APPROVED PIL

For

PREXUM 5+10 mg

Registration No.:

Prexum® 5 mg: A39/7.1.3/0232

Prexum® 10 mg: A39/7.1.3/0233

Date Approved: April 2022

Confidential Information

PATIENT INFORMATION LEAFLET

Prexum 5 and 10 mg Film-coated tablets

Perindopril arginine

Contains sugar (lactose)

Prexum 5 mg contains 72,58 mg of lactose monohydrate

Prexum 10 mg contains 145,16 mg of lactose monohydrate

SCHEDULING STATUS: S3

Read all of this leaflet carefully before you start taking Prexum

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, ~~or~~ pharmacist, nurse or healthcare provider.
- **Prexum** has been prescribed to 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 **Prexum** is and what it is used for
2. What you need to know before you take **Prexum**
3. How to take **Prexum**
4. Possible side effects
5. How to store **Prexum**
6. Contents of the pack and other information

1. What Prexum is and what it is used for

Each **Prexum 5 mg**, film-coated tablet contains 5 mg perindopril arginine salt.

Each **Prexum 10 mg**, film-coated tablet contains 10 mg perindopril arginine salt.

Prexum is an angiotensin converting enzyme (ACE) inhibitor. These work by widening the blood vessels, which makes it easier for your heart to pump blood through them.

Prexum is used:

- to treat high blood pressure (hypertension),
- to treat heart failure (a condition where the heart is unable to pump enough blood to meet the body's needs).

2. What you need to know before you take Prexum

Do not take Prexum if

- you are allergic to perindopril, or to any other ACE-inhibitor or to any of the ingredients of **Prexum** (listed in Section 6),
- you are pregnant or trying to become pregnant,
- you are breastfeeding or plan to breastfeed,
- you have experienced symptoms such as wheezing, swelling of the face, tongue or throat, intense itching or severe skin rashes with previous ACE-inhibitor treatment or if you or a member of your family have had these symptoms in any other circumstances (This rare condition is known as angioedema),
- If you have porphyria,
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren,
- if you are having dialysis or any other type of blood filtration. Depending on the machine that is used, **Prexum** may not be suitable for you,
- if you have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis),

- if you are being treated with sacubitril/valsartan, a medicine for heart failure as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased (see (see Take special care and Taking other medicines and **Prexum**),
- If you take fluoroquinolones (antibiotics).

Warnings and precautions

Take special care

- If you are undergoing desensitisation treatment, or have had an allergic reaction during previous desensitisation treatment (e.g. treatments using bee, wasp or ant venom),
- are to undergo LDL apheresis (which is removal of cholesterol from your blood by a machine),
- If you are to undergo anaesthesia and/or surgery,
- if you have recently suffered from diarrhoea or vomiting, or are dehydrated,
- You have any other health problems, including:
  - Kidney disease or if you are receiving dialysis
  - Liver disease
  - Diabetes
  - Heart disease
- Contact your doctor to re-evaluate your treatment if you are treated with ACE-inhibitors/Angiotensin receptor blockers together with a fluoroquinolone antibiotic,
- if you have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism),
- If you have aortic stenosis (narrowing of the main blood vessel leading from the heart) or hypertrophic cardiomyopathy (heart muscle disease) or renal artery stenosis (narrowing of the artery suppling the kidney with blood),
- If you have been told by your doctor that you have an intolerance to some sugars,
- If you suffer from a collagen vascular disease such as systemic lupus erythematosus or scleroderma,

- if you are on a salt restricted diet or use salt substitutes which contain potassium,
- if you are taking any of the following medicines used to treat high blood pressure:
  an “angiotensin II receptor blocker” (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems,
- if you are taking aliskiren (medicines used to treat hypertension). Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals,
- if you are of black origin since you may have a higher risk of angioedema and this medicine may be less effective in lowering your blood pressure than in non-black patients,
- if you are taking any of the following medicines, the risk of angioedema is increased:
- racecadotril (used to treat diarrhoea),
- sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTor inhibitors (used to avoid rejection of transplanted organs and for cancer),
- sacubitril (available as fixed-dose combination with valsartan), used to treat long-term heart failure,
- linagliptin, saxagliptin, sitagliptin, vildagliptin and other drugs belonging to the class of the also called gliptins (used to treat diabetes).

