

# TOPAMAX®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using TOPAMAX?

TOPAMAX contains the active ingredient topiramate. TOPAMAX is used for the treatment of various types of seizures in adults and children, aged 2 years and over. It can also be used for the prevention of migraines in adults.

For more information, see Section [1. Why am I using TOPAMAX?](#) in the full CMI.

### 2. What should I know before I use TOPAMAX?

Do not use if you have ever had an allergic reaction to topiramate or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use TOPAMAX?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with TOPAMAX and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use TOPAMAX?**

- Epilepsy (adults): Treatment starts at a low dose of 25 mg to 50 mg per day. The dose is then gradually increased by 25 mg to 100 mg over weekly periods or longer, until the most suitable dose is reached.
- Epilepsy (children 2 years and over): Treatment starts at 25 mg or less per day, depending on the body weight. This dose is then gradually increased over weekly periods or longer, until the most suitable dose is reached.
- Migraine (adults): Treatment starts at a low dose of 25 mg nightly for one week. The dose is then increased over weekly periods or longer by 25mg/day, until the most suitable dose is reached.

More instructions can be found in Section [4. How do I use TOPAMAX?](#) in the full CMI.

## 5. What should I know while using TOPAMAX?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using TOPAMAX</li><li>• Drink plenty of water</li><li>• Women who can become pregnant must use highly effective contraception while taking TOPAMAX</li><li>• Tell your doctor immediately if you notice any of the following: become pregnant or trying to become pregnant, notice changes to your menstrual bleeding while on contraceptives</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly without checking with your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• TOPAMAX may cause drowsiness, dizziness, visual disturbances and/or blurred vision. Make</li></ul>

	<p>sure you know how you are affected by this medicine before you drive or use machinery.</p>
<p><b>Drinking alcohol</b></p>	<ul style="list-style-type: none"> <li>• Do not drink alcohol while taking TOPAMAX. Alcohol may increase the risk of unwanted side effects.</li> </ul>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>• Keep TOPAMAX in original pack in a cool, dry place where the temperature is below 25°C. Capsules: Do not store the drug/food mixture.</li> </ul>

For more information, see Section [5. What should I know while using TOPAMAX?](#) in the full CMI.

## 6. Are there any side effects?

Like all medicines, TOPAMAX can cause side effects, although not everybody gets them. Your doctor will discuss potential side effects with you and will explain the risks and benefits of your treatment. Some side effects can be serious, and you may require urgent medical attention.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



# TOPAMAX®

**Active ingredient(s):** *topiramate*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using TOPAMAX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TOPAMAX.**

**Where to find information in this leaflet:**

- [1. Why am I using TOPAMAX?](#)
- [2. What should I know before I use TOPAMAX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use TOPAMAX?](#)
- [5. What should I know while using TOPAMAX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using TOPAMAX?

**TOPAMAX contains the active ingredient topiramate.** TOPAMAX belongs to a group of medicines known as antiepileptics. It prevents seizures and migraines by acting on the nerves and chemicals in the brain.

**TOPAMAX is used for the treatment of various types of seizures in adults and children, aged 2 years and over. It can also be used for the prevention of migraines in adults. TOPAMAX is not used to treat severe migraines that come on suddenly (acute).**

Your doctor may prescribe TOPAMAX on its own, or in addition to another medicine for controlling your seizures or migraines.

Your doctor may have prescribed TOPAMAX for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

## **2. What should I know before I use TOPAMAX?**

### **Warnings**

#### **Do not use TOPAMAX if:**

- you are allergic to topiramate, or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic or hypersensitivity reaction may include: rash, itching or hives on the skin, shortness of breath, wheezing or difficulty breathing and swelling of the face, lips, tongue or other parts of the body.

- Always check the ingredients to make sure you can use this medicine.
- the tablets or capsules are not as described under Product Details at the end of this leaflet.

## **Migraine prevention**

- You must not take TOPAMAX if you are pregnant.
- If you are a woman who can become pregnant, you must not take TOPAMAX, unless you use highly effective contraception (birth control) during your treatment. See below under "[Pregnancy and breastfeeding](#)".

