Package leaflet: Information for the user

Vigabatrin MSN 500 mg granules for oral solution
vigabatrin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Vigabatrin MSN is and what it is used for

Vigabatrin MSN is used to help control various forms of epilepsy.

It is used together with your current medication to treat "difficult to control" epilepsy. It will initially be prescribed by a specialist. Your response to the treatment will be monitored.

It is also used to control infantile spasms (West's syndrome).

2. What you need to know before you take Vigabatrin MSN

Do not take Vigabatrin MSN
- if you are allergic to vigabatrin or any of the other ingredients of this medicine (listed in Section 6).

Warnings and precautions
Talk to your doctor before taking Vigabatrin MSN if:
- you are breast-feeding
- you are pregnant or plan to become pregnant
- you have or have had depression or any other psychiatric illness in the past
- you have had any kidney problems
- you have had any problems with your eyes

Visual field loss (loss of sight from the edges of your field of vision) may occur during treatment with Vigabatrin MSN. You should discuss this possibility with your doctor before you begin treatment with this medicine. This visual field loss may be severe, up to tunnel vision or loss of vision, and irreversible, so it must be found early. A deterioration of this visual field loss after the treatment is discontinued cannot be excluded. It is important that you inform your doctor promptly if you become aware of any change to your vision.

It is recommended that your healthcare provider test your (or your child's) vision (including peripheral vision) and visual acuity (ability to read an eye chart) before you (or your child) start Vigabatrin MSN or within 4 weeks after starting Vigabatrin MSN, and every 3 to 6 months until Vigabatrin MSN is stopped. It is also recommended that you (or your child) have a vision test about 3 to 6 months after Vigabatrin MSN is stopped.

Vigabatrin MSN may cause reduced vision due to eye problems such as retinal disorder, blurred vision, optic atrophy or optic neuritis (see section 4). If your vision changes consult your ophthalmologist.

If you develop symptoms like sleepiness, reduced consciousness and movements (stupor) or confusion consult your doctor who will decide upon a dose reduction or withdrawal.

A small number of people being treated with antiepileptics have had thoughts of harming or killing themselves.
If at any time you have these thoughts, immediately contact your doctor.

Children
Movement disorders and abnormalities in magnetic resonance imaging (MRI) brain scans have been seen in young infants treated for infantile spasms (West's syndrome). If you observe unusual movement disorders in the child, consult your doctor who will decide if it is necessary to consider changing the treatment.

Other medicines and Vigabatrin MSN
Please tell your doctor if you are taking clonazepam as the concomitant use with Vigabatrin MSN can increase the risk of sedation.

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Vigabatrin MSN should not be used in combination with other medicines that may have side effects related to the eye.

Pregnancy, breast-feeding and fertility
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Do not take Vigabatrin MSN during pregnancy unless your doctor tells you to. Vigabatrin MSN may cause problems to unborn children. However, do not stop taking the medicine suddenly because this may risk the mother's health as well as the baby's health.

Vigabatrin MSN passes into breast milk. If you are breast-feeding, ask your doctor for advice before taking this medicine. Breast-feeding should not be done during treatment.

Driving and using machines
Do not drive or operate machinery if your epilepsy is uncontrolled.
Vigabatrin MSN sometimes causes symptoms like drowsiness or dizziness and your ability to concentrate and react may be reduced. If such symptoms occur whilst taking Vigabatrin MSN, 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 taking this medicine. 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.

3. How to take Vigabatrin MSN

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

It is important to follow your doctor's instructions exactly. Never change the dose yourself. The doctor prescribes the dose and adjusts it individually for patients.
The usual starting dose for adults is 1 g (2 sachets) daily. However, your doctor may wish to increase or decrease the dose depending on your response; the usual adult daily dose is 2 to 3 g (4 to 6 sachets). The highest recommended dose is 3 g/day.

If you are older people and/or have kidney problems, your doctor may wish to give you a smaller dose.

Use in children
Resistant partial epilepsy

For children, the dose is based on age and weight. The usual starting dose for children is 40 milligrams per kilogram bodyweight daily. The following table gives the number of sachets to give to a child according to his/ her bodyweight. Remember that this is just a guideline. The child's doctor may wish to have slightly different doses.

Bodyweight	10-15 kg	0.5-1 g (1-2 sachets)/day
	15-30 kg	1-1.5 g (2-3 sachets)/day
	30-50 kg	1.5-3 g (3-6 sachets)/day
greater than 50 kg		2-3 g (4-6 sachets)/day (adult dose).

