

## **Package leaflet: Information for the patient**

**Gabapentin Athlone 100mg Capsules**  
**Gabapentin Athlone 300mg Capsules**  
**Gabapentin Athlone 400mg Capsules**

**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 or pharmacist
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet**

1. What gabapentin is and what it is used for
2. What you need to know before you take gabapentin
3. How to take gabapentin
4. Possible side-effects
5. How to store gabapentin
6. Contents of the pack and other information

## **1. What Gabapentin is and what it is used for**

Gabapentin is used as an anticonvulsant for the treatment of various types of epilepsy. It is used to reduce the risk of an epileptic fit or to stop one that is in progress.

Anticonvulsant drugs stop the excessive electrical activity in your brain which is causing epileptic fits. You should take gabapentin in addition to your current treatment unless your doctor tells you otherwise. It can also be used on its own to treat adults and children over 12 years of age.

Gabapentin belongs to a group of medicines used to treat chronic (long lasting) pain caused by damage to the nerves. This pain is known as peripheral neuropathic pain. Peripheral neuropathic pain is caused by a variety of diseases such as diabetes, shingles, trauma or diseases of the nervous system. Pain sensations may be described as hot, burning, throbbing, shooting, stabbing, sharp, cramping, aching, tingling, pins and needles etc.

Your doctor will have explained the reason for prescribing gabapentin capsules to you.

## **2. What you need to know before you take gabapentin**

### **Do not take Gabapentin if:**

- you have had an allergic reaction or are allergic to gabapentin or similar medicines or to any of the ingredients ( listed in section 6)

### **Warnings and precautions**

#### **Talk to your doctor or pharmacist before taking Gabapentin**

- you suffer from kidney problems
- you develop signs such as persistent stomach pain, feeling sick and being sick. Contact your doctor immediately if you develop any of these signs.
- you are taking any other medicines apart from your current epilepsy or neuropathic pain relief.
- you have had thoughts of harming or killing yourself. If at any time you have these thoughts, immediately contact your doctor.

Cases of abuse and dependence have been reported for gabapentin from the post-marketing experience. Talk to your doctor if you have a history of abuse or dependence.

### **Children**

Use of gabapentin is not recommended in children under 6 years of age.

### **Patients with a history of psychosis**

Check with your doctor or pharmacist before taking gabapentin, if you suffer from hallucinations, thought disorders, nervousness or anxiety.

### **Other medicines and Gabapentin**

Tell your doctor or pharmacist if you are taking, have recently taken or might to take any other medicines, including herbal remedies and those you have obtained without a prescription.

- antacids containing aluminium and magnesium may cause decreased absorption of gabapentin from the stomach. It is therefore recommended that gabapentin is taken about two hours after any antacid administration.
- Gabapentin is not expected to interact with other anti-epileptic drugs or the oral contraceptive pill.
- If you require an operation or visit to your doctor or dentist, always let them know if you are taking gabapentin.
- Gabapentin may interfere with some laboratory tests, if you require a urine test tell your doctor or hospital that you are taking gabapentin
- Medicines containing morphine may increase the effect of gabapentin capsules.

### **Gabapentin with food and drink**

Food has no effect on the absorption or efficacy of Gabapentin

### **Pregnancy and breast-feeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine. This medicine should ONLY be used while pregnant/breast-feeding if clearly justified and directed by the treating physician.

### **Driving and using machines**

Gabapentin can cause dizziness, drowsiness and tiredness. If affected you should not drive or operate machinery

### **Gabapentin contains lactose.**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## **3. How to take Gabapentin**

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

- Your doctor will determine the dose that is appropriate for you.
- If you feel the dose is too strong or too weak for you, talk to your doctor or pharmacist.
- Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.
- Always swallow the capsules whole with plenty of water.

### **The recommended dose is**

#### **Epilepsy**

##### **Adults and children over 12 years:**

900 – 3600mg daily in three divided doses i.e. in the morning, in the middle of the day and in the

evening. The maximum time between two successive doses should not exceed 12 hours in a three times daily schedule. Gabapentin can be taken with or without food.

### **Elderly**

Elderly patients may require dosage adjustment by their doctor. If you have problems with your kidneys, speak to your doctor before taking this medicine.

### **Children 6-12 years of age**

The recommended dose of gabapentin is 25 to 35 mg/Kg/day given in three divided doses i.e. one in the morning, one in the middle of the day and one in the evening. You should always follow your doctors instructions.

### **Neuropathic pain**

#### **Adults (over 18 years of age)**

Your doctor will usually build up your dose by starting you on 300mg once a day on day one, 300mg twice a day on day two and 300mg three times a day on day three. The dose may be increased to 3600mg each day given in three divided doses, i.e. in the morning, in the middle of the day and in the evening. Gabapentin can be taken with or without food.

If you think gabapentin is causing problems or alternatively if you experience complete pain relief please talk to your doctor or pharmacist straight away.

Keep taking your capsules for as long as your doctor has asked you to.

### **If you take more Gabapentin than you should**

If you accidentally take too many capsules, tell your doctor immediately, or go to your nearest hospital casualty department as soon as possible. Take the pack with you so that the hospital can easily tell what medicine you have taken. Symptoms of an overdose can include dizziness, double vision, slurred speech, drowsiness, loss of consciousness, lethargy and mild diarrhoea.

### **If you forget to take Gabapentin**

If you miss a dose, just take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Gabapentin**

Do not stop taking your medicine unless your doctor tells you to. Stopping your medicine without asking your doctor's advice could put you at risk of rebound epilepsy, an epileptic seizure or recurring seizures, if you are taking this medication for epilepsy.

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

## **4. Possible Side Effects**

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

**Tell your doctor immediately** if you experience any of the following symptoms after taking this medicine. Although they are very rare, these symptoms can be serious.

- Severe skin reactions, swelling of the lips and face, skin rash and redness and hair loss (these may be symptoms of a serious allergic reaction).
- persistent stomach pain, feeling sick and being sick (these may be symptoms of acute pancreatitis-swelling of your pancreas).
- Serious or life-threatening allergic reaction that may affect parts of your body such as liver or blood cells and skin. You may or may not have a rash when you get this type of a reaction. Notify your doctor if you have any of the following symptoms:

- skin rash

- hives
- fever
- swollen glands
- swelling of the lip and tongue
- bruising or bleeding that is unusual
- yellowing of the skin or of the whites of the eyes
- severe fatigue or weakness
- unexpected muscle pain
- frequent infection

**These symptoms may be the first signs of a serious reaction. A doctor should examine you to decide if you should continue taking Gabapentin**

Other side effects include:

**Very common side effects** (affect more than one person in 10)

- Viral infection
- Feeling drowsy, dizziness, lack of coordination
- Feeling tired, fever

**Common side effects** (affects more than one person in 100)

- Pneumonia, respiratory infection, urinary tract infection, inflammation of the ear
- Low white blood cell count, decrease in white blood cells
- Anorexia (loss of appetite), increased appetite, increase in weight
- Anger towards others, confusion, fluctuation in mood, depression, anxiety, nervousness, difficulty with thinking.
- Convulsions, jerky movements, tremor, difficulty with co-ordination
- Difficulty with speaking
- Difficulty sleeping, headache, loss of memory
- Sensitive skin, pins and needles, decreased sensation
- Increased, decreased or absent