## **Treatment of epilepsy**

- You must not take TOPAMAX if you are pregnant, unless no other treatment gives sufficient seizure control for you.
- If you are a woman who can become pregnant, you must not take TOPAMAX unless you use highly effective contraception (birth control) during your treatment. Do not stop taking TOPAMAX or your contraception until you have discussed this with your doctor. Your doctor will advise you further and make sure you are aware of and understand all of the risks of taking TOPAMAX during pregnancy and the risks of seizures during pregnancy. See below under "[Pregnancy and breast feeding](#)".

## **Check with your doctor if you:**

- have any other medical conditions particularly:
  - have or have ever had a personality disorder or mental illness
  - have or have ever had kidney stones, kidney disease or have a family history of kidney stones

- have or have ever had liver disease
- have eye problem or high pressure in the eye
- have a history of metabolic acidosis (too much acid in the blood, which may cause an increased rate of breathing).
- take any medicines for any other condition

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking TOPAMAX.

Your doctor will advise you whether or not to take TOPAMAX or if you need to adjust the dose or adapt your treatment.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

**Check with your doctor if you are pregnant or intend to become pregnant.**

**TOPAMAX can harm an unborn child. If you are a woman who can become pregnant, talk to your doctor about other possible treatments. Visit your doctor to review your treatment and discuss the risk.**

## **Migraine prevention**

- For migraine, you must not use TOPAMAX if you are pregnant.

- For migraine, you must not use TOPAMAX if you are a woman who can become pregnant unless you are using highly effective contraception (birth control).
- Before the start of treatment with TOPAMAX a pregnancy test should be performed in a woman who can become pregnant.

### **Treatment of epilepsy**

- For epilepsy, you must not use TOPAMAX if you are pregnant, unless you and your doctor have agreed that no other treatment gives sufficient seizure control for you.
- For epilepsy, you must not use TOPAMAX if you are a woman who can become pregnant unless you are using highly effective contraception. Do not stop taking TOPAMAX or your contraception (birth control) until you have discussed this with your doctor. Your doctor will make sure you have received information about the risks of taking TOPAMAX during pregnancy and about the risks of seizures during pregnancy, which may put you or your unborn child at risk.
- Before the start of treatment with TOPAMAX a pregnancy test should be performed in a woman who can become pregnant.

### **The risks of topiramate when taken during pregnancy:**

- The risks apply whether topiramate is taken for migraine prevention or treatment of epilepsy.
- There is a risk of harm to the unborn child if TOPAMAX is used during pregnancy.

- If you take TOPAMAX during pregnancy, your child has a higher risk for birth defects, particularly
  - Cleft lip (split in the top lip) and cleft palate (split in the roof of the mouth).
  - Newborn boys may also have a malformation of the penis (hypospadias).

These defects can develop early in pregnancy, even before you know you are pregnant.

- Your child may be smaller and weigh less than expected at birth.
- Your child may have higher risk for autism spectrum disorders, intellectual disabilities, or attention deficit hyperactivity disorder (ADHD).

**Talk to your doctor if you have questions about this risk during pregnancy.**

**Always use highly effective contraception (birth control) recommended by your doctor during your treatment.** Talk to your doctor about the method of birth control that is most appropriate for you. If you are taking hormonal contraceptives, there is the risk for reduced effectiveness of hormonal contraceptives due to topiramate. Therefore, an additional barrier contraceptive method such as a condom or pessary/diaphragm should be used.

**You must tell your doctor if you are breastfeeding or intend to breastfeed.** TOPAMAX may appear in breast milk and it is not recommended to breastfeed while taking TOPAMAX.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with TOPAMAX and affect how it works.**

In particular, tell your doctor or pharmacist if you are taking:

- other medicines for epilepsy, such as phenytoin or carbamazepine
- digoxin (used to treat heart disease)
- contraceptives such as oestrogen-containing or progestin only contraceptives
- metformin, pioglitazone or glibenclamide (used to treat diabetes)
- lithium or risperidone (used to treat bipolar disorder and schizophrenia)
- haloperidol (used to treat psychoses)
- hydrochlorothiazide (used to treat swelling or high blood pressure)
- propranolol (used in high blood pressure, some heart conditions, tremors, tumor or migraine headaches)
- diltiazem (used to treat hypertension and prevent angina)
- valproic acid (used to treat epilepsy or mood disorders)

