APPROVED PIL

For

Triveram

Registration No.:

Triveram 10 mg/5 mg/5 mg: 50/7.1.3/0893

Triveram 20 mg/5 mg/5 mg: 50/7.1.3/0894

Triveram 20 mg/10 mg/5 mg: 50/7.1.3/0895

Triveram 20 mg/10 mg/10 mg: 50/7.1.3/0896

Triveram 40 mg/10 mg/10 mg: 50/7.1.3/0897

Date Approved: July 2021

Confidential Information

SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD
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Registered PIL	
Applicant:	Servier Laboratories SA (Pty) Ltd
Product:	**Triveram 10/5/5; 20/5/5; 20/10/5; 20/10/10; 40/10/10**
Registration date:	27 July 2021

Patient Information Leaflet

SCHEDULING STATUS S4

Triveram 10/5/5 mg film-coated tablets

Triveram 20/5/5 mg film-coated tablets

Triveram 20/10/5 mg film-coated tablets

Triveram 20/10/10 mg film-coated tablets

Triveram 40/10/10 mg film-coated tablets

atorvastatin / perindopril arginine / amlodipine

Contains sugar (lactose)

27,46 mg for **Triveram 10/5/5 mg**,

54,92 mg for **Triveram 20/5/5 mg, 20/10/5 mg and 20/10/10 mg**, and

109,84 mg for **Triveram 40/10/10 mg**

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

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

1. What Triveram is and what it is used for

Triveram contains three active ingredients, atorvastatin, perindopril arginine and amlodipine in one tablet.

Atorvastatin belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines.

Perindopril arginine is an angiotensin converting enzyme (ACE) inhibitor. In patients with high blood pressure, it works by widening the blood vessels, which makes it easier for your heart to pump blood through them.

Amlodipine belongs to a group of medicines called calcium antagonists. In patients with high blood pressure it works by relaxing blood vessels, so that blood passes through them more easily. In patients with angina (which causes chest pain), it works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented.
Triveram is used to treat high blood pressure (hypertension) and/or stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) in adults who also suffer from one of the following conditions:

- Elevated cholesterol levels (primary hypercholesterolaemia), or
- Elevated cholesterol and fat (triglyceride) levels at the same time (combined or mixed hyperlipidaemia).

Triveram is intended for patients already on treatment with atorvastatin, perindopril arginine and amlodipine as single tablets. Instead of taking atorvastatin, perindopril arginine and amlodipine as single tablets you will receive one tablet of **Triveram** which contains the three active ingredients in the same strength.

2. What you need to know before you take Triveram

Do not take Triveram

- if you are allergic to atorvastatin or any other statin, to perindopril or any other ACE-inhibitor, to amlodipine or any other calcium antagonist, or to any of the other ingredients of this medicine (listed in section 6),
- if you have a disease which affects the liver,
- if you have had any unexplained abnormal blood tests for liver function,
- if you have severe low blood pressure (hypotension),
- if you have a cardiogenic shock (a condition where your heart is unable to supply enough blood to the body),
  if you have a blockage of the blood flow from the left ventricle of the heart (e.g. hypertropic obstructive cardiomyopathy and high-grade aortic stenosis and/or narrowing (stenosis) of your mitral heart valve),
- if you suffer from heart failure after a heart attack,
- if 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 (a condition called angioedema),

- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren),
- if you are on dialysis or any other type of blood filtration procedure. Depending on the type of machine that is used for your dialysis or blood filtration procedure, **Triveram** may not be suitable for you,

  if you have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis (narrowing)), or a single kidney with a reduced blood supply to this kidney,
- if you are being treated with sacubitril/valsartan, a medicine for heart failure (see "Warning and Precaution" and "Other medicines and **Triveram**"),
- if you are pregnant or trying to become pregnant, or if you are a woman able to have children and not using reliable contraception,
- if you are breastfeeding your baby.
-

Warnings and precautions

Talk to your doctor or pharmacist before taking **Triveram** if you:

