

# Sandomigran®

*Pizotifen malate*

## Consumer Medicine Information

---

### What is in this leaflet

---

This leaflet answers some common questions about Sandomigran.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. Some more recent information on the medicine may be available.

**You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.**

**You can also download the most up to date leaflet from [www.novartis.com.au](http://www.novartis.com.au).**

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Sandomigran against the benefits they expect it will have for you.

**If you have any concerns about this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

---

### What Sandomigran is used for

---

Sandomigran is used to prevent "vascular" headaches, including migraine, cluster headaches and vasomotor headaches.

Vascular headaches are thought to be caused by temporary changes in the size of small blood vessels in the brain. These changes cause the pain and problems with vision that often happen during a severe headache. Sandomigran prevents an attack by stopping the blood vessels from changing in size.

Sandomigran is only used to prevent severe headaches from happening. It will not stop an attack once it has started.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

Sandomigran is only available with a doctor's prescription. It is not addictive.

There is not enough information to recommend this medicine for children.

---

### Before you take Sandomigran

---

*When you must not take it*

**Do not take Sandomigran if you have an allergy to pizotifen (the active ingredient) or to any of the other ingredients of Sandomigran listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing;
- swelling of the face, lips, tongue or other parts of the body;

- rash, itching or hives on the skin.

**Do not take Sandomigran after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

In that case, return it to your pharmacist.

*Before you start to take it*

**Tell your doctor if you have any of the following medical conditions:**

- increased pressure in the eye due to glaucoma
- difficulty in passing urine (water), due to prostate trouble or any other cause
- convulsions, fits, or seizures

Your doctor may want to take special precautions if you have one of the above conditions.

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

Experience with Sandomigran in pregnancy is very limited. If it is necessary for you to take this medicine during pregnancy, your doctor will discuss with you the benefits and risks involved.

**Tell your doctor if you are breast-feeding or intend to breast-feed.**

Small amounts of Sandomigran pass into breast milk. Although such small amounts are unlikely to harm your baby, breast-feeding while taking this medicine is not recommended. Your doctor will discuss with you the benefits and the risks involved.

**Tell your doctor if you are lactose intolerant.**

This medicine contains lactose.

**Tell your doctor if you have allergies to any other medicines, foods, dyes or preservatives.**

Your doctor will want to know if you are prone to allergies.

### *Taking other medicines*

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

Some medicines and Sandomigran may interfere with each other. These may include:

- medicines to calm you down, treat anxiety, or help you to sleep
- medicines found in cough, cold and allergy preparations (antihistamines)
- monoamine oxidase inhibitors (MAOI) which belong to a group of medicines called antidepressants
- cisapride, a medicine used to treat heartburn

These medicines may worsen the drowsiness that sometimes happens when you take Sandomigran. You may need to take different amounts of your medicines or you may need to take different medicines. Your doctor and pharmacist have more information.

**If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.**

---

## How to take Sandomigran

---

**Follow all directions given to you by your doctor and pharmacist carefully.**

These instructions may differ from the information contained in this leaflet.

**If you do not understand the instructions on the label, ask your doctor or pharmacist for help.**

### *How much to take*

The usual starting dose is one tablet of Sandomigran each day. To avoid making you drowsy, the dose is gradually increased, usually to three tablets each day.

If your headaches are still not controlled, your doctor may gradually increase the dose up to a maximum of nine tablets each day, divided into two or three doses.

### *When to take it*

Your doctor may tell you to take all of the tablets at one time (usually at night) or he/she may tell you to divide the tablets over the day (for example, 1 tablet in the morning and 2 tablets at night).

### *How to take it*

**Take the tablets with a full glass of water.**

They can be taken with or without food.

**Try to take the tablets at about the same times each day.**

Taking them at the same times each day will help you to remember to take them.

### *How long to take it*

**Continue taking Sandomigran every day for as long as your doctor prescribes.**

To prevent severe headaches, you must take this medicine every day, even if you feel well.

### *If you forget to take it*

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

**Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.**

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

This may increase the chance of you getting an unwanted side effect.