Angioedema

Angioedema (a severe allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing) has been reported in patients treated with ACE-inhibitors, including **Prexum**. This may occur at any time during treatment. If you develop such symptoms, you should stop taking **Prexum** and see a doctor immediately (see Possible side effects). (Also see section 4).
You must tell your doctor if you think that you are (or might become) pregnant. **Prexum** is not recommended as it may cause serious harm to your baby (see Pregnanacy section).

Children and adolescents

Prexum is not recommended for children and adolescents.

Other medicines and Prexum

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

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Taking **Prexum** may change the effect of some medicines, and some medicines may affect how well **Prexum** works.

The medicines that may interact with **Prexum** include the following:

- Non steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high dose aspirin, a substance presents in many medicines used to relieve pain and lower fever, as well as to prevent blood clotting,
- Lithium medications (used to treat mood swings and some types of depression/mania),
- Potassium-sparing diuretics (e.g. triamterene, amiloride), sources of potassium, like potassium tablets and salt substitutes containing potassium, other medicines which can increase potassium in your body (such as heparin, a medicine used to thin blood to prevent clots, trimethoprim and co-trimoxazole also known as trimethoprim/sulfamethoxazole for infections caused by bacteria),
- potassium-sparing medicines used in the treatment of heart failure: eplerenone and spironolactone at doses between 12,5 mg to 50 mg by day,
- other medicines for treating high blood pressure, including angiotensin II receptor blocker (ARB) or aliskiren or diuretics (medicines which increase the amount of urine produced by the kidneys),
- medicines used to treat diabetes (tablets and insulin),
- baclofen (used to treat muscle stiffness in diseases such as multiple sclerosis),

- medicines to treat mental disorders such as depression, anxiety, schizophrenia (i.e. tricyclic antidepressants, antipsychotics),
- immunosuppressants (medicines which reduce the defence mechanism of the body) used for the treatment of auto-immune disorders or following transplant surgery (e.g. ciclosporin, tacrolimus).
- trimethoprim (for the treatment of infections),
- estramustine (used in cancer therapy),
- medicines, which are most often used to treat diarrhoea (racecadotril) or avoid rejection of transplanted organs (sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTor inhibitors). See section Warnings and precautions
- sacubitril/valsartan (used to treat long-term heart failure). See “Do not take **Prexum** and Warnings and precautions”,
- allopurinol (for the treatment of gout),
- procainamide (for the treatment of irregular heartbeat),
- vasodilators including nitrates (products that make the blood vessels become wider),
- medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline),
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis).

It is a good idea to remind your doctor of all other medicines you take. Your doctor or pharmacist has more information on medicines that you need to be careful with or avoid while taking **Prexum.**

Prexum with food and drink

It is preferable to take **Prexum** before a meal.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Pregnancy

Prexum must not be taken while pregnant. Should you become pregnant or contemplate pregnancy while using **Prexum** consult your doctor without delay. The switch to an alternative treatment should be initiated as soon as possible.

You must tell your doctor if you think that you are (or might become) pregnant. **Prexum** should not be taken while pregnant or breastfeeding. Should you become pregnant while using **Prexum** the medicine must immediately be stopped and consult your doctor without delay.

Breastfeeding

Tell your doctor if you are breastfeeding or about to start breastfeeding. **Prexum** is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breastfeed, especially if your baby is newborn, or was born prematurely.

Driving and using machines:

When driving vehicles or operating machines it should be taken into account that occasionally dizziness or weariness may occur. If affected, your ability to drive or to operate machinery may be impaired.