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

Method of administration
The route of administration is oral use (by mouth).
Do not open the sachets until it is time for you to take your medicine. To take a dose you should dissolve all the powder from the recommended number of sachets in half a drinking glass full of cold water or soft drink, like juice or milk. When all the powder has dissolved, drink all of the solution straight away and do not leave it standing.
You can take Vigabatrin MSN before or after meals.
The daily dose can be taken as a single dose or divided in two doses.

If you take more Vigabatrin MSN than you should
If you or your child accidentally take too many Vigabatrin MSN sachets, tell your doctor immediately or go to your nearest hospital or Poison Information Centre.
Possible signs of overdose include drowsiness or loss/depressed level of consciousness.

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

If you stop taking Vigabatrin MSN
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 as this may cause your seizures to occur again.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
As with other antiepileptic medicines, some patients may experience an increase in the number of seizures (fits) whilst taking this medicine. If this happens to you, or to your child, contact your doctor immediately.

Talk to your doctor immediately if you experience:
Very common side effects (may affect more than 1 in 10 people)
- Visual field changes – About ⅓ or 33 out of 100 patients treated with Vigabatrin MSN may have changes in the visual field (narrow visual field). This "visual field defect" can range from mild to severe. It is usually detected after months or years of treatment with Vigabatrin MSN. The changes in the visual field may be irreversible, so it must be found early. If you or your child experience(s) visual disturbances, contact your doctor or hospital immediately.

Other side effects include:
Very common side effects (may affect more than 1 in 10 people)
- Tiredness and pronounced sleepiness
- Joint pain

Common side effects (may affect up to 1 in 10 people)
- Headache
- Weight gain
- Shaking (tremor)
- Swelling (oedema)
- Dizziness
- Sensation of numbness or tingling (pins and needles)
- Disturbance of concentration and memory
- Psychological disturbances including agitation, aggression, nervousness, irritability, depression, thought disturbance and paranoia, insomnia. These side effects are usually reversible when the dose is reduced or gradually discontinued. However, do not decrease your dose without first talking to your doctor. Contact your doctor if you experience these side effects.
- Nausea, vomiting and abdominal pain
- Blurred vision, double vision and rapid involuntary movement of the eye
- Speech disorder
- Decrease in the number of red blood cells (anaemia)
- Unusual hair loss or thinning (alopecia)

Uncommon side effects (may affect up to 1 in 100 people)
- Lack of coordination in movements or fumbling
- More severe psychological disturbances such as hypomania, mania and psychosis
- Skin rash

Rare side effects (may affect up to 1 in 1,000 people)
- Serious allergic reaction, which causes swelling of the face or throat. If you experience these symptoms, you should tell your doctor immediately.
- Hives or nettle rash
- Marked sedation, stupor and confusion. These side effects are usually reversible when the dose is reduced or gradually discontinued. However, do not decrease your dose without first talking to your doctor. Contact your doctor if you experience these side effects.
- Suicide attempt
- Other eye problems such as retinal disorder

Very rare side effects (may affect up to 1 in 10,000 people)
- Other eye problems such as optic neuritis and optic atrophy
- Hallucinations

- Liver problems

Not known frequency (frequency cannot be estimated from the available data)
- Decreased sharpness of vision
- Abnormal changes in brain pictures taken by MRI
- Swelling in the protective layer of nerve cells in part of the brain as observed in MRI pictures

Additional side effects in children
Very common side effects (may affect more than 1 in 10 people)
- Excitation or restless

Not known frequency (frequency cannot be estimated from the available data)
- Movement disorders in young infants treated for infantile spasm
- Abnormal changes in brain pictures taken by MRI, particularly in infants
- Swelling in the protective layer of nerve cells in part of the brain as observed in MRI pictures, particularly in infants

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vigabatrin MSN

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer cardboard box and sachets. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via waste or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Vigabatrin MSN contains
- The active substance is vigabatrin. Each sachet contains 500 mg vigabatrin.
- The other ingredient is: Povidone K30

What Vigabatrin MSN looks like and contents of the pack
Vigabatrin MSN appears as white to off-white granular powder.
It is available in packs of 50, 60 or 100 sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

MSN Laboratories Europe Ltd,
Invision House, Wilbury Way,
Hitchin, SG4 0TY

Manufacturer

Pharmadox Healthcare Ltd.
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This leaflet was last approved in January 2026.