- vitamin K-antagonist anticoagulant medications (such as warfarin)
- amitriptyline (used to treat depression)
- flunarizine
- any medicine which slows your reactions (CNS depressants). This may include medicines to help you sleep or relieve pain, antidepressants, tranquillisers or antihistamines which can make you drowsy.
- any medicine which may cause kidney stone

These medicines may be affected by TOPAMAX or may affect how well TOPAMAX works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TOPAMAX.**

## **4. How do I use TOPAMAX?**

### **How much to take**

#### **Adults**

#### **Epilepsy**

- Treatment starts at a low dose of 25 mg to 50 mg per day. The dose is then gradually increased by 25 mg to 100 mg over weekly periods or longer, until the most suitable dose is reached.

#### **Migraine prevention**

- Treatment starts at a low dose of 25 mg nightly for one week. The dose is then increased over weekly periods or longer by 25mg/day, until the most suitable dose is reached.

## **Children (2 years and over)**

### **Epilepsy**

- Treatment starts at 25 mg or less per day, depending on the body weight. This dose is then gradually increased over weekly periods or longer, until the most suitable dose is reached.

Follow the instructions provided and use TOPAMAX until your doctor tells you to stop.

### **How to take it**

- You can take the tablets or capsules with or without food. Always swallow the tablets whole with plenty of water.
- TOPAMAX Sprinkle capsules are available for people who cannot swallow tablets. These capsules can be opened and all of the contents sprinkled onto a teaspoon of soft food which does not require chewing. This mixture should be swallowed immediately and not chewed. It should not be stored for future use. The capsules can also be swallowed whole with water.
- The doses shown above are the usual recommended doses. However, your doctor may tell you to take higher or lower doses. Your doctor will start with a low dose and slowly increase the dose to the lowest amount needed to control your epilepsy.

## **When to take TOPAMAX**

- At the start of treatment TOPAMAX may be taken once a day, preferably at night. After the dose is increased, it is taken twice a day.
- TOPAMAX should be used as prescribed by your doctor depending on your condition. Follow the instructions provided and use TOPAMAX until your doctor tells you to stop. Before stopping, it is recommended that the dose be reduced gradually

## **If you forget to use TOPAMAX**

TOPAMAX should be used regularly at the same time each day. If you miss your dose at the usual time, take your dose as soon as you remember, and then continue to take it as you would normally.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

**If you have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.**

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

## **If you use too much TOPAMAX**

If you think that you have used too much TOPAMAX, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (in Australia telephone **13 11 26** and in New Zealand telephone **0800 POISON** or **0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

### **You should do this even if there are no signs of discomfort or poisoning.**

If you take too much TOPAMAX, you may experience headache, dizziness, light-headedness, drowsiness, convulsions, speech disturbances, double or blurred vision, difficulty with thinking, abnormal coordination, stomach pain, depression, agitation, faster breathing or you may lose consciousness.

## **5. What should I know while using TOPAMAX?**

### **Things you should do**

- Drink plenty of water. TOPAMAX has been known to cause kidney stones and drinking water may help prevent this.
- Always follow your doctor's instructions carefully.

- If you are about to start taking a new medicine, tell your doctor or pharmacist that you are taking TOPAMAX.
- If you wish to become pregnant while taking TOPAMAX:
  - Schedule an appointment with your doctor.
  - Do not stop using your contraception until you have discussed this with your doctor and do not become pregnant until you have discussed your options with your doctor.

### **Call your doctor straight away if you:**

- notice changes to your menstrual bleeding while on contraceptives
- become pregnant or think you may be pregnant while taking TOPAMAX.
  - If you are taking TOPAMAX for epilepsy, do not stop taking this medicine until you have discussed this with your doctor, as this may worsen your illness. Worsening of your epilepsy may put you or your unborn child at risk.
  - If you are taking TOPAMAX to prevent migraine, stop taking the medicine straight away, and contact your doctor to evaluate if you need alternative treatment.

Remind any doctor, dentist or pharmacist you visit that you are using TOPAMAX.