Prexum contains lactose

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

Prexum contains sodium

Prexum contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Prexum

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

Always take **Prexum** exactly as your doctor has instructed you. You should check with your doctor if you are unsure. Swallow your tablet(s) with a glass of water, preferably in the morning before a meal. The dose of **Prexum** you may need each day will be decided and adjusted by your doctor. The usual dosages are as follows:

Dosage in high blood pressure

The recommended dosage is 5 mg orally taken in the morning before breakfast, which can be increased to a single daily dose of 10 mg if necessary, after one month of treatment.

Dosage in elderly patients and heart failure

In elderly patients and patients with heart failure, treatment should be started at a dose of 2,5 mg, which may progressively be increased to 5 mg after one month, then to 10 mg if necessary, depending on kidney function.

Use in children and adolescent

Use in children and adolescent is not recommended.

If you take more Prexum 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.

The most likely effect in case of overdose is low blood pressure which can make you feel dizzy or faint. If this happens, lying down with the legs raised can help.

If you forget to take Prexum

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of **Prexum**, take the next dose at the usual time.

Do not take a double dose to make up for the forgotten individual doses.

If you stop taking Prexum

As the treatment with **Prexum** is usually life-long, you should discuss with your doctor before stopping this medicine.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Prexum can have side effects.

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

If you experience any of the following, stop taking the medicinal product at once and tell your doctor immediately:

- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing (angioedema) (See section 2 “Warnings and precautions”),
- severe dizziness or fainting, due to low blood pressure,
- unusual fast or irregular heartbeat, chest pain (angina), heart attack,
- weakness of arms or legs, or problems speaking which could be a sign of a possible stroke,
- sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing (bronchospasm),

- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell
- yellowing of the skin or eyes (jaundice) which could be a sign of hepatitis, skin rash which often starts with red itchy patches on your face, arms or legs (erythema multiforme),
- skin rash which often starts with red itchy patches on your face, arms or legs (erythema multiforme).

In decreasing order of frequency, side effects can include:

Frequent

- headache,
- dizziness,
- vertigo,
- pins and needles,
- vision disturbances,
- tinnitus (sensation of noises in the ears),
- cough,
- shortness of breath (dyspnoea),
- gastro-intestinal disorders (nausea, vomiting, abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation),
- allergic reactions (such as skin rashes, itching),
- muscle cramps,
- feeling of tiredness.

Less Frequent

- depression
- mood swings,
- sleep disturbances,
- dry mouth,
- intense itching or severe skin rashes),

- formation of blister clusters over the skin,
- kidney problems,
- impotence,
- sweating,
- excess of eosinophils (a type of white blood cells),
- somnolence,
- fainting,
- palpitations,
- tachycardia,
- vasculitis (inflammation of blood vessels),
- photosensitivity reaction (increased sensitivity of the skin to sun),
- arthralgia (joint pain),
- myalgia (muscle pain),
- chest pain,
- malaise,
- peripheral oedema,
- fever,
- fall,
- change in laboratory parameters: high blood level of potassium reversible on discontinuation, low level of sodium, hypoglycaemia (very low blood sugar level) in case of diabetic patients, increased blood urea, and increased blood creatinine,
- acute renal failure,
- dark urine, feeling sick (nausea) or being sick (vomiting), muscle cramps, confusion and seizures. These may be symptoms of a condition called SIADH (inappropriate antidiuretic hormone secretion),
- decreased or absent urine output,
- flushing,

- worsening of psoriasis,
- changes in laboratory parameters: Increased level of liver enzymes, high level of serum bilirubin,
- confusion,
- eosinophilic pneumonia (a rare type of pneumonia),
- rhinitis (blocked up or runny nose),
- changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets,
- If you have these symptoms contact your doctor as soon as possible,
- Frequency not known (cannot be estimated from available data): Discoloration, numbness and pain in fingers or toes (Raynaud's phenomenon),

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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. By reporting side effects, you can help provide more information on the safety of **Prexum.**

5. How to store Prexum

Store at or below 30 °C in a dry place.

Store all medicine out of reach of children.

