

Applicant: Aurogen South Africa (Pty) Ltd
Product Name: AXORN CO 80 mg/12,5 mg; 160/12,5mg; 160/25mg;
320/12,5; 320/25 mg
Dosage form and strength: Film-coated tablet, Each film coated tablet
contains Valsartan and Hydrochlorothiazide Ph.Eur.
80 mg/12,5 mg; 160/12,5mg; 160/25mg; 320/12,5; 320/25 mg

1.3.2 South African Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULE STATUS

S3

AXORN CO 80/12,5 mg(film-coated tablets)

AXORN CO 160/12,5 mg (film-coated tablets)

AXORN CO 160/25 mg (film-coated tablets)

AXORN CO 320/12,5 mg (film-coated tablets)

AXORN CO 320/25 mg (film-coated tablets)

Valsartan and Hydrochlorothiazide

Contains sugar: 60 mg, 120 mg, 120 mg, 240 and 240 mg of Lactose monohydrate,
respectively per tablet.

Read all of this leaflet carefully before you start taking AXORN CO

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

(Valsartan 80 mg and 12,5 mg Hydrochlorothiazide, film-coated tablet)
(Valsartan 160 mg and 12,5 mg Hydrochlorothiazide, film-coated tablet)
(Valsartan 160 mg and 25 mg Hydrochlorothiazide, film-coated tablet)
(Valsartan 320 mg and 12,5 mg Hydrochlorothiazide, film-coated tablet)
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80 mg/12,5 mg; 160/12,5mg; 160/25mg; 320/12,5; 320/25 mg

What is in this leaflet

1. What **AXORN CO** is and what it is used for
2. What you need to know before you take **AXORN CO**
3. How to take **AXORN CO**
4. Possible side effects
5. How to store **AXORN CO**
6. Contents of the pack and other information

What AXORN CO is and what it is used for

AXORN CO film-coated tablets contain two active substances called valsartan and hydrochlorothiazide.

Both of these substances help to control high blood pressure (hypertension).

- Valsartan belongs to a class of medicines known as “angiotensin II receptor antagonists”, which help to control high blood pressure. Angiotensin II is a substance in the body that causes vessels to tighten, thus causing your blood pressure to increase. Valsartan works by blocking the effect of angiotensin II. As a result, blood vessels relax, and blood pressure is lowered.
- Hydrochlorothiazide belongs to a group of medicines called thiazide diuretics (also known as “water tablets”). Hydrochlorothiazide increases urine output, which also lowers blood pressure.

AXORN CO is used to treat high blood pressure, which is not adequately controlled by a single substance alone.

(Valsartan 80 mg and 12,5 mg Hydrochlorothiazide, film-coated tablet)
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2. What you need to know before you take AXORN CO

Do not take AXORN CO:

- if you are allergic (hypersensitive) to valsartan, hydrochlorothiazide or any of the other ingredients of **AXORN CO** (listed in section 6).
- if you have developed swelling of the face, lips, mouth, tongue or throat and giant wheals on your skin when previously taking medicines called angiotensin- converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) – you should never take these medicines again.
- if you suffer from obstruction of blood vessels to your heart or kidneys.
- if you suffer from severe kidney function impairment.
- if you suffer from porphyria.
- if you are currently taking lithium.
- if you are currently taking potassium sparing water tablets containing spironolactone, triamterene or amiloride.
- if you are taken fluoroquinolones (antibiotics to treat infections)
- if you are currently taking aliskiren-containing medicines.
- if you are pregnancy or breast-feeding.
- if the level of potassium or sodium in your blood is lower than normal, or if the level of calcium in your blood is higher than normal despite treatment.

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- if you have previously had or currently have cancer of the skin and/or lip.

