SCHEDULING STATUS

Schedule 3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

AMLOTEL 40 / 5 (Tablets**)**

AMLOTEL 40 / 10 (Tablets**)**

AMLOTEL 80 / 5 (Tablets**)**

AMLOTEL 80 / 10 (Tablets**)**

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

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor or your pharmacist
- **AMLOTEL** has been prescribed for you personally and you should not share **AMLOTEL** with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT AMLOTEL CONTAINS

AMLOTEL tablets contain two active substances called telmisartan and amlodipine.

AMLOTEL 40 / 5 mg tablets: Each tablet contains 40 mg telmisartan

and 5 mg amlodipine base (as besylate salt).

Contains sugar (mannitol) 169,94 mg per tablet

AMLOTEL 40 / 10 mg tablets: Each tablet contains 40 mg telmisartan

and 10 mg amlodipine base (as besylate salt).

Contains sugar (mannitol) 169,94 mg per tablet

AMLOTEL 80 / 5 mg tablets: Each tablet contains 80 mg telmisartan

and 5 mg amlodipine base (as besylate salt).

Contains sugar (mannitol) 339,88 mg

AMLOTEL 80 / 10 mg tablets: Each tablet contains 80 mg telmisartan

and 10 mg amlodipine base (as besylate salt).

Contains sugar (mannitol) 339,88 mg

The other ingredients of **AMLOTEL** are:

mannitol, meglumine, povidone-k, sodium stearyl fumarate, magnesium stearate, microcrystalline cellulose, corn starch, iron oxide black, blue colourant, crospovidone.

2. WHAT IS AMLOTEL USED FOR

AMLOTEL is used to treat high blood pressure (also known as essential hypertension) in patients using the same components as individual components, or when treatment with amlodipine alone did not lower your blood pressure enough.

3. BEFORE YOU TAKE AMLOTEL

Do not take AMLOTEL if you are pregnant, are considering becoming pregnant or are breast-feeding. A switch to a suitable alternative treatment should be carried out in advance of planned pregnancy

Do not take AMLOTEL:

- if you are allergic to telmisartan, amlodipine or any of the other ingredients included in **AMLOTEL** tablets.
- If you are allergic to other medicines of the dihydropyridine type (one type of calcium channel blocker).
- If you are pregnant or breast feeding
- If you have developed swelling and giant wheals on your skin when having previously taken medicines called angiotensin converting enzyme inhibitors (ACE inhibitors) or angiotensin receptor blockers (ARB's).
- If you have a narrowing of the aortic blood vessel.
- If both blood vessels to the kidneys are narrowed or if you have a single kidney and the blood vessel to the kidney is narrowed.
- If you suffer from severe liver problems.
- If you suffer from biliary obstruction (a problem with the drainage of the bile from the liver and gall bladder).
- If you suffer from porphyria.
- If you are currently taking lithium or potassium sparing water tablets

containing spironolactone, triamterene or amiloride.

- If you suffer from low heart output because of a serious heart problem.
- If you suffer from severe renal impairment.
- If you are currently taking aliskiren-containing products

Take special care with AMLOTEL and tell your doctor:

- If you suffer from kidney disease or have ever had a kidney transplant.
- If you suffer from liver problems.
- If you have heart problems.
- If you are planning to become pregnant.
- If you already take a medicine called an angiotensin converting enzyme inhibitor (ACE-I).
- If you have been told that you have raised aldosterone levels (water and salt retention I the body along with imbalance of various blood minerals).
- If you have low blood pressure (hypotension), which is likely to occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy ("water tablets"), low-salt diet, diarrhea, or vomiting.
- If you have high potassium levels in your blood or use salt substitutes that contain potassium.

In case of surgery or anaesthesia, you should tell your doctor that you are taking **AMLOTEL**.

The use of **AMLOTEL** in children and adolescents up to the age of 18 years is not recommended.

Taking AMLOTEL with food and drink:

You can take **AMLOTEL** with or without food.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine. **Do not take AMLOTEL if you are pregnant, are considering becoming pregnant or are breast-feeding**. A switch to a suitable alternative treatment should be carried out in advance of planned pregnancy**.**

Women who are of childbearing age should ensure adequate contraception if they are using **AMLOTEL**.

Driving and using machines:

You may experience side effects such as fainting, sleepiness, dizziness or a feeling of spinning (vertigo) when they are treated for high blood pressure. If you experience these side-effects, do not drive or operate machinery.

Important information about some of the ingredients of AMLOTEL:

AMLOTEL contains mannitol and may have laxative effect.

Taking other medicines with AMLOTEL:

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

- Digitalis glycosides (digoxin) which is a heart medicine.
- Other antihypertensive medicines
- Medicines with blood pressure lowering potential like baclofen, amifostine, alcohol, barbiturates, narcotics, or antidepressants.
- Corticosteroids (injections):
- Lithium-containing medicines used to treat some types of depression.
- Anticonvulsant medicines (e.g. carbamazepine, phenobarbitone, phenytoin, fosphenytoin, primidone).
- Rifampicin
- St. John's wort
- Medicines used for HIV/AIDS (e.g. ritonavir) or for treatment of fungal infections (e.g. ketoconazole, itraconazole).
- **AMLOTEL** may increase the blood pressure lowering effect of other medicines used to treat high blood pressure or of medicines with blood pressure lowering potential (e.g. antidepressants, barbiturates, narcotics) or alcohol.
- **AMLOTEL** can interfere with ACE-inhibitors.