Do not use after the expiry date stated on the blister.

Return all unused medicine to your pharmacist.

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

6. Content of the pack and other information

What Prexum 5 mg contains

The active substance is perindopril arginine. One film-coated tablet contains 3,395 mg perindopril (corresponding to 5 mg perindopril arginine).

What Prexum 10 mg contains

The active substance is perindopril arginine. One film-coated tablet contains 6,790 mg perindopril (corresponding to 10 mg perindopril arginine).

The other ingredients in the tablet core are: lactose monohydrate, magnesium stearate, maltodextrin, hydrophobic colloidal silica, sodium starch glycolate (type A), and in the tablet film-coating: glycerol, hypromellose, copper chlorophyllin, macrogol 6 000, magnesium stearate, titanium dioxide.

What Prexum 5 mg looks like and contents of the pack

Prexum 5 mg tablets are light-green, rod-shaped film-coated tablets engraved with * on one face and scored on both edges. The tablet can be divided into equal halves.

What Prexum 10 mg looks like and contents of the pack

Prexum 10 mg tablets are Green, round biconvex, film-coated tablet, engraved with ♡ on one face and * on the other face.

Prexum is packed into pack sizes of 30 tablets into a polypropylene white tube with a low-density polyethylene flow reducer and a low-density polyethylene white stopper, containing 2 g of white desiccant gel and placed into an outer carton.

Holder of certificate of registration

Servier Laboratories South Africa (Pty) Ltd

3rd Floor, Building J

Hertford Office Park

90 Bekker Road

Vorna Valley

Midrand

2196

This leaflet was last revised in

29 April 2022

Registration number

Prexum 5 mg: A39/7.1.3/0232

Prexum 10 mg: A39/7.1.3/0233

Namibia Details

Prexum 5: 07/7.1.3/0102 (NS2)

Prexum 10: 07/7.1.3/0103 (NS2)

Botswana Details

Prexum 5: BOT2500122 (S2)

Prexum 10: BOT2500140 (S2)

PATIENT INFORMATION LEAFLET

Prexum 5 en 10 mg filmbedekyte tablette

Perindopril arginine

Bevat suiker (laktose)

Prexum 5 mg bevat 72,58 mg of laktose monohidraat

Prexum 10 mg bevat 145,16 mg of laktose monohidraat

SKEDULERINGSTATUS S3

Lees die hele pamflet deeglik deur voordat jy Prexum begin neem.

- Hou hierdie pamflet. Dit is moontlik dat jy dit weer sal wil lees.
- Indien jy enige verdere vrae het, vra jou dokter of apteker.
- Prexum is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.

Wat is in hierdie pamflet

1. Wat Prexum is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy Prexum neem
3. Hoe om Prexum te neem
4. Moontlike newe-effekte
5. Hoe om Prexum Plus te bewaar
6. Inhoud van die pakkie en ander inligting

2. What Prexum is and what it is used for

Elke Prexum 5 mg, filmbedekte tablet bevat 5 mg perindopril arginine sout.

Elke Prexum 10 mg, filmbedekte tablet bevat 10 mg perindopril arginine sout.

Prexum is 'n angiotensien-omsettingsensiem (AOE)- remmer. Dit werk deur die bloedvate te verwyd, wat dit dan vir jou hart makliker maak om bloed daardeur te pomp.

Prexum word gebruik

- vir die behandeling van hoë bloeddruk (hipertensie)
- vir die behandeling van hartversaking ('n kondisie waar die hart nie genoeg bloed pomp vir die liggam se behoeftes nie)