Warnings and precautions

Take special care with AXORN CO:

- if you are taking potassium-sparing medicines, potassium supplements, salt substitutes containing potassium or other medicines that increase the amount of potassium in your blood such as heparin. Your doctor may need to check the amount of potassium in your blood regularly.
- if you have low levels of potassium in your blood.
- if you have diarrhoea or severe vomiting.
- if you are taking high doses of water tablets (diuretics).
- if you have severe heart disease.
- if you are suffering from heart failure or have experienced a heart attack. Follow your doctor's instruction for the starting dose carefully. Your doctor may also check your kidney function.
- if you suffer from a narrowing of the kidney artery.
- if you have recently received a new kidney.
- if you suffer from hyperaldosteronism. This is a disease in which your adrenal glands make too much of the hormone aldosterone. If this applies to you, the use of **AXORN CO** is not recommended.
- if you have liver or kidney disease.
- if you have ever experienced swelling of the tongue and face caused by an allergic

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reaction called angioedema when taking another drug (including ACE inhibitors), tell your doctor. If these symptoms occur when you are taking **AXORN CO**, stop taking **AXORN CO** immediately and never take it again. See also section 4, "Possible side effects".

- if you have fever, rash and joint pain, which may be signs of systemic lupus erythematosus (SLE, a so-called autoimmune disease).
- if you have diabetes, gout, high levels of cholesterol or triglycerides in your blood.
- if you have had allergic reactions with the use of other blood pressure-lowering medicines of this class (angiotensin II receptor antagonists) or if you have allergy or asthma.
- if you experience a decrease in vision or eye pain. These could be symptoms of an increase of pressure in your eye and can happen within hours to a week of taking **AXORN CO**. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulphonamide allergy you can be at higher risk of developing this.
- if you are taking any of the following medicines used to treat high blood pressure:
 - an ACE inhibitors (for example enalapril, lisinopril, Ramipril), in particular if you have diabetes-related kidney problems.
 - aliskiren.
- if you have had skin cancer or if you develop an unexpected skin lesion during the treatment.

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Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer).

Protect your skin from sun exposure and UV rays while taking **AXORN CO**.

Contact your doctor to re-evaluate your treatment If you are treated with ACE inhibitors/Angiotensin receptor blockers together with a fluoroquinolone antibiotic.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading “**Do not take AXORN CO**”

AXORN CO may cause increased sensitivity of the skin to sun.

Children and adolescents

The use of **AXORN CO** in children and adolescents (below the age of 18 years) is not recommended.

Taking other medicines with AXORN CO

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

The effect of the treatment can be influenced if **AXORN CO** is taken together with certain other medicines. It may be necessary to change the dose, to take other

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precautions, or in some cases to stop taking one of the medicines. This especially applies to the following medicines:

- lithium, a medicine used to treat some types of psychiatric diseases.
- medicines or substances that may increase the amount of potassium in your blood.
These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin.
- medicines that may reduce the amount of potassium in your blood, such as diuretics (water tablets), corticosteroids, laxatives, carbenoxolone, amphotericin or penicillin G.
- some antibiotics (rifamycin group), a medicine used to protect against transplant rejection (ciclosporin) or an antiretroviral medicine used to treat HIV/AIDS infection (ritonavir). These medicines may increase the effect of **AXORN CO**.
- medicines that may induce “torsades de pointes” (irregular heart beat), such as antidysrhythmics (medicines used to treat heart problems) and some antipsychotics.
- medicines that may reduce the amount of sodium in your blood, such as antidepressants, antipsychotics, antiepileptics.
- medicines for the treatment of gout, such as allopurinol, probenecid, sulfinpyrazone.
- therapeutic vitamin D and calcium supplements.
- medicines for the treatment of diabetes (oral medicines such as metformin or insulins).
- other medicines to lower your blood pressure including methyldopa, ACE inhibitors (such as enalapril, lisinopril, etc.) or aliskiren (see also information under the

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headings “Do not take **AXORN CO**” and “Warnings and precautions”).