- have a liver problem or a history of liver disease,
- have moderate to severe kidney problems,
- regularly drink a large amount of alcohol,
- are taking or have taken in the last 7 days a medicine called fusidic acid (a medicine for bacterial infection) orally or by injection. The combination of fusidic acid and **Triveram** can lead to serious muscle problems (rhabdomyolysis),
- have had repeated or unexplained muscle aches or pains, a personal history or family history of muscle problems,
- have or close family member have a muscle problem which runs in the family,
- have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other '-statin' or '-fibrate' medicines),
- have an under-active thyroid gland (hypothyroidism),
- have a condition or situation leading to increased levels of atorvastatin in your blood,
- are developing symptoms of severe respiratory failure (difficult breathing, shortness of breath, rapid breathing, anxiety) while under treatment,
- have diabetes (high blood glucose),
- have heart failure or any other heart problem,
- have or have had a recent heart attack,
- have recently suffered from diarrhoea or vomiting, or are dehydrated,

- have non-severe aortic or mitral valve stenosis (narrowing of the aortic heart valve and/or main blood vessel leading from the heart or the mitral valve of the heart)
- have kidney problems; recently underwent a kidney transplantation or if you are receiving dialysis
- have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism),
- are elderly (65 years of age or older),
- are experiencing a severe allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing (angioedema). This may occur at any time during treatment. If you develop such symptoms, you should stop taking **Triveram** and see a doctor immediately,
- are of black origin since you may have a higher risk of angioedema and **Triveram** may be less effective in lowering your blood pressure than in non-black patients,
- are taking any of the following medicines, as the risk of angioedema is increased:
  - racecadotril (used to treat diarrhea),
  - sirolimus, everolimus, temsirolimus and other medicines belonging to the class of so-called mTor inhibitors (used to avoid rejection of transplanted organs),
  - sacubitril (available as fixed-dose combination with valsartan), used to treat long-term heart failure,
- are to undergo LDL apheresis (which is removal of cholesterol from your blood by a machine),
- are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings,
- are to undergo anesthesia and/or major surgery,
- suffer from a collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma,
- are on a salt restricted diet or use salt substitutes which contain potassium,
- have been told by your doctor that you have an intolerance to some sugars,
- 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.
- aliskiren

If any of the above applies to you, consult your doctor before or while taking **Triveram.**
Your doctor may need to carry out a blood test during your treatment to check your muscles (see Section 2 “Other medicines and **Triveram**”).

Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines might be needed to diagnose and treat this.
Your doctor may check your kidney function, blood pressure, and the blood levels of electrolytes (e.g. potassium) in your blood at regular intervals. See also information under the heading "Do not take **Triveram**".
While you are on **Triveram** your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fat in your blood, are overweight and have high blood pressure.

Children and adolescents
Triveram is not recommended for use in children and adolescents younger than 18 years.

Other medicines and Triveram
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.) There are some medicines that may change the effect of **Triveram** or their effect may be changed by **Triveram**. This type of interaction could make one or both of the medicines less effective. Alternatively, it could increase the risk or severity of side effects, including the muscle wasting condition known as rhabdomyolysis described in Section 4.

Make sure to tell your doctor if you are taking any of the following medicines:
- 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),
- ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole (anti-fungal medicines),
- rifampicin, erythromycin, clarithromycin, telithromycin, fusidic acid*, trimethoprim (antibiotics for infection caused by bacteria),
- Colchicine (used in the treatment of gout, a disease with painful, swollen joints caused by uric acid crystals),
- other medicines to regulate lipid levels, e.g. gemfibrozil, other fibrates, colestipol, ezetimibe,
- some calcium channel blockers used for angina or high blood pressure, e.g. diltiazem,
- medicines to regulate your heart rhythm e.g. digoxin, verapamil, amiodarone,
- medicines used in the treatment of HIV e.g. delavirdine, efavirenz, ritonavir, lopinavir, atazanavir, indinavir, darunavir, etc.,
- warfarin (which reduces blood clotting),

