gaan sit of lê totdat u beter voel en behoort u situasies te vermy waar u mag val of uself beseer. U dokter mag besluit om u bloeddruk gereeld aan die begin van terapie na te gaan om die moontlikheid van die hierdie effekte te verminder.
- As u aan 'n kondisie wat angina pectoris genoem word, of hartversaking ly.

Swangerskap en Borsvoeding:
Moenie **URODOXA** gebruik as u swanger is of borsvoed nie. Die veiligheid van **URODOXA** in swangerskap en borsvoeding is nie vasgestel nie.

As u swanger is of u baba borsvoed, moet u asseblief u dokter, apteker of ander gesondheidsbeampte vir advies nader voordat u **URODOXA** gebruik.

Bestuur en die gebruik van masjinerie:
Wees versigtig wanneer u bestuur of met masjinerie werk. **URODOXA** tablette kan u vermoë om te bestuur of veilig met masjinerie te werk beïnvloed, veral wanneer u begin om die tablette te gebruik. **URODOXA** mag u lomerig of duiselig maak. As u so geaffekteer word, moet u nie bestuur of met masjinerie werk nie.

Belangrike inligting oor sommige van die bestanddele van URODOXA:
URODOXA bevat laktose. Pasiënte met selde voorkomende probleme van galaktoseïntoleransie, die Lapp-laktasetekort of met glukose-galaktase wanabsorpsie behoort nie **URODOXA** te gebruik nie.

Die neem van ander medisyne saam met URODOXA:
- Voordat u **URODOXA** gebruik, moet u u dokter in kennis stel as u tans ander medisyne gebruik of onlangs gebruik het.
- As u enige ander medisyne gebruik, mag dit moontlik wees dat u nie **URODOXA** sal kan gebruik nie, of die dosis sal moontlik aangepas moet word, of u dokter mag u moontlik gereeld vir newe effekte monitor.
- As u enige ander medisyne gebruik om hoë bloeddruk te behandel (soos PDE-5 inhibeerders), asook alkohol, kan dit 'n gevaarlike afname in u bloeddruk veroorsaak, veral na die eerste dosis.
- **URODOXA** kan u bloeddruk nog verder verlaag as u reeds ander medisyne gebruik om u hoë bloeddruk te behandel.

Stel altyd u professionele gesondheidswerker in kennis as u ander medisyne neem. (Dit sluit komplimentêre en tradisionele medisyne in).

4. HOE OM URODOXA TE NEEM:
- Neem **URODOXA** slegs soos deur u dokter aanbeveel.
- As u **URODOXA** vir die eerste keer gebruik, is die dosis 1 mg een keer per dag. Hierna is die normale dosis 2 mg tot 4 mg per dag. In sommige gevalle mag dit na 'n maksimum van 8 mg per dag verhoog word as u vir vergroting van die prostaatklier behandel word, of tot 'n maksimum van 16 mg as u vir hoë bloeddruk behandel word
- U dokter sal u dosis geleidelik met tussenposes van 1 tot 2 weke verhoog.

Neem **URODOXA** altyd presies soos deur u dokter voorgeskryf. Bevestig met u dokter of apteker as u onseker is. As u onder die indruk is dat die effek van **URODOXA** te sterk of te swak is, moet u asseblief u dokter of apteker raadpleeg.

As u te veel URODOXA ontvang het:

In die geval van oordosering moet u u dokter of apteker raadpleeg. Indien hulle nie beskikbaar is nie, moet u na u naaste hospitaal of gifbeheersentrum gaan.

As u vergeet het om URODOXA te neem:
As u vergeet het om **URODOXA** te neem, moet u dit so as wat u daarvan onthou neem. Indien dit egter byna tyd vir die volgende dosis is, moet u die dosis oorslaan en met u gereelde dosisskedulering voortgaan. Moenie 'n dubbeldosis neem om vir 'n oorgeslaande dosis op te maak nie.

5. MOONTLIKE NEWE EFFEKTE :
URODOXA kan newe effekte hê.

Kry nood mediese hulp as u enige van hierdie tekens van 'n allergiese reaksie toon:
- Moeite met asemhaling.
- Swelling van die u gesig, lippe, tong of keel.

Raadpleeg onmiddellik u dokter as u enige van die volgende ernstige newe effekte ondervind:
- Borspyn.
- Angina.