- medicines to increase blood pressure, such as noradrenaline or adrenaline.
- digoxin or other digitalis glycosides (medicines used to treat heart problems).
- medicines that may increase blood sugar levels, such as diazoxide or beta blockers.
- cytotoxic medicines (used to treat cancer), such as methotrexate or cyclophosphamide.
- pain killers such as non-steroidal anti-inflammatory medicines (NSAIDs), including selective cyclo-oxygenase-2 inhibitors (Cox-2 inhibitors) and acetylsalicylic acid > 3 g.
- muscle relaxing medicines, such as tubocurarine.
- anti-cholinergic medicines (medicines used to treat a variety of disorders such as gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscular spasms, Parkinson's disease and as an aid to anaesthesia).
- amantadine (medicine used to treat Parkinson's disease and also used to treat or prevent certain illnesses caused by viruses).
- cholestyramine and colestipol (medicines used mainly to treat high levels of lipids in the blood).
- ciclosporin, a medicine used for organ transplant to avoid organ rejection.
- alcohol, sleeping pills and anaesthetics (medicines with sleeping or painkilling effect used for example during surgery).
- iodine contrast media (agents used for imaging examinations).

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AXORN CO with food and drink

AXORN CO may be taken with or without food. Avoid drinking alcohol as alcohol may make your blood pressure fall more and/or increase the risk of you becoming dizzy or feeling faint.

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking **AXORN CO**.

Do not take **AXORN CO** if you are pregnant, are considering becoming pregnant or are breastfeeding.

If you are a woman of childbearing age, you must use effective contraception.

Driving and using machines

Before you drive a vehicle, use tools or operate machines or carry out other activities that require concentration, make sure you know how **AXORN CO** affects you. Like many other medicines used to treat high blood pressure, **AXORN CO** may occasionally cause dizziness and affect the ability to concentrate.

AXORN CO contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **AXORN CO**.

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80 mg/12,5 mg; 160/12,5mg; 160/25mg; 320/12,5; 320/25 mg

How to take AXORN CO

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

Always take **AXORN CO** exactly as your doctor has told you. Check with your doctor if you are not sure.

Your doctor will tell you exactly how many tablets of **AXORN CO** to take. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

- The recommended dose of **AXORN CO** is one tablet per day.
- Do not change the dose or stop taking the tablets without consulting your doctor.
- **AXORN CO** should be taken at the same time each day, usually in the morning.
- You can take **AXORN CO** with or without food.
- Swallow the tablet with a glass of water.

AXORN CO tablets are only for adults and should not be taken by children and adolescents up to 18 years.

If you have the impression that **AXORN CO** is too strong or too weak, talk to your doctor or pharmacist.

If you take more AXORN CO than you should

If you experience severe dizziness and/or fainting, contact your doctor immediately and lie down. In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take AXORN CO

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If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten dose.

Effects when treatment with AXORN CO is stopped:

Stopping your treatment with **AXORN CO** may cause your high blood pressure to get worse. Do not stop taking your medicine unless your doctor tells you to.

4. Possible side effects

AXORN CO can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to **AXORN CO**. You may need urgent medical attention or hospitalisation.

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Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- severe skin disease that causes rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (toxic epidermal necrolysis),
- decrease in vision or pain in your eyes due to high pressure (possible signs of acute angleclosure glaucoma),
- fever, sore throat, more frequent infections (agranulocytosis).

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

Tell your doctor if you notice any of the following:

Frequent:

- low level of potassium in the blood,
- increase of lipids in the blood,
- low level of sodium in the blood,
- low level of magnesium in the blood
- high level of uric acid in the blood,
- itchy rash and other types of rash,
- reduced appetite,
- mild nausea and vomiting,
- dizziness, fainting on standing up,
- inability to achieve or maintain erection

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Less frequent:

- cough,
- low blood pressure,
- light-headedness,
- dehydration (with symptoms of thirst, dry mouth and tongue, infrequent urination, dark colored urine, dry skin),
- muscle pain,
- tiredness,
- tingling or numbness,
- blurred vision,
- noises (e.g. hissing, buzzing) in ears,
- diarrhoea,
- joint pain.
- spinning sensation,
- abdominal pain
- swelling and blistering of the skin (due to increased sensitivity to sun),
- high level of calcium in the blood,
- high level of sugar in the blood,
- sugar in the urine,
- worsening of diabetic metabolic state,