- oral contraceptives,
- stiripentol (an anti-convulsant for epilepsy),
- cimetidine (used for heartburn and peptic ulcers),
- phenazone (a painkiller),
- antacids (indigestion products containing aluminium or magnesium),
- medicine obtained without a prescription: *hypericum perforatum* or St John's Wort (herbal treatment used for depression),
- dantrolene (infusion for severe body temperature abnormalities),
- other medicines for high blood pressure, including aliskiren, angiotensin II receptor blockers (e.g. valsartan) see also information under the headings "Do not take **Triveram**" and "Warnings and precautions"),
- potassium-sparing medicines (e.g. triamterene, amiloride, eplerenone, spironolactone), potassium supplements or potassium-containing salt substitutes, other medicines which can increase potassium in your body (such as heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole),
- estramustine (used in cancer therapy),
- lithium for mania or depression,
- medicines, which are most often used to treat diarrhoea (racecadotril) or avoid rejection of transplanted organs (sirolimus, everolimus, temsirolimus and other medicines belonging to the class of so-called mTor inhibitors). See section "Warnings and precautions",
- sacubitril/valsartan (used to treat long-term heart failure). See sections "Do not take **Triveram**" and "Warnings and precautions",
- medicines to treat diabetes (such as insulin, metformin or gliptins),
- baclofen (used to treat muscle stiffness in diseases such as multiple sclerosis),
- non-steroidal anti-inflammatory medicines (e.g. ibuprofen) for pain relief or treatment of inflammation (e.g. in case of rheumatoid arthritis) or high dose aspirin,
- vasodilators including nitrates (products that make the blood vessels become wider),
- medicines to treat mental disorders such as depression, anxiety, schizophrenia etc (e.g. tricyclic antidepressants, antipsychotics),
- medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline (epinephrine)),
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis),
- allopurinol (for the treatment of gout),
- procainamide (for the treatment of an irregular heart beat).

*If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using **Triveram**. Your doctor will tell you when it is safe to restart **Triveram**.

Taking **Triveram** with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.
Contact your doctor to re-evaluate your treatment if you are treated with ACE-inhibitors/Angiotensin blockers together with a fluoroquinolone antibiotic.

Triveram with food, drink and alcohol
You should take **Triveram** before a meal.

Grapefruit and grapefruit juice
You should not use grapefruit juice and grapefruit if you are taking **Triveram**. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of **Triveram**, as well as an increased effect of the active ingredient atorvastatin.

Alcohol
Avoid drinking too much alcohol while taking this medicine. See Section 2 “Warnings and precautions” for details.

Pregnancy
Do not take **Triveram** if you are pregnant, if you are trying to become pregnant or if able to become pregnant unless you use reliable contraceptive measures (see “Do not take **Triveram**”).
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Triveram must not be used during pregnancy as it will cause serious harm to your unborn baby.

Breastfeeding
You must not take **Triveram** if you are breastfeeding your baby. Tell your doctor immediately if you are breastfeeding your baby or about to start breastfeeding.

Driving and using machines
Triveram may cause dizziness, headache, fatigue or nausea. If you are affected in this way, your ability to drive or to operate machinery may be impaired, especially at the start of the treatment. You should not drive and use machines until you know how treatment with **Triveram** affects you.

Triveram contains lactose

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

Triveram contains sodium

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

3. How to take Triveram

Do not share medicines prescribed for you with any other person.
Always take **Triveram** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
The recommended dose is one tablet per day. Swallow your tablet with a glass of water preferably at the same time each day, in the morning before a meal.

Use in children and adolescents

Triveram is not recommended for use in children and adolescents younger than 18 years.

If you take more Triveram 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. Take your pack(s) of medicine with you.
Taking too many tablets may cause your blood pressure to become low or even dangerously low. It can make you feel dizzy, lightheaded, faint or weak. If this happens, lying down with the legs raised can help. If blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness.

If you forget to take Triveram

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of **Triveram**, take the next dose at the usual time.
Do not take a double dose to make up for forgotten individual doses.

If you stop taking Triveram

As the treatment with **Triveram** is usually life-long, you should discuss with your doctor before stopping **Triveram.**
If you have any further questions on the use of **Triveram**, ask your doctor or pharmacist.