3. Wat jy moet weet voordat jy Prexum neem

Moenie Prexum neem nie

- As jy allergies is vir perindopril, of enige ander AOE remmer of vir enige ander bestanddele van Prexum (gelys in Seksie 6).
- As jy swanger is of prober om swanger to word.
- As jy borsvoed of beplan om te borsvoed.
- as jy simptome ervaar het soos hyging, swelling in die gesig of tong of keel, intense jeuk of erge veluitslag tydens ’n vorige behandeling met ’n AOE-remmer, of as jy of ’n familielid hierdie simptome onder enige ander omstandighede ervaar het (hiedie rare toestand word angio-edeem genoem),
- as jy porfirie het.
- as jy diabetes of verswakte nierfunksie het en jy word behandel met ’n bloeddrukverlagende medisyne wat aliskiren bevat,
- as jy dialise ontvang of enige ander tipe bloed filtrasie. Afhangend van die masjien wat gebruik word, is **Prexum** moontlik nie geskik vir jou nie,
- as jy erge nierprobleme het waar die bloedtoevoer na die niere verminder is (nieraar stenose),
- as jy met sakubitril/valsartan behandel word, 'n medisyne vir hartversaking aangesien die risiko van angio-edeem (vinnige swelling onder die vel in 'n area soos die keel) verhoog word (sien (sien Neem spesiale sorg en Neem ander medisyne en Prexum).
- as jy met fluorokinolone behandel word (’n antibiotika).

Warnings and precautions

Take special care

- If you are undergoing desensitisation treatment, or have had an allergic reaction during previous desensitisation treatment (e.g. treatments using bee, wasp or ant venom).
- are to undergo LDL apheresis (which is removal of cholesterol from your blood by a machine),
- If you are to undergo anaesthesia and/or surgery.
- if you have recently suffered from diarrhoea or vomiting, or are dehydrated,

You have any other health problems, including:

- Kidney disease or if you are receiving dialysis.
- Liver disease.
- Diabetes.
- Heart disease.
- Contact your doctor to re-evaluate your treatment if you are treated with ACE-inhibitors/Angiotensin receptor blockers together with a fluoroquinolone antibiotic,
- if you have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism),
- If you have aortic stenosis (narrowing of the main blood vessel leading from the heart) or hypertrophic cardiomyopathy (heart muscle disease) or renal artery stenosis (narrowing of the artery suppling the kidney with blood).
- If you have been told by your doctor that you have an intolerance to some sugars.
- If you suffer from a collagen vascular disease such as systemic lupus erythematosus or scleroderma.
- if you are on a salt restricted diet or use salt substitutes which contain potassium,
- if you are taking any of the following medicines used to treat high blood pressure:
  an “angiotensin II receptor blocker” (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems.
- if you are taking aliskiren (medicines used to treat hypertension).

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

- if you are of black origin since you may have a higher risk of angioedema and this medicine may be less effective in lowering your blood pressure than in non-black patients,
- if you are taking any of the following medicines, the risk of angioedema is increased:
- racecadotril (used to treat diarrhoea),

- sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTor inhibitors (used to avoid rejection of transplanted organs and for cancer),
- sacubitril (available as fixed-dose combination with valsartan), used to treat long-term heart failure.
- linagliptin, saxagliptin, sitagliptin, vildagliptin and other drugs belonging to the class of the also called gliptins (used to treat diabetes).

Angioedema

Angioedema (a severe allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing) has been reported in patients treated with ACE-inhibitors, including Prexum. This may occur at any time during treatment. If you develop such symptoms, you should stop taking Prexum and see a doctor immediately (see Possible side effects). (Also see section 4).
You must tell your doctor if you think that you are (or might become) pregnant. Prexum is not recommended as it may cause serious harm to your baby (see Pregnanacy section).

Children and adolescents

Prexum is not recommended for children and adolescents.

Other medicines and Prexum

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Taking Prexum may change the effect of some medicines, and some medicines may affect how well Prexum works.
The medicines that may interact with Prexum include the following:

- Non steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high dose aspirin, a substance presents in many medicines used to relieve pain and lower fever, as well as to prevent blood clotting,
- Lithium medications (used to treat mood swings and some types of depression/mania).

- Potassium-sparing diuretics (e.g. triamterene, amiloride), sources of potassium, like potassium tablets and salt substitutes containing potassium, other medicines which can increase potassium in your body (such as heparin, a medicine used to thin blood to prevent clots, trimethoprim and co-trimoxazole also known as trimethoprim/sulfamethoxazole for infections caused by bacteria),
- potassium-sparing medicines used in the treatment of heart failure: eplerenone and spironolactone at doses between 12,5 mg to 50 mg by day,
- other medicines for treating high blood pressure, including angiotensin II receptor blocker (ARB) or aliskiren or diuretics (medicines which increase the amount of urine produced by the kidneys),

- medicines used to treat diabetes (tablets and insulin).
- baclofen (used to treat muscle stiffness in diseases such as multiple sclerosis),
- medicines to treat mental disorders such as depression, anxiety, schizophrenia (i.e. tricyclic antidepressants, antipsychotics).
- immunosuppressants (medicines which reduce the defence mechanism of the body) used for the treatment of auto-immune disorders or following transplant surgery (e.g. ciclosporin, tacrolimus).
- trimethoprim (for the treatment of infections),
- estramustine (used in cancer therapy),
- medicines, which are most often used to treat diarrhoea (racecadotril) or avoid rejection of transplanted organs (sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTor inhibitors). See section Warnings and precautions
- sacubitril/valsartan (used to treat long-term heart failure). See “Do not take Prexum and Warnings and precautions”.

- allopurinol (for the treatment of gout).
- procainamide (for the treatment of irregular heartbeat).
- vasodilators including nitrates (products that make the blood vessels become wider),

- medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline),
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis).

It is a good idea to remind your doctor of all other medicines you take. Your doctor or pharmacist has more information on medicines that you need to be careful with or avoid while taking Prexum.

Prexum with food and drink

It is preferable to take Prexum before a meal.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Pregnancy

Prexum must not be taken while pregnant. Should you become pregnant or contemplate pregnancy while using Prexum consult your doctor without delay. The switch to an alternative treatment should be initiated as soon as possible.

You must tell your doctor if you think that you are (or might become) pregnant. Prexum should not be taken while pregnant or breastfeeding. Should you become pregnant while using Prexum the medicine must immediately be stopped and consult your doctor without delay.

Breastfeeding

Tell your doctor if you are breastfeeding or about to start breastfeeding. Prexum is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breastfeed, especially if your baby is newborn, or was born prematurely.

Driving and using machines:

When driving vehicles or operating machines it should be taken into account that occasionally dizziness or weariness may occur. If affected, your ability to drive or to operate machinery may be impaired.

Prexum contains lactose

Prexum contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Prexum.

Prexum contains sodium

Prexum contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

4. How to take Prexum

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

Always take Prexum exactly as your doctor has instructed you. You should check with your doctor if you are unsure. Swallow your tablet(s) with a glass of water, preferably in the morning before a meal. The dose of Prexum you may need each day will be decided and adjusted by your doctor. The usual dosages are as follows:

Dosage in high blood pressure

The recommended dosage is 5 mg orally taken in the morning before breakfast, which can be increased to a single daily dose of 10 mg if necessary, after one month of treatment.

Dosage in elderly patients and heart failure

In elderly patients and patients with heart failure, treatment should be started at a dose of 2,5 mg, which may progressively be increased to 5 mg after one month, then to 10 mg if necessary, depending on kidney function.

Use in children and adolescent

Use in children and adolescent is not recommended.

If you take more Prexum 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.

The most likely effect in case of overdose is low blood pressure which can make you feel dizzy or faint. If this happens, lying down with the legs raised can help.

If you forget to take Prexum

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Prexum, take the next dose at the usual time.

Do not take a double dose to make up for the forgotten individual doses.

If you stop taking Prexum

As the treatment with Prexum is usually life-long, you should discuss with your doctor before stopping this medicine.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Prexum can have side effects.

