

# SANDOMIGRAN<sup>®</sup>

## 500 mcg tablet

### Pizotifen malate

## 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.medsafe.govt.nz](http://www.medsafe.govt.nz).**

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 this medicine is expected to have for you.

**If you have any concerns about taking 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 contains the active ingredient pizotifen. It is used to prevent attacks of migraine (severe periodic headache). Migraine attacks are thought to be caused by temporary changes in the size of small blood vessels in the brain. These changes to the blood vessels cause the pain and problems with vision that often happen during a migraine. Sandomigran prevents migraine attacks by stopping the blood vessels from changing in size. Sandomigran can only be used to prevent migraine. It does not work during a migraine attack.

**Ask your doctor if you have any questions about why Sandomigran 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.

## Before you take Sandomigran

### *When you must not take it*

**Do not take Sandomigran if you have an allergy to:**

- pizotifen (the active ingredient in Sandomigran)
- any of the other ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include: hives or an itchy skin rash, swelling of the face, lips or tongue, wheezing or troubled breathing, faintness or other symptoms if you take it.

**Do not take Sandomigran if the packaging is torn or shows signs of tampering.**

In that case, return it to your pharmacist.

**Do not take Sandomigran after the use by (expiry) date printed on the pack.**

If you take it after the expiry date has passed, it may not work as well as it should.

**Do not give this medicine to a child.**

Sandomigran is not recommended for use in children under 2 years of age as there is not enough information on its use in people of that age.

## ***Before you start to take it***

**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.

If you have been told by your doctor that you have an intolerance to some sugars (lactose), contact your doctor before taking Sandomigran.

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

- a condition which makes passing urine (water) difficult (eg. prostate trouble)
- increased pressure in the eye due to glaucoma
- convulsions, seizures or fits

Your doctor may want to take special precautions if you have any of these conditions. Sandomigran could make these conditions worse.

**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, your doctor will discuss with you the benefits and risks of taking it during pregnancy.

**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 the baby, breastfeeding while taking this medicine is not recommended. Your doctor will discuss the benefits and risks of taking it when breast-feeding.

**If you have not told your doctor about any of these things, tell them before you take Sandomigran.**

## ***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 include:

- medicines to calm you down, treat anxiety, or help you to sleep
- antihistamines, found in cough, cold and allergy preparations (antihistamines)
- monoamine oxidase inhibitors (MAOIs) 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 on medicines to be careful with or avoid while taking Sandomigran.

## **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***

### **Adults and Children**

Your doctor will usually start you on one tablet of Sandomigran each day. To avoid making you drowsy, the dose is gradually increased, usually to three tablets each day.

If your migraine attacks 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***

The tablets can be taken all at once (usually at night) or they can be divided throughout the day (eg. 1 tablet in the morning and 2 tablets at night).

## ***How to take it***

**Take the tablets with water or other liquid. They can be taken with or without food.**

**For the best effect, 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.**

This medicine helps to prevent migraine. It must be taken 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 National Poisons and Hazardous Information Centre (telephone number 0800 POISON OR 0800 764 766), or go to the Accident and Emergency Department 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), low blood pressure, dizziness, difficulty breathing, coma, and convulsions (particularly in children). Children may also become hyperactive.

## **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.

**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.

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

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

### ***Things you must not do***

**Do not give this medicine to anyone else even if their symptoms seem to be the same as yours.**

**Do not use Sandomigran to treat any other complaints unless your doctor tells you to.**

**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 more drowsy 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 this list 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 if you notice any of the following and they worry you:**

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

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

- swollen ankles or other signs of fluid buildup
- 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

You may need medical attention if you get these side effects.

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

Some people may get other side effects when taking Sandomigran.

## **After using Sandomigran**

### ***Storage***

- Keep your tablets in the original container until it is time to take them.
- Store the tablets in a cool dry place where the temperature stays below 30°C.
- 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.

Heat and dampness can destroy some medicines. Sandomigran will keep well if it is cool and dry.

**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 Sandomigran or you find that it has passed the expiry date, ask your pharmacist what to do with any medicine you have left over.**

## **Product description**

### ***What it looks like***

Sandomigran is an off-white- pale yellow sugar-coated tablet; packed in blister packs of 100 tablets and plastic bottle of 100 tablets.

## ***Ingredients***

Sandomigran tablets contain 500 microgram pizotifen (as the malate salt) as the active ingredient. They also contain:

- silica colloidal anhydrous
- lactose
- magnesium stearate
- starch-maize
- talc-purified
- povidone
- acacia
- sucrose
- titanium dioxide
- cetyl palmitate

## ***Sponsor***

Sandomigran is supplied in New Zealand by:

AFT Pharmaceuticals Ltd.

PO Box 33203

Takapuna

Auckland

0740

Ph: 09 488 0232

Fax: 09 488 0234

## ***Date of preparation***

This leaflet was prepared in September 2015 based on the current data sheet for this product.

## ***Date of last revision***

June 2019