

If your doctor decides to stop your treatment, return any leftover tablets to your pharmacist. Only keep them if your doctor tells you to.

Leave your tablets in their packing and keep them in a safe place out of the reach and sight of children.

Date of last revision of text: December 2001

For your information

The following centres can provide additional information on epilepsy:-

England:-

British Epilepsy Association

New Anstey House
Gate Way Drive, Yeadon
Leeds LS19 7XY
Tel: 0113 210 8800
Helpline: 0808 800 5050

National Society for Epilepsy

Chalfont Centre for Epilepsy
Chalfont St Peter
Gerrards Cross
Bucks SL9 0RJ
Tel: 01494 873991
Information line: 01494 872049

Northern Ireland:-

British Epilepsy Association

Northern Ireland Office
Old Postgraduate Centre
Belfast City Hospital
Lisburn Road
Belfast BT9 7AB
Tel: 01232 248414

ROI:-

Brainwave

The Irish Epilepsy Association
249 Crumlin Road
Dublin 12
Tel: (00353) 1 455 7500

Scotland:-

Epilepsy Association of Scotland

48 Govan Road
Glasgow G51 1JL
Tel: 0141 427 4911

Wales:-

Wales Epilepsy Association

Y Pant Teg
Brynteg
Dolgellau
Gwynedd LL40 1RP
Tel: 01341 423339

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Tablets 500 mg

vigabatrin

 **Aventis**

Please read this leaflet carefully before you start to take your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

What is in your medicine?

The name of your medicine is Sabril Tablets 500mg. Each tablet contains 500mg of the active ingredient vigabatrin. The tablets also contain povidone, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, hydroxypropyl methylcellulose, titanium dioxide and polyethylene glycol 8000.

Each pack contains 100 tablets. The tablets are white, oval, biconvex, film-coated tablets with a breakline on one side and "SABRIL" on the other.

What you should know about Sabril Tablets 500mg

Sabril Tablets 500mg are used to help control various forms of epilepsy.

The company responsible (also known as the Marketing Authorisation Holder) for this product in the UK is: Aventis Pharma Ltd., 50 Kings Hill Avenue, Kings Hill, West Malling, Kent, ME19 4AH, UK., and in the Republic of Ireland is Aventis Pharma Ltd., Lake Drive, 3004 Citywest, Naas Road, Dublin 24, Republic of Ireland.

The product is made by: Patheon France SA, Boulevard de Champaret, 38300 Bourgoin-Jallieu, France.

What are Sabril Tablets 500mg for?

Sabril Tablets 500mg are used together with your current medication to treat "difficult to control" epilepsy. They will initially be prescribed by a specialist. Your response to the treatment will be monitored.

Sabril Tablets 500mg are also used on their own to control infantile spasms (West's syndrome).

Before taking your medicine

Do not take Sabril Tablets 500mg if you know you are allergic to any of the tablet ingredients listed above.

Tell your doctor immediately if you are pregnant or if you become pregnant during

your treatment. If you are planning to become pregnant, you should discuss this with your doctor before taking your medicine.

You should also tell your doctor if :

- You are breast feeding
- You have had any psychiatric or nervous illness in the past
- You have had any kidney problems
- You have any visual disorders

Your doctor may wish to carry out regular checks on your nervous system function to monitor your condition. You will also need to undergo regular testing of your vision. You should also tell your doctor if you are taking any other medicines, in particular phenytoin - another drug used in the treatment of epilepsy.

Driving and Sabril Tablets 500mg

Do not drive or operate machinery if your epilepsy is uncontrolled.

Sabril sometimes causes drowsiness. If you do feel drowsy whilst taking these tablets, you should not do any hazardous tasks such as driving or operating machinery. Visual disorders, which can affect your ability to drive and use machines, have been found in some patients receiving Sabril therapy. If you wish to continue driving, you must be tested regularly (every six months) for the presence of visual disorders even if you do not notice any changes to your vision.

Taking your medicine

It is important to follow your doctor's instructions exactly. Never change the dose yourself. Always swallow the tablets with plenty of water. You can take the tablets before or after meals.

The usual starting dose for adults is 2 tablets daily. However, your doctor may wish to increase or decrease the dose depending on your response; the usual adult daily dose is 2 to 3g (4 to 6 tablets).

Also if you are elderly and/or have kidney problems, your doctor may wish to give you a smaller dose.

The usual starting dose for children is 40 milligrams per kilogram bodyweight daily.

The following table gives the number of Sabril tablets to give to a child according to his/her bodyweight. Remember that this is just a guideline. The child's doctor may wish to give slightly different doses.

Bodyweight	10-15kg	1-2 tablets/day
	15-30kg	2-3 tablets/day
	30-50kg	3-6 tablets/day
	greater than 50kg	4-6 tablets/day (adult dose)

The recommended starting dose for children with West's Syndrome (infantile spasms) is 50 milligrams per kilogram bodyweight per day although higher doses may be used sometimes.

The daily dose can be taken in single or divided doses.

If you or your child accidentally take too many Sabril Tablets 500mg, tell your doctor immediately or go to your nearest casualty department.



If you forget to take a dose, take it as soon as you do remember, unless it is almost time for your next dose, in which case, just take the dose. Do not take a double dose to make up for the missed dose.

Do not stop taking this medicine without talking to your doctor. If your doctor decides to stop your treatment you will be advised to gradually reduce the dose. Do not stop suddenly.

After taking your medicine

This medicine can cause side-effects.

Visual field loss (loss of sight from the edges of your field of vision) may well occur during Sabril therapy. This visual field loss may be irreversible, so it must be found early. It is important that you inform your doctor promptly if you become aware of any change to your vision. As you may not notice this side-effect when it first occurs, your doctor will carry out tests of your vision at regular intervals.

- Other visual and retinal disorders including blurred vision, double vision, rapid involuntary movement of the eye, sensitivity to light and feelings of discomfort in the eye may occur.

If you experience any of these effects contact your doctor.

If you develop any of the following you should tell your doctor:-

- psychological disturbances including agitation, nervousness, aggression, irritability, depression, hallucinations, thought disturbances and paranoia. Rarely, more severe disturbances of this type can occur.
- suicidal thoughts, suicide attempt
- children may become over excited or restless
- drowsiness, tiredness, dizziness, confusion, difficulty in concentrating, memory loss. These generally wear off with continued treatment. However, if these become severe you should tell your doctor immediately.
- stomach problems such as nausea, vomiting and abdominal pain
- headache
- pins and needles, tremor or difficulty balancing and clumsiness
- weight gain
- swelling, especially of the face
- skin rash (with or without itching)
- loss of appetite
- Rarely, yellowing of the skin and eyes (jaundice) may occur.

As with other antiepileptic drugs, some patients may experience an increase in the number of seizures (fits) whilst taking Sabril. If this happens to you, or to your child, tell your doctor immediately.

Sabril may affect the results of some blood tests.

You should also tell your doctor or pharmacist if you notice any other unusual effect not mentioned above.

Storing your medicine

Do not use your medicine after the expiry date shown on the box.