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- constipation, diarrhoea, discomfort of the stomach or bowels, liver disorders which can occur together with yellow skin and eyes,
- irregular heartbeat,
- headache,
- sleep disturbances,
- sad mood (depression),
- low level of blood platelets (sometimes with bleeding or bruising underneath the skin),
- inflammation of blood vessels with symptoms such as rash, purplish-red spots, fever (vasculitis),
- rash, itching, hives, difficulty breathing or swallowing, dizziness (hypersensitivity reactions),
- facial rash, joint pain muscle disorder, fever (lupus erythematosus),
- severe upper stomach pain (pancreatitis),
- difficulty breathing with fever, wheezing, breathlessness (respiratory distress including pneumonitis and pulmonary oedema),
- pale skin, tiredness, breathlessness, dark urine (haemolytic anaemia),
- fever, sore throat or mouth ulcers due to infections (leucopenia,)
- confusion, tiredness, muscle twitching and spasm, rapid breathing (hypochloraemic alkalosis).

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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 via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/>

By reporting side effects, you can help provide more information on the safety of **AXORN CO**.

5. How to store AXORN CO

- Keep out of the sight and reach of children.
- Store at or below 25 °C.
- Store in the original package in order to protect from light and moisture.
- Do not use **AXORN CO** after the expiry date, which is stated on the package. The expiry date refers to the last day of that month
- If your tablets become discoloured or show any other signs of deterioration, consult your doctor or pharmacist who will tell you what to do.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

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What AXORN CO contains

AXORN CO 80 /12,5mg; 160/12,5 mg; 160/25 mg; 320/12,5 mg; 320/25 mg

Each film coated tablet contains 80 /12,5mg; 160/12,5 mg, 160/25 mg, 320/12,5 mg, 320/25 mg Valsartan and Hydrochlorothiazide respectively.

Contains sugar: 60 mg, 120 mg, 120 mg, 240 and 240 mg of Lactose monohydrate, respectively.

The other ingredients of AXORN CO are

Cellulose, Microcrystalline Ph.Eur (Avicel PH 101)

Cellulose, Microcrystalline Ph.Eur (Avicel PH 112)

Lactose Monohydrate (Pharmatose 200M) Ph.Eur.

Crospovidone (Polyplasdone XL 10) Ph.Eur.

Silica, Colloidal Anhydrous (Aerosil-200) Ph.Eur.

Hypromellose (Methocel E5LV premium) Ph.Eur.

Sodium Lauryl Sulphate (Texapon K 12 P PH) Ph.Eur.

Talc Ph.Eur.

Magnesium Stearate Ph.Eur

Ingredients of Coating material:

AXORN CO 80 /12,5 mg:

Opadry 03F84793 Pink Powder IH

AXORN CO 160 /12,5 mg:

(Valsartan 80 mg and 12,5 mg Hydrochlorothiazide, film-coated tablet)
(Valsartan 160 mg and 12,5 mg Hydrochlorothiazide, film-coated tablet)
(Valsartan 160 mg and 25 mg Hydrochlorothiazide, film-coated tablet)
(Valsartan 320 mg and 12,5 mg Hydrochlorothiazide, film-coated tablet)
(Valsartan 320 mg and 25 mg Hydrochlorothiazide, film-coated tablet)



Applicant: Aurogen South Africa (Pty) Ltd
Product Name: AXORN CO 80 mg/12,5 mg; 160/12,5mg; 160/25mg; 320/12,5; 320/25 mg
Dosage form and strength: Film-coated tablet, Each film coated tablet contains Valsartan and Hydrochlorothiazide Ph.Eur.
80 mg/12,5 mg; 160/12,5mg; 160/25mg; 320/12,5; 320/25 mg

Opadry 03F86845 Brown Powder IH

AXORN CO 160 /25 mg:

Opadry 03F86762 Brown Powder IH

AXORN CO 320 /12,5 mg:

Opadry 03F84782 Pink Powder IH

AXORN CO 320 /25 mg:

Opadry 03F82604 Yellow Powder IH

What AXORN CO looks like and contents of the pack

AXORN CO 80 mg/12,5 mg

Light orange coloured, ovaloid, beveled edge, biconvex film-coated tablets debossed with 'I' on one side and '61' on other side.