4. HOW TO TAKE AMLOTEL:

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

Always take **AMLOTEL** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose of **AMLOTEL** is one tablet per day. Try to take the tablet at the same time each day.

Remove your **AMLOTEL** tablet from the blister only immediately prior to intake.

You can take **AMLOTEL** with or without food. The tablets should be swallowed with some water. It is important that you take **AMLOTEL** every day until your doctor tells you otherwise. If you have the impression that the effect of **AMLOTEL** is too strong or too weak, talk to your doctor or pharmacist.

If your liver is not working properly, the usual dose should not exceed **AMLOTEL 40/5** mg or **AMLOTEL 40/10** mg once daily.

If you take more AMLOTEL than you should:

In the event of overdosage or accidental intake, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take AMLOTEL:

If you forget to take a dose, do not worry. Take it as soon as you remember on the same day. If you do not take your tablet on that same day, take your normal dose on the next day. Do not take a double dose to make up for forgotten individual doses

5. POSSIBLE SIDE EFFECTS

AMLOTEL can have side effects.

Not all side-effects reported for **AMLOTEL** are included in this leaflet. Should your general health worsen while taking **AMLOTEL**, please consult your doctor, pharmacist, or other healthcare professional for advice

***If you have any of the following happens, stop taking AMLOTEL and tell your doctor immediately or go to the casualty department at your nearest hospital*.**

Frequent:

- Dizziness, swelling of the ankles

Less frequent

- Allergic reaction (e.g. rash, difficulty breathing, wheezing, swelling of the face or low blood pressure),
- Infections
- Low blood pressure (hypotension),
- Dizziness on standing up (orthostatic hypotension),
- Weakness,
- Swelling,
- Depression,
- Feeling anxious
- Fainting
- Rash, severe skin reactions,
- Itching,
- Feeling unwell
- Yellowing of the skin (jaundice),

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

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

Less frequent

- Slow heart rate, palpitations (awareness of your heart beat),
- Chest pain, tiredness,
- Tingling or numbness of the hands or feet,
- Feeling of spinning (vertigo),
- Painful limbs,
- Urge to urinate during the night,
- shortness of breath,
- increased sweating
- Sore throat, common cold

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

Tell your doctor if you notice any of the following:

Less frequent:

- Sleepiness,
- Migraine,
- Flushing,
- Cough,
- Abdominal pain,
- Diarrhoea,
- Feeling sick (nausea),
- Joint pain,
- Muscle cramps,
- Muscle pain,

- Inability to obtain an erection,
- Sleeplessness,
- taste abnormalities,
- Trembling,
- Vomiting,
- Swollen gums,
- Discomfort in the abdomen,
- Dry mouth,
- Eczema (a skin disorder),
- Redness of the skin,
- Back pain,
- Increased levels of uric acid in the blood.
- Bloating,
- Stomach discomfort,
- Abnormal liver function,
- Swollen, pale red bumps or plaques (wheals) on the skin that appear suddenly (hives)
- Rash,
- Flu-like illness,
- Mood changes,
- Impaired vision,
- Ringing in the ears,

- Sneezing/running nose,
- Change of bowel habit,
- Abdominal bloating
- Hair loss,
- Unusual bruising and bleeding skin discolouration,
- Rapid swelling of skin and mucosa),
- Enlarging of male breasts,
- Pain,
- Weight increased,
- Weight decreased.

6. STORING AND DISPOSING OF AMLOTEL

Store at or below 30 °C in the original package in order to protect from light and moisture.

Keep out of reach of children.

Remove your **AMLOTEL** tablet from the blister only immediately prior to intake.

Do not take **AMLOTEL** after the expiry date stated on the blister strips and carton. The expiry date refers to the last day of that month. Return all unused or expired medicines to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF AMLOTEL:

AMLOTEL 80/5: 30 Tablets in aluminium blister strips of 10 tablets per strip with 3 strips packed in a unit carton

AMLOTEL 80/10: 30 Tablets in aluminium blister strips of 10 tablets per strip with 3

strips packed in a unit carton

AMLOTEL 40/5: 30 Tablets in aluminium blister strips of 10 tablets per strip with 3 strips packed in a unit carton

AMLOTEL 40/10: 30 Tablets in aluminium blister strips of 10 tablets per strip with 3 strips packed in a unit carton

8. IDENTIFICATION OF AMLOTEL:

AMLOTEL 80/5: Oval shaped biconvex, bilayer, uncoated tablets with one white to off-White colour layer and one blue colour mottled layer debossed with “L391”

AMLOTEL 80/10: Oval shaped biconvex, bilayer, uncoated tablets with one white to off- white colour layer and one blue colour mottled layer debossed with “L388”

AMLOTEL 40/5: Oval shaped biconvex, bilayer, uncoated tablets with one white to off- white colour layer and one blue colour mottled layer debossed with “L389”

AMLOTEL 40/10: Oval shaped biconvex, bilayer, uncoated tablets with one white to off- white colour layer and one blue colour mottled layer debossed with “L390”

9. REGISTRATION NUMBERS

AMLOTEL 40/5 mg: 50/7.1.3/0344

AMLOTEL 40/10 mg: 50/7.1.3/0345

AMLOTEL 80/5 mg: 50/7.1.3/0346

AMLOTEL 80/10 mg: 50/7.1.3/0347

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Innovata Pharmaceuticals

Crownwood office Park

100 Northern Parkway

Ormonde

Johannesburg

2091

11. DATE OF PUBLICATION

11 February 2020