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

### *If you take too much (Overdose)*

**Immediately telephone your doctor or the Poisons Information Centre (telephone number 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Sandomigran. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.**

Some of the symptoms of an overdose may include drowsiness, nausea (feeling sick), dizziness or light headedness, slow breathing, coma, and convulsions (particularly in children). Children may also become overexcited.

---

## While you are taking Sandomigran

---

### *Things you must do*

**If you become pregnant while taking Sandomigran, tell your doctor.**

Your doctor can discuss with you the risks of taking it while you are pregnant.

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Sandomigran.**

**Be sure to keep all of your doctor's appointments so that your progress can be checked.**

This helps your doctor to give you the best treatment and to prevent unwanted side effects from happening.

**Tell any other doctor, dentist or pharmacist who treats you that you are taking Sandomigran.**

## *Things you must not do*

**Do not take Sandomigran to treat a severe headache once it has started.**

This medicine is only used to prevent severe headaches. It will not stop an attack once it has started.

**Do not give this medicine to anyone else, even if their condition seems similar to yours.**

**Do not take it to treat any other complaints unless your doctor tells you to.**

This medicine is not appropriate for common 'tension' headaches.

**Do no change or stop taking your tablets without checking with your doctor first.**

Your doctor may want you to reduce the dosage gradually before stopping completely. This is to prevent any worsening of your condition and reduce the risk of withdrawal symptoms such as depression, trembling, nausea, anxiety, generally feeling unwell, dizziness, sleep disorder and weight loss.

## *Things to be careful of*

**Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Sandomigran affects you.**

This medicine may make you feel drowsy, dizzy, or have other central nervous system effects, especially when you first start to take it. If that happens, do not drive or do anything else that could be dangerous.

**Be careful when drinking alcohol while you are taking Sandomigran.**

The combination could make you feel drowsier than usual.

---

## Side effects

---

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Sandomigran.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Do not be alarmed by these lists of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor as soon as possible if you notice any of the following:**

- signs of fluid build up such as swelling of the ankles, feet or lower legs
- faintness, dizziness or lightheadedness
- numbness or tingling feeling in arms or legs
- skin rash
- seeing, feeling or hearing things that are not there (hallucinations)
- signs of an allergic reaction such as swelling of the face or itchy skin
- yellowing of your skin or the whites of your eyes, abnormal darkening of the urine or unexplained nausea, vomiting and tiredness (signs of jaundice or hepatitis)
- convulsions, fits, or seizures

**Tell your doctor if you notice any of the following and they worry you:**

- drowsiness
- fatigue
- dry mouth
- nausea (feeling sick)
- constipation
- aching muscles
- increased appetite, weight gain
- problems with sexual function
- problems sleeping
- a feeling of deep sadness, anxiety or sudden mood changes

**Tell your doctor if you notice anything else that is making you feel unwell.**

Some people may have other side effects not yet known or mentioned in this leaflet.

---

## After taking Sandomigran

---

### *Storage*

- Keep your medicine in the original container until it is time to take it.
- Store it in a cool dry place.
- Do not store Sandomigran or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

**Keep the medicine where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### *Disposal*

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

---

## Product description

---

### *What it looks like*

Sandomigran is an off-white, sugar-coated tablet supplied in packs of 100 tablets.

### *Ingredients*

Sandomigran tablets contain 0.5 mg pizotifen (as the malate salt) as the active ingredient. They also contain:

- colloidal anhydrous silica
- lactose
- magnesium stearate

- maize starch
- purified talc
- povidone
- acacia
- sucrose
- titanium dioxide
- cetyl palmitate

### *Sponsor*

Sandomigran is supplied in Australia  
by:

**NOVARTIS Pharmaceuticals  
Australia Pty Limited**

ABN 18 004 244 160

54 Waterloo Road

North Ryde NSW 2113

Telephone 1 800 671 203

® = Registered Trademark

This leaflet was prepared in May  
2011.

### **Australian Registration Number:**

Sandomigran 0.5 mg tablet

AUST R 69608

(smg050215c based on PI  
smg050215i)