4. Possible side effects

Triveram can have side effects.

Not all side effects reported for **Triveram** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **Triveram**, please consult your healthcare provider for advice.

Stop taking Triveram and see a doctor immediately, if you experience any of the following side effects that can be serious:

- swelling of eyelids, the face, lips, mouth, tongue or throat, difficulty in breathing (angioedema) (See section 2 “Warnings and precautions”),
- severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome, Toxic Epidermal Necrolysis) or other allergic reactions,
- muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown which can be life-threatening and lead to kidney problems,
- weakness of arms or legs, or problems speaking which could be a sign of a possible stroke, severe dizziness or fainting due to low blood pressure,
- unusual fast or irregular heartbeat,
- chest pain (angina) or heart attack,
- 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,
- if you experience problems with unexpected or unusual bleeding or bruising, this may be suggestive of a liver complaint,
- 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).

Tell your doctor if you notice any of the following side effects:

Frequent:

- oedema (fluid retention),
- inflammation of the nasal passages, pain in the throat, nose bleed,
- allergic reactions (such as skin rashes, itching),
- increases in blood sugar levels (if you have diabetes continue careful monitoring of your blood sugar levels), increase in blood creatine kinase,
- headache, dizziness, vertigo, pins and needles, feeling of tiredness
- vision impairment, double vision,
- tinnitus (sensation of noises or ringing in the ears),
- cough, shortness of breath (dyspnoea),
- gastro-intestinal disorders: feeling sick (nausea), being sick (vomiting), constipation, wind, indigestion, change of bowel habit, diarrhoea, abdominal pain, taste disturbances, dyspepsia,
- joint pain, muscle pain, muscle spasms and back pain,
- fatigue, weakness,
- ankle swelling, palpitations (awareness of your heartbeat), flushing,
- blood test results that show your liver function can become abnormal.

Less frequent:

- anorexia (loss of appetite), weight gain or weight decrease, decreases in blood sugar levels (if you have diabetes you should continue careful monitoring of your blood sugar levels),
- having nightmares, insomnia, sleep disturbances, somnolence, mood altered, anxiety, depression,
- numbness or tingling in the fingers and toes or in your limbs, reductions of sensation to pain or touch, change in sense of taste, loss of memory,
- vision blurred,
- low blood pressure,
- sneezing/running nose caused by inflammation of the lining of the nose (rhinitis),
- belching, dry mouth, abdominal pain upper and lower,
- intense itching or severe skin rashes, red patches on skin, skin discoloration, formation of blister clusters over the skin, hives, photosensitivity reaction (increased sensitivity of the skin to sun), hair loss,
- kidney problems, disorder in passing urine, increased need to urinate at night, increased number of times of passing urine,
- inability to obtain an erection, impotence, discomfort or enlargement of the breasts in men

- neck pain, muscle fatigue,
- feeling unwell, trembling, fainting, fall, chest pain, malaise, raised temperature (fever), increased sweating, pain,
- tachycardia (fast heartbeat), vasculitis (inflammation of blood vessels)
- excess of eosinophils (a type of white blood cells),
- urine tests that are positive for white blood cells,
- 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,
- worsening psoriasis,
- confusion,
- unexpected bleeding or bruising,
- cholestasis (yellowing of the skin and whites of the eyes),
- tendon injury,
- changes in laboratory parameters: increased level of liver enzymes, high level of serum bilirubin,
- disorder of the nerves which can cause weakness, tingling or numbness,
- eosinophilic pneumonia (a rare type of pneumonia),
- hearing loss,
- sensitivity to light,
- increased muscle tension,
- swelling of the gums,
- acute kidney failure,
- abdominal bloating (gastritis),
- hepatic function abnormal, yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests,
- changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets which may result in unusual bruising or easy bleeding (red blood cell damage), illness resulting from the destruction of red blood cells,
- muscle weakness that is constant,
- trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk,
- discoloration, numbness and pain in fingers or toes (Raynaud’s phenomenon).

Concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate ADH (anti-diuretic hormone) secretion can occur with ACE-inhibitors. If you have these symptoms contact your doctor as soon as possible.

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 **Triveram**.

5. How to store Triveram

Store at or below 30 °C.

Store all medicine out of reach of children.

Do not store in bathrooms.

Do not use this medicine after the expiry date stated on the outer carton and blister.

The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Keep the container tightly closed in order to protect from moisture.

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

Tablets are stable 30 days after opening in the 30-tablet polypropylene container.

6. Contents of the pack and other information

What Triveram contains

- The active substances are atorvastatin, perindopril arginine and amlodipine,
- Each tablet of **Triveram 10/5/5 mg** contains 10,82 mg atorvastatin calcium trihydrate equivalent to 10 mg atorvastatin, 5 mg perindopril arginine equivalent to 3,40 mg perindopril and 6,94 mg amlodipine besilate equivalent to 5 mg amlodipine.
- Each tablet of **Triveram 20/5/5 mg** contains 21,64 mg atorvastatin calcium trihydrate equivalent to 20 mg atorvastatin, 5 mg perindopril arginine equivalent to 3,40 mg perindopril and 6,94 mg amlodipine besilate equivalent to 5 mg amlodipine.
- Each tablet of **Triveram 20/10/5 mg** contains 21,64 mg atorvastatin calcium trihydrate equivalent to 20 mg atorvastatin, 10 mg perindopril arginine equivalent to 6,79 mg perindopril and 6,94 mg amlodipine besilate equivalent to 5 mg amlodipine.
- Each tablet of **Triveram 20/10/10 mg** contains 21,64 mg atorvastatin calcium trihydrate equivalent to 20 mg atorvastatin, 10 mg perindopril arginine equivalent to 6,79 mg perindopril and 13,87 mg amlodipine besilate equivalent to 10 mg amlodipine.

- Each tablet of **Triveram 40/10/10 mg** contains 43,28 mg atorvastatin calcium trihydrate equivalent to 40 mg atorvastatin, 10 mg perindopril arginine equivalent to 6,79 mg perindopril and 13,87 mg amlodipine besilate equivalent to 10 mg amlodipine.
- The other ingredients are:
- tablet core: lactose monohydrate, calcium carbonate (E170), hydroxypropylcellulose (E463), sodium starch glycolate (type A), microcrystalline cellulose (E460), maltodextrin, magnesium stearate (E572).
- tablet film-coating: glycerol (E422), hypromellose (E464), macrogol 6 000, magnesium stearate (E572), titanium dioxide (E171), iron oxide yellow (E172).

What Triveram looks like and contents of the pack

Triveram 10/5/5 mg tablets are yellow round film-coated tablets of 7 mm diameter, with a curvature radius of 25 mm, engraved with "1" on one face, and  on the other face.

Triveram 20/5/5 mg tablets are yellow round film-coated tablets of 8,8 mm diameter, with a curvature radius of 32 mm, engraved with "2" on one face, and on the other face.

Triveram 20/10/5 mg tablets are yellow square-shaped film-coated tablets of 9 mm side length, with a curvature radius of 16 mm, engraved with "3" on one face, and  on the other face.

Triveram 20/10/10 mg tablets are yellow oblong-shaped film-coated tablets of 12,7 mm length and 6.35 mm width, engraved with "4" on one face, and  on the other.

Triveram 40/10/10 mg tablets are yellow oblong-shaped film-coated tablets of 16 mm length and 8 mm width, engraved with "5" on one face, and  on the other face.

Tablet container of 30 film-coated tablets white polypropylene tablet container and a white opaque stopper containing a desiccant gel placed into a carton.

Registered PIL	
Applicant:	Servier Laboratories SA (Pty) Ltd
Product:	**Triveram 10/5/5; 20/5/5; 20/10/5; 20/10/10; 40/10/10**
Registration date:	27 July 2021

Holder of Certificate of Registration

Servier Laboratories South Africa (Pty) Ltd

Building Number 4

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21 Woodlands Drive

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2191

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