## Things you should not do

- Do not stop using this medicine suddenly without checking with your doctor, unless you become pregnant or think you may be pregnant. See additional information under Section [5. What should I know while using TOPAMAX?](#) – Call your doctor straight away if you.
- Do not drink alcohol.
- Do not use TOPAMAX to treat any other complaint unless your doctor says so.
- Do not give this medicine to anyone else to use.

## Things to be careful of

### Changes to your medication

If you are seizure free or your seizures are well controlled, a reduction in your dose, discontinuation or substitution of your current medication should first be assessed by your doctor and pharmacist, and any changes should be implemented gradually.

### Effects on thoughts and behaviour

Medicines used to treat epilepsy can increase the risk of suicidal thoughts and behaviour. If you experience feelings of deep sadness and unworthiness (depression) or a worsening of these feelings, any unusual changes in your mood or the emergence of suicidal thoughts, behaviour or thoughts of self-harm, you should report this to your doctor immediately.

## **Decreased sweating and elevation in body temperature**

TOPAMAX may cause decreased sweating and increased body temperature (fever). People, especially children, should be watched for signs of decreased sweating and fever, especially in hot temperatures. Some people may need to be hospitalised for this condition.

Call your healthcare provider right away if you have a high fever, a fever that does not go away, or decreased sweating.

## **Serious skin reactions**

Tell your doctor immediately if you develop a skin rash and/or blisters.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how TOPAMAX affects you.**

TOPAMAX may cause drowsiness, dizziness or other symptoms which could affect your ability to drive or operate machinery. It may also cause visual disturbances and/ or blurred vision. Make sure you know how you are affected by this medicine before you drive or use machinery.

Particular care is recommended when you first start taking TOPAMAX or if the amount of TOPAMAX or any other medicine you are taking is increased or decreased.

## **Drinking alcohol**

### **Tell your doctor if you drink alcohol.**

Do not drink alcohol while taking TOPAMAX. Alcohol may increase the risk of unwanted side effects.

## **Looking after your medicine**

- Keep TOPAMAX tablets or capsules in the original pack until it is time to take them.
- Keep TOPAMAX tablets in a cool, dry place where the temperature is below 25°C.
- Keep TOPAMAX Sprinkle capsules in a cool, dry place where the temperature is below 25°C. Do not store the drug/food mixture.
- Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

### **Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Metabolism and nutrition-related:</b></p> <ul style="list-style-type: none"><li>● decrease in appetite or weight loss</li></ul> <p><b>Skin-related:</b></p> <ul style="list-style-type: none"><li>● itchy skin or skin rash</li></ul> <p><b>Gastrointestinal-related:</b></p> <ul style="list-style-type: none"><li>● nausea, diarrhoea, vomiting or constipation</li><li>● abdominal pain or discomfort</li></ul> <p><b>Ear-related:</b></p> <ul style="list-style-type: none"><li>● ear pain, buzzing or ringing in ears, deafness</li></ul> <p><b>Psychiatric-related:</b></p>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● inability to sleep</li> <li>● mood alterations such as aggression, agitation or anger</li> <li>● expressive language disorder</li> <li>● depression</li> <li>● nervousness or feeling anxious</li> </ul> <p><b>Nervous system-related:</b></p> <ul style="list-style-type: none"> <li>● dizziness</li> <li>● disturbance in attention</li> <li>● difficulty with memory or memory impairment</li> <li>● slowing of thought processes</li> <li>● abnormal behaviour</li> <li>● difficulty in speaking</li> <li>● balance disorder</li> <li>● co-ordination problems</li> <li>● decreased feeling or sensitivity, especially in the skin</li> <li>● tingling and numbness of hands and feet (pins and needles)</li> <li>● unusual weakness</li> </ul>	

Less serious side effects	What to do
<p><b>Other-related:</b></p> <ul style="list-style-type: none"> <li>● unusual hair loss or thinning</li> <li>● abnormal frequent urination</li> <li>● fever or high temperature</li> <li>● decreased or lack of sweating or overheating (mainly in children) ever or high temperature</li> <li>● taste disturbance or loss of taste</li> </ul>	

