

kigabeq[®] 100 mg
kigabeq[®] 500 mg

soluble tablets
vigabatrin

For children aged 1 month
to less than 7 years

Read all of this leaflet carefully before you give this medicine to your child because it contains important information.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your child's doctor or pharmacist.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects, talk to your child's doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Kigabeq is and what it is used for
2. What you need to know before your child takes Kigabeq
3. How to give Kigabeq
4. Possible side effects
5. How to store Kigabeq
6. Contents of the pack and other information

1. What Kigabeq is and what it is used for

Kigabeq contains vigabatrin and it is used for treating infants and children aged from 1 month to less than 7 years. It is used to treat infantile spasms (West's syndrome) or, together with other epilepsy medicines to treat partial epilepsy that is not controlled well enough with current treatment.

2. What you need to know before your child takes Kigabeq

Do not give Kigabeq:

- if your child is allergic to vigabatrin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

- Talk to your child's doctor before you give Kigabeq if your child:
- has or has had depression or any other psychiatric illness in the past
 - has had any kidney problems as he/she could develop symptoms like sedation or confusion
 - has had any eye problems.

Visual field loss (loss of sight from the edges of your child's field of vision) may occur during treatment with vigabatrin. You should discuss this possibility with the doctor before your child begins treatment and the doctor will tell you how to detect this side effect. This visual field loss may be severe and permanent, so it must be detected early to avoid progression. Worsening of visual field loss may continue after stopping treatment. It is important that you tell the doctor promptly if there is any change in your child's vision. The doctor will check your child's visual field before your child starts taking vigabatrin and carry on checking it at regular intervals during the treatment.

If your child develops symptoms like sleepiness, reduced consciousness and movements (stupor) or confusion, tell your child's doctor who may reduce the dose or stop Kigabeq treatment. A small number of people being treated with epilepsy medicines such as vigabatrin have had thoughts of harming or killing themselves. Look for symptoms suggestive of such thoughts:

disturbed sleep, loss of appetite or weight, isolation, loss of interest for favorite activities. If at any time your child has had these symptoms, immediately contact child's doctor.

Movement disorders can occur in young infants treated for infantile spasms (West's syndrome). If you see unusual movements in your child, tell your child's doctor who may change the treatment.

Tell your child's doctor if your child has had or is going to perform laboratory tests because this medicine may lead to abnormal results. You must speak to your child's doctor if your child's condition does not improve within a month of starting vigabatrin.

Children

Do not give this medicine to children less than 1 month of age or more than 7 years of age.

Other medicines and Kigabeq

Tell your child's doctor if the child is taking, has recently taken or might take any other medicines.

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

Pregnancy and breast-feeding

This medicine is not intended for use in women of child-bearing potential or in breast-feeding women.

Driving and using machines

Your child should not ride a bicycle, climb or take part in hazardous activity if the child has symptoms like drowsiness or dizziness with Kigabeq. Visual disorders, which can affect the ability to cycle, climb or take part in hazardous activity, have occurred in some patients taking this medicine.

3. How to give Kigabeq

Always give this medicine to your child exactly as the doctor has told you. Check with the doctor or pharmacist if you are not sure.

Dose

Never change the dose yourself. The doctor works out the dose individually for your child, taking account of the child's body weight.

Kigabeq is available as 100 mg or 500 mg tablets which can be given together to make up the right dose for your child. Always check the label and the size of the tablets to make sure you are giving the right dose.

In infantile spasms (West's Syndrome), the recommended starting dose is 50 milligrams per kilogram bodyweight daily. In resistant partial epilepsy (focal onset seizures), the recommended starting dose is 40 milligrams per kilogram daily. The doctor will adjust the dose during treatment as necessary. If your child has kidney problems, the doctor may prescribe a smaller dose.

The following table gives the number of Kigabeq tablets to give to your child according to the dose prescribed by your child's doctor.

Dose (mg per day)	Number of tablets (strength) Morning	Number of tablets (strength) Evening
150	Half a tablet (100 mg)	One tablet (100 mg)
200	One tablet (100 mg)	One tablet (100 mg)
250	One tablet (100 mg)	One and a half tablets (100 mg)
300	One and a half tablets (100 mg)	One and a half tablets (100 mg)
350	One and a half tablets (100 mg)	Two tablets (100 mg)
400	Two tablets (100 mg)	Two tablets (100 mg)
450	Two tablets (100 mg)	Two and a half tablets (100 mg)
500	Half a tablet (500 mg) or two and a half tablets (100 mg)	Half a tablet (500 mg) or two and a half tablets (100 mg)
550	Two and a half tablets (100 mg)	Three tablets (100 mg)
600	Three tablets (100 mg)	Three tablets (100 mg)
650	Three tablets (100 mg)	Three and a half tablets (100 mg)
700	Three and a half tablets (100 mg)	Three and a half tablets (100 mg)
750	Half a tablet (500 mg)	One tablet (500 mg)
800	Four tablets (100 mg)	Four tablets (100 mg)
850	Four tablets (100 mg)	Four and a half tablets (100 mg)
900	Four and a half tablets (100 mg)	Four and a half tablets (100 mg)
950	Four and a half tablets (100 mg)	One tablet (500 mg)
1000	One tablet (500 mg)	One tablet (500 mg)
1100	One tablet (500 mg)	One tablet (500 mg) and one tablet (100 mg)
1200	One tablet (500 mg) and one tablet (100 mg)	One tablet (500 mg) and one tablet (100 mg)
1300	One tablet (500 mg) and one tablet (100 mg)	One tablet (500 mg) and two tablets (100 mg)
1400	One tablet (500 mg) and two tablets (100 mg)	One tablet (500 mg) and two tablets (100 mg)
1500	One and a half tablets (500 mg)	One and a half tablets (500 mg)

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How to give this medicine?

