

SABRIL(R)

Vigabatrin

Consumer Medicines Information

What is in this leaflet

This leaflet answers some common questions about SABRIL. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SABRIL 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 SABRIL is used for

SABRIL is a medicine used to help control epilepsy.

SABRIL is an anticonvulsant. It works by stopping the breakdown of an important chemical transmitter ("messenger") in the brain and this helps reduce seizure activity.

Your doctor, however, may have prescribed SABRIL for another reason. Ask your doctor if you have any questions about why SABRIL has been prescribed for you.

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

Before taking SABRIL

SABRIL must not be taken if

1. you have an allergy to:

- * SABRIL or any of the ingredients listed at the end of this leaflet (Product Description)

Symptoms of an allergic reaction to these medicines may include:

- * asthma, wheezing or shortness of breath
 - * swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
 - * hives, itching or skin rash
 - * fainting
- 2. the packaging is torn or shows signs of tampering.**
- 3. the expiry date on the pack has passed.**

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

If you are not sure whether you should start taking SABRIL, contact your doctor.

Before you start to take it

Tell your doctor if:

1. you have any allergies to:

- * any other medicines
- * any other substances

2. you have or have had any of the following medical conditions:

- * kidney problems
- * nervous or mental illness

3. you are pregnant or intend to become pregnant.

Like most medicines for epilepsy, SABRIL may affect your unborn baby. However, it is very important to control your epilepsy while you are pregnant, since seizures may also affect your baby. Your doctor will help you decide whether or not you should take SABRIL during pregnancy.

4. you are breast-feeding or plan to breast-feed

If you have not told your doctor about any of the above, tell them before you take any SABRIL.

Your doctor may want to test your eyesight before you start taking SABRIL and during the course of your treatment so that any changes in your sight can be detected.

Some anti-epilepsy medicines may affect eyesight. In rare cases, patients treated with SABRIL have experienced changes to their peripheral vision (i.e., they had trouble seeing things that were not directly in front of them). Please ask your doctor if you want more information about this.

Taking other medicines

SABRIL is very unlikely to affect other medications (including other antiepilepsy medications and the oral contraceptive).

However, before you take SABRIL you should tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Your doctor or pharmacist has more information about medicines to be careful with or avoid while taking SABRIL.

How to take SABRIL

Follow all directions given to you by your doctor and pharmacist carefully. These directions may differ from the information contained in this leaflet.

How much to take

SABRIL tablets and sachets are taken by mouth either once or twice a day. The dose of SABRIL varies between patients. Your doctor will tell you how much to take.

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

How to take it

Tablets

You should swallow your tablet(s) whole with plenty of water. Do not chew them.

Sachets

The contents of the sachets should be dissolved in water, juice or soft drink just before you plan to give it. It will dissolve easily and has no taste or smell. Give the required amount immediately.

Once mixed, any remaining solution should be discarded within 24 hours.

When and how long to take it

You can take or give SABRIL with or without food.

Do not stop taking or giving SABRIL until your doctor tells you.

If you forget to take or give a dose

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

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

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

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

If too much is taken (overdose)

Immediately telephone your doctor or Poisons Information Centre or go to casualty at your nearest hospital if you think that you or anyone else may have taken too much SABRIL. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While using SABRIL

Things you must do

If you become pregnant while you are taking SABRIL, tell your doctor.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking SABRIL.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking SABRIL.

Things you must not do

Do not stop taking or giving the tablets or sachets until your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how SABRIL affects you.

SABRIL may cause dizziness or light-headedness in some people. Make sure you know how you react to SABRIL before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or light-headed. This effect decreases with time.

Side Effects

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

All medicines can cause side effects and this may occur with the normal use of SABRIL. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side-effects.

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
- * nervousness, irritability, depression
- * dizziness
- * confusion

Tell your doctor immediately if you notice any of the following:

- * an increase in the number of seizures
- * changes in your usual behaviour or mood
- * severe sedation or confusion
- * changes in your eyesight

You should not stop taking SABRIL without consulting your doctor first.

Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using SABRIL

Storage

Keep your tablets or sachets in the container until it is time to take them.

Keep SABRIL in a cool dry place where the temperature stays below 30 degrees C. Do not store SABRIL 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.

Keep SABRIL where children cannot reach it.

Disposal

If your doctor tells you to stop taking or giving SABRIL tablets or sachets or the expiry date has passed, ask your pharmacist what to do with any tablets or sachets that are left over.

Product description

What SABRIL looks like

Tablets

SABRIL 500 mg are white to off-white, biconvex oval shaped tablets with a single breakline on one face and SABRIL inscribed in the other. They come in a blister pack of 100 tablets.

Sachets

SABRIL sachets contain 500 mg of vigabatrin. They come in a pack of 60 sachets.

Ingredients

SABRIL does not contain gluten, sucrose, tartrazine or any other azo dyes.

Tablets

The active ingredient in SABRIL tablets is vigabatrin. There is 500 mg of vigabatrin in every tablet. Each tablet also contains some inactive ingredients. These are: povidone, cellulose microcrystalline, sodium starch glycollate, magnesium stearate, hydroxypropyl methylcellulose, titanium dioxide, polyethylene glycol 8000 and purified water.

Sachets

SABRIL sachets contain 500 mg of vigabatrin powder and povidone (an inactive agent).

Manufacturer/Distributor

SABRIL is supplied in Australia by:
Aventis Pharma Pty Ltd
27 Sirius Road
Lane Cove NSW 2066

SABRIL tablets: AUST R 49209
SABRIL sachets: AUST R 52985

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