## Serious side effects

Serious side effects	What to do
<p><b>Nervous system-related:</b></p> <ul style="list-style-type: none"> <li>● unusual tiredness, drowsiness, irritability or lack of energy</li> </ul> <p><b>Respiratory-related:</b></p> <ul style="list-style-type: none"> <li>● difficulty breathing, fast or irregular heartbeat or tightening of chest</li> </ul> <p><b>Psychiatric-related:</b></p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● thoughts of harming yourself or thoughts of suicide</li> </ul> <p><b>Kidney-related:</b></p> <ul style="list-style-type: none"> <li>● kidney stones</li> <li>● pain when passing urine</li> </ul> <p><b>Vision-related:</b></p> <ul style="list-style-type: none"> <li>● sudden changes in your eyesight (e.g. blurred vision, double vision or loss of vision) or rapid uncontrollable movements of the eyes</li> <li>● eye pain or increased pressure in eye</li> </ul> <p><b>Other-related:</b></p> <ul style="list-style-type: none"> <li>● unexplained bleeding or bleeding more frequently</li> <li>● severe blisters and bleeding in mucosal sites (such as lips, eyes, mouth, nose, genitals).</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online in Australia at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems) or in New Zealand at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What TOPAMAX tablets contain

<b>Active ingredient (main ingredient)</b>	topiramate
<b>Other ingredients (inactive ingredients)</b>	lactose monohydrate pregelatinised maize starch carnauba wax microcrystalline cellulose

	<p>sodium starch glycollate</p> <p>magnesium stearate</p> <p>25 mg strength: Opadry White YS-1-7706-G (ARTG PI No. 2635)</p> <p>50 mg strength: Opadry Light Yellow YS-1-6382-G (ARTG PI No. 2636)</p> <p>100 mg strength: Opadry Yellow YS-1-6370-G (ARTG PI No. 2637)</p> <p>200mg strength: Opadry Pink YS-1-1456-G (ARTG PI No. 2638)</p>
<b>Potential allergens</b>	sugars as lactose

## What TOPAMAX capsules contain

<b>Active ingredient (main ingredient)</b>	topiramate
<b>Other ingredients (inactive ingredients)</b>	<p>sucrose</p> <p>povidone</p> <p>cellulose acetate</p> <p>15 mg strength: Empty Hard Gelatin Capsule Size 2 White Op/Nat</p>

	<p>G2HCSRR0446 (ARTG PI No. 106893)</p> <p>25 mg strength: Empty Hard Gelatin Capsule Size 1 White Op/Nat Part # G1HCSRR0602 (ARTG PI No. 106866)</p> <p>50 mg strength: Empty Hard Gelatin Capsule Size 0 White Op/Nat Part # G0HCSRR0796 (ARTG PI No. 106894)</p>
<b>Potential allergens</b>	sugars

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What TOPAMAX tablets look like**

TOPAMAX tablets are available in blister packs of 20 (25 mg only), 30 (50 mg only - sample pack) or 60:

- 25 mg tablets are round and white and marked "TOP" on one side and "25" on the other (AUST R 62709)
- 50 mg tablets are round and light yellow and marked "TOP" on one side and "50" on the other (AUST R 62710)
- 100 mg tablets are round and yellow and marked "TOP" on one side and "100" on the other (AUST R 62711)

- 200 mg tablets are round and salmon coloured and marked "TOP" on one side and "200" on the other (AUST R 62712)

Not all pack type or pack sizes may be marketed.

## **What TOPAMAX capsules look like**

TOPAMAX Sprinkle capsules are available in bottles of 60. The capsules consist of a clear cap and a white body. They contain white to off-white spheres:

- 15 mg capsules are marked "TOP" on the cap and "15 mg" on the body (AUST R 167729)
- 25 mg capsules are marked "TOP" on the cap and "25 mg" on the body (AUST R 167730)
- 50 mg capsules are marked "TOP" on the cap and "50 mg" on the body (AUST R 167731)

## **Who distributes TOPAMAX**

JANSSEN-CILAG Pty Ltd

17 Khartoum Road

Macquarie Park NSW 2113 Australia

Telephone: 1800 226 334

NZ Office: Auckland New Zealand

Telephone: 0800 800 806

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