AXORN CO 160 mg/12,5 mg

Dark red coloured, ovaloid, beveled edge, biconvex film-coated tablets debossed with 'I' on one side and '62' on other side.

AXORN CO 160 mg/25 mg

Brown-orange coloured, ovaloid, beveled edge, biconvex film-coated tablets debossed with "I" on one side and '63' on other side.

AXORN CO 320 mg/12,5 mg

(Valsartan 80 mg and 12,5 mg Hydrochlorothiazide, film-coated tablet)
(Valsartan 160 mg and 12,5 mg Hydrochlorothiazide, film-coated tablet)
(Valsartan 160 mg and 25 mg Hydrochlorothiazide, film-coated tablet)
(Valsartan 320 mg and 12,5 mg Hydrochlorothiazide, film-coated tablet)
(Valsartan 320 mg and 25 mg Hydrochlorothiazide, film-coated tablet)

Applicant: Aurogen South Africa (Pty) Ltd
Product Name: AXORN CO 80 mg/12,5 mg; 160/12,5mg; 160/25mg; 320/12,5; 320/25 mg
Dosage form and strength: Film-coated tablet, Each film coated tablet contains Valsartan and Hydrochlorothiazide Ph.Eur.
80 mg/12,5 mg; 160/12,5mg; 160/25mg; 320/12,5; 320/25 mg

Pink coloured, oval, beveled edge, biconvex film-coated tablets debossed with 'I' on one side and '64' on other side.

AXORN CO 320 mg/25 mg

Yellow coloured, oval, beveled edge, biconvex film-coated tablets debossed with 'I' on one side and '65' on other side.

AXORN CO 80 /12,5mg; 160/12,5 mg; 160/25 mg; 320/12,5 mg; 320/25 mg:

Blister Pack

PVC laminated with Aclar - Aluminium foil blister pack:

Blister pack comprises of PVC laminated with Aclar as the forming material and Aluminum foil with heat seal lacquer as the lidding material.

Pack size: Printed cardboard carton containing 3 blisters of 10 film coated tablets each.

HDPE Container Pack:

For 80/12,5 mg, 160/12,5 mg, 160/25 mg, 320/12,5 mg and 320/25 mg:

White opaque round HDPE container with neck finish closed with white opaque polypropylene closure with wad having induction sealing liner. Each HDPE container shall contain 1 no of 1 g silica gel sachet.

Pack Size: 30's (HDPE)

(Valsartan 80 mg and 12,5 mg Hydrochlorothiazide, film-coated tablet)
(Valsartan 160 mg and 12,5 mg Hydrochlorothiazide, film-coated tablet)
(Valsartan 160 mg and 25 mg Hydrochlorothiazide, film-coated tablet)
(Valsartan 320 mg and 12,5 mg Hydrochlorothiazide, film-coated tablet)
(Valsartan 320 mg and 25 mg Hydrochlorothiazide, film-coated tablet)



Applicant: Aurogen South Africa (Pty) Ltd
Product Name: AXORN CO 80 mg/12,5 mg; 160/12,5mg; 160/25mg; 320/12,5; 320/25 mg
Dosage form and strength: Film-coated tablet, Each film coated tablet contains Valsartan and Hydrochlorothiazide Ph.Eur.
80 mg/12,5 mg; 160/12,5mg; 160/25mg; 320/12,5; 320/25 mg

Holder of Certificate of Registration

AUROGEN SOUTH AFRICA (PTY) Ltd
Woodhill Office Park,
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Meyersdal, Ext. 12, 1448
Johannesburg
South Africa

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06 March 2023

Registration Number

AXORN CO 80/12,5 mg: 48/7.1.3/0856
AXORN CO 160/12,5 mg: 48/7.1.3/0857
AXORN CO 160/25 mg: 48/7.1.3/0858
AXORN CO 320/12,5 mg: 48/7.1.3/0859
AXORN CO 320/25 mg: 48/7.1.3/0860

Access to the corresponding Professional Information

06 March 2023

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