Ask your child's doctor to show you how to give this medicine. Check with the doctor or pharmacist if you are not sure. Kigabeq is to be given by mouth and may be taken before or after meals. The tablet can be cut into equal halves.

Use only water to prepare solution.

- Pour one or two teaspoonfuls (about 5 to 10 ml) of water into a drinking glass or beaker
- Add the right dose of Kigabeq tablets (as whole or half tablets) to the water
- Wait until the tablet has broken down completely. This takes less than a minute but you can speed it up by stirring the mixture gently by hand
- The mixture will be whitish and cloudy. This is normal and the cloudiness is because the tablet contains some non-active ingredients that do not dissolve completely
- Give the mixture straightway to your child direct from the drinking glass or beaker
- If your child cannot drink from the glass or beaker then you can use an oral syringe to gently squirt the mixture into your child's mouth, taking care not to cause choking: sit just in front and below your child in order that he/she has the head leaning forward and administer the mixture against his cheek
- Rinse the glass or beaker with one or two teaspoonfuls (about 5 to 10 ml) of water and give this to your child to make sure that the child receives all the medicine
- If the child cannot swallow, the mixture can be given through a gastric tube, using a suitable syringe. The tube should be rinsed with 10 ml of water

If your child takes too much Kigabeq

If your child accidentally takes too many Kigabeq tablets, tell the doctor immediately or go to your nearest hospital or poison information centre. Possible signs of overdose include drowsiness or reduced level of consciousness.

If you forget to give your child Kigabeq

If you forget to give your child a dose, give the dose as soon as you remember. If it is almost time for the next dose, just give one dose. Do not give a double dose to make up for a forgotten tablet.

If you stop giving Kigabeq to your child

Do not stop giving this medicine without talking to your child's doctor. If the doctor decides to stop the treatment you will be advised to gradually reduce the dose. Do not stop suddenly as this may cause your child's seizures to occur again.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some patients may have more seizures (fits) whilst taking Kigabeq. If this happens, contact your child's doctor immediately.

Serious side effects

Get medical advice immediately if your child has the following: Very common side effects (may affect more than 1 in 10 people)

- Visual field changes – About 33 out of 100 patients treated with vigabatrin 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. The changes in the visual field may be permanent, so it is important to detect them early to avoid progression. If your child has visual disturbances, contact your child's doctor or hospital immediately.

Other side effects include:

Very common side effects (may affect more than 1 in 10 people)

- excitation or restlessness
- 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)
- reduced concentration and memory
- psychological problems including agitation, aggression, nervousness, irritability, depression, thought disturbance, feeling suspicious without reason (paranoia) and insomnia. These side effects usually stop when vigabatrin doses are reduced or the medicine is gradually discontinued. However, do not decrease the dose without first talking to your child's doctor. Contact the doctor if your child has these psychological effects
- nausea (feeling sick), vomiting and abdominal pain
- blurred vision, double vision and uncontrolled movement of the eye, which may cause dizziness
- 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 or fumbling
- more severe psychological problems such as feeling elated or over-excited, which causes unusual behaviour, and feeling detached from reality
- 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 your child has these symptoms, you should tell his/her doctor immediately
 - hives or nettle rash
 - marked sedation (sleepiness), stupor and confusion (encephalopathy). These side effects usually stop when doses are reduced or the medicine is gradually discontinued. However, do not decrease the dose without first talking to your child's doctor. Contact the doctor if your child has these effects
 - suicide attempt
 - other eye problems such as retinal disorder, causing, for example, poor vision at night and difficulty adjusting from bright to dim areas, sudden or unexplained loss of vision, sensitivity to light
- Very rare side effects (may affect up to 1 in 10,000 people)
- other eye problems such as pain in eyes (optic neuritis) and loss of vision, including colour vision (optic atrophy)
 - hallucinations (feeling, seeing or hearing things that are not there)
 - liver problems

Not known (frequency cannot be estimated from the available data)

- movement disorders and abnormalities in magnetic resonance imaging (MRI) brain scans in young infants treated for infantile spasms
- swelling in the protective layer of nerve cells in part of the brain as observed in MRI pictures, particularly in infants
- decreased sharpness of vision

Reporting of side effects

If your child gets any side effects, talk to your child's doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 Kigabeq?

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 carton and the bottle. The expiry date refers to the last day of that month. This medicine should be used within 100 days after first opening.

This medicinal product does not require any special storage conditions. The solution should be administered immediately after preparation. Do not throw away any medicines via wastewater 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 Kigabeq contains

- The active substance is vigabatrin.
- One soluble tablet of Kigabeq 100 mg contains 100 mg vigabatrin
- One soluble tablet of Kigabeq 500 mg contains 500 mg vigabatrin
- The other ingredients are: crospovidone type B, mannitol, sodium stearyl fumarate

What Kigabeq looks like and contents of the pack

Kigabeq are white oval scored soluble tablets.

100 mg tablet size: 9.4 mm x 5.3 mm

500 mg tablet size: 16.0 mm x 9.0 mm

The solution in water is whitish and cloudy.

Pack sizes:

Kigabeq 100 mg is supplied in packs of 100 soluble tablets.

Kigabeq 500 mg is supplied in packs of 50 soluble tablets

Marketing Authorisation Holder

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60000 Beauvais - France

Distributed by

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Other sources of information

Detailed information on this medicine is available on MHRA and EMA websites:

<https://products.mhra.gov.uk/> - <http://www.ema.europa.eu>

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