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

If you experience any of the following, stop taking the medicinal product at once and tell your doctor immediately:

- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing (angioedema) (See section 2 “Warnings and precautions”),
- severe dizziness or fainting, due to low blood pressure,
- unusual fast or irregular heartbeat, chest pain (angina), heart attack.
- weakness of arms or legs, or problems speaking which could be a sign of a possible stroke
- sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing (bronchospasm),
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell
- yellowing of the skin or eyes (jaundice) which could be a sign of hepatitis, skin rash which often starts with red itchy patches on your face, arms or legs (erythema multiforme).
- skin rash which often starts with red itchy patches on your face, arms or legs (erythema multiforme)

In decreasing order of frequency, side effects can include:

Frequent

- headache,
- dizziness,
- vertigo,
- pins and needles,
- vision disturbances,
- tinnitus (sensation of noises in the ears),
- cough,
- shortness of breath (dyspnoea),

- gastro-intestinal disorders (nausea, vomiting, abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation),
- allergic reactions (such as skin rashes, itching),
- muscle cramps,
- feeling of tiredness.
- **Less Frequent**
- depression
- mood swings,
- sleep disturbances,
- dry mouth,
- intense itching or severe skin rashes),
- formation of blister clusters over the skin,
- kidney problems,
- impotence,
- sweating,
- excess of eosinophils (a type of white blood cells),
- somnolence,
- fainting,
- palpitations,
- tachycardia,
- vasculitis (inflammation of blood vessels),
- photosensitivity reaction (increased sensitivity of the skin to sun),
- arthralgia (joint pain),
- myalgia (muscle pain),
- chest pain,
- malaise,

- peripheral oedema,
- fever,
- fall,
- change in laboratory parameters: high blood level of potassium reversible on discontinuation, low level of sodium, hypoglycaemia (very low blood sugar level) in case of diabetic patients, increased blood urea, and increased blood creatinine.
- acute renal failure,
- dark urine, feeling sick (nausea) or being sick (vomiting), muscle cramps, confusion and seizures. These may be symptoms of a condition called SIADH (inappropriate antidiuretic hormone secretion).
- decreased or absent urine output,
- flushing,
- worsening of psoriasis,
- changes in laboratory parameters: Increased level of liver enzymes, high level of serum bilirubin.
- confusion,
- eosinophilic pneumonia (a rare type of pneumonia),
- rhinitis (blocked up or runny nose),
- changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets.
- If you have these symptoms contact your doctor as soon as possible.
- Frequency not known (cannot be estimated from available data): Discoloration, numbness and pain in fingers or toes (Raynaud's phenomenon).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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. By reporting side effects, you can help provide more information on the safety of Prexum**.**

5. How to store Prexum

Store at or below 30 °C in a dry place.

Store all medicine out of reach of children.

Do not use after the expiry date stated on the blister.

Return all unused medicine to your pharmacist.

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

6. Content of the pack and other information

What Prexum 5 mg contains

The active substance is perindopril arginine. One film-coated tablet contains 3,395 mg perindopril (corresponding to 5 mg perindopril arginine).

What Prexum 10 mg contains

The active substance is perindopril arginine. One film-coated tablet contains 6,790 mg perindopril (corresponding to 10 mg perindopril arginine).

The other ingredients in the tablet core are: lactose monohydrate, magnesium stearate, maltodextrin, hydrophobic colloidal silica, sodium starch glycolate (type A), and in the tablet film-coating: glycerol, hypromellose, copper chlorophyllin, macrogol 6 000, magnesium stearate, titanium dioxide.

What Prexum 5 mg looks like and contents of the pack

Prexum 5 mg tablets are light-green, rod-shaped film-coated tablets engraved with  on one face and scored on both edges. The tablet can be divided into equal halves.

What Prexum 10 mg looks like and contents of the pack

Prexum 10 mg tablets are Green, round biconvex, film-coated tablet, engraved with on one face and  on the other face.

Prexum is packed into pack sizes of 30 tablets into a polypropylene white tube with a low-density polyethylene flow reducer and a low-density polyethylene white stopper, containing 2 g of white desiccant gel and placed into an outer carton.

Holder of certificate of registration

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2196

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