APPROVED PATIENT INFORMATION LEAFLET

S3

ANNIN 25 mg (tablet)

ANNIN 50 mg (tablet)

ANNIN 100 mg (tablet)

Losartan potassium

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

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

The active substance is losartan potassium.

ANNIN 25 mg: Each film-coated tablet contains 25 mg losartan potassium.

ANNIN 50 mg: Each film-coated tablet contains 50 mg losartan potassium.

ANNIN 100 mg: Each film-coated tablet contains 100 mg losartan potassium.

The other ingredients are microcrystalline cellulose, lactose monohydrate, pregelatinised starch, low substituted hydroxypropyl cellulose, magnesium stearate and opadry white powder. The coating agent, opadry, contains hydroxypropyl cellulose, hypromellose and titanium dioxide (C.I. No: 77891).

2. WHAT ANNIN ARE USED FOR

Losartan is used to treat high blood pressure (hypertension). Losartan works by blocking the action of a substance in the body that causes blood vessels to tighten. As a result, losartan relaxes blood vessels. This lowers blood pressure.

3. BEFORE YOU TAKE ANNIN

Do not take ANNIN:

- If you have ever had an unusual or allergic reaction to losartan or to any of the ingredients of the product.
- If you have or have ever had angioedema (a condition that causes difficulty swallowing or breathing and painful swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs) whilst taking previous angiotensin-converting enzyme (ACE) inhibitor medication or angiotensin receptor blockers (ARBs). You must never again take these medicines.
- If you have abnormal thickening of the heart muscle.
- If you have moderate to severe kidney disease.
- If you have narrowing of the renal arteries to both kidneys.
- If you have narrowing of the renal artery with a single kidney.
- If you have abnormal narrowing of the aortic valve.
- If you are currently taking diuretics (water tablets) that increase potassium in the blood such as triamterene, amiloride or spironolactone.
- If you have porphyria (an inherited disorder of blood pigment metabolism).
- In combination with thiazide diuretics (water that cause the body to lose potassium as well as water) such as hydrochlorothiazide, if you have Addison's disease. Addison's disease is a condition that results when your body produces insufficient amounts of certain hormones produced by your adrenal gland.

  This combination therapy must also not be used if you have severe kidney disease, are unable to urinate, or are allergic to any medicine that contains sulphur.
- If you are taking lithium, a medicine used to treat mental illness. **ANNIN** may increase the lithium level in your blood.
- If you are pregnant.
- If you are breastfeeding.
- For use in children. The safety and effectiveness of **ANNIN** in children have not been established.

Take special care with ANNIN:

- If your blood vessels are volume-depleted (e.g. if you are being treated with high-dose diuretics (water pills), since a low blood pressure may occur. Your doctor may decide to correct your condition before giving you **ANNIN,** or start you on a lower dose.
- Make sure you tell your doctor if you have cirrhosis (scarred liver) or liver disease – Your doctor may need to halve your dose.
- Make sure you tell your doctor if you have kidney disease.
- Make sure you tell your doctor if you have severe congestive heart failure.

Pregnancy and Breastfeeding:

- Check with your doctor immediately if you think that you are pregnant.
- **ANNIN** must not be used in pregnancy, as birth defects in the baby may occur if **ANNIN** are taken during pregnancy.
- To avoid pregnancy, adequate contraceptive measures should be used while being treated with **ANNIN**.
- **ANNIN** must not be used if you are breastfeeding.

If you are pregnant or breastfeeding your baby, please inform your doctor, pharmacist or other health care professional for advice, before you start taking this medicine.

Driving and using machinery:

This medicine will not affect your ability to drive and use machines.

Taking other medicines with ANNIN:

- Tell your doctor if you are taking other medicines to lower blood pressure – the blood pressure lowering effects of losartan may be increased by other medicines that lower blood pressure.
- Tell your doctor of you are taking potassium supplements, potassium-sparing water pills or other medicines that can cause too much potassium in the blood.
- Tell your doctor of you are taking non-steroidal anti-inflammatory medicines.

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines).

Important information about some of the ingredients of ANNIN:

ANNIN contain lactose. **ANNIN** should not be taken by patients who have inherited problems such as an intolerance to some sugars, Lapp lactase deficiency (this is when the body is unable to digest milk or milk products due to lack of an enzyme) or glucose-galactose malabsorption (this is when the small intestine is unable to absorb and transport the sugars glucose and galactose).

- **HOW TO TAKE ANNIN** Take this medicine only as directed by your doctor.
- This medicine may be taken with or without food.
- This medicine may be taken with other medicines which reduce high blood pressure.
- **Dose:**

  - For high blood pressure:

  Adults - The usual starting and maintenance dose is 50 mg once a day for most patients. The dose may be increased to 100 mg once a day.

  Patients with blood vessels that are volume-depleted (e.g. those treated with high-dose water pills) – A starting dose of 25 mg once daily should be considered.

  Elderly patients and patients with kidney disease – No initial dosage adjustment is necessary.

Patients with liver disease – A lower dose should be considered.

Always take **ANNIN** 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 **ANNIN** is too strong or too weak, talk to your doctor or pharmacist.

If you take more ANNIN than you should:

Taking an overdose of **ANNIN** may lead to low blood pressure and an increased rate of heart beat. An abnormally slow pulse rate could occur.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

5. POSSIBLE SIDE EFFECTS

ANNIN can have side effects.

Contact your doctor immediately if any of the following side effects occur: Swelling of face, mouth, hands, or feet, trouble in swallowing or breathing (sudden).

The following side effects may occur: Lack of energy/fatigue, abdominal pain, chest pain, swelling, rapid irregular action of heart, increased rate of heart beat, diarrhoea, indigestion, nausea, back pain, muscle cramps, headache, migraine, hives, dizziness, inability to sleep, cough, nasal congestion, inflammation of mouth and throat, sinus problems, upper respiratory infection.

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

6. STORING AND DISPOSING OF ANNIN

Store at or below 25 °C.

Do not store in the bathroom, near the kitchen sink, or in other damp places. Moisture may cause the medicine to break down.

Keep blisters in the original carton until required for use.

Store all medicines out of the reach 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 ANNIN

ANNIN 25 mg, **ANNIN 50 mg**, **ANNIN 100 mg:**

Blister Packs:

Tablets are packed in blister packs composed of white opaque PVC / PE / PVdC film or white opaque PVC coated with 60 g/m2 PVdC film and printed silver-coloured aluminium foil. Each blister contains 10 tablets.

Pack size: 30s – Each carton contains 3 blisters of 10 each.

8. IDENTIFICATION OF ANNIN

ANNIN 25 mg: White to off – white, oval shaped, biconvex, film – coated tablets, debossed with “E” on one side and “45” on the other side.

ANNIN 50 mg: White to off – white, oval shaped, biconvex, film – coated tablets, debossed with “E” on one side and “46” on the other side.

ANNIN 100 mg: White to off – white, oval shaped, biconvex, film – coated tablets, debossed with “E” on one side and “47” on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

ANNIN 25 mg: 43/7.1.3/0493

ANNIN 50 mg: 43/7.1.3/0494

ANNIN 100 mg: 43/7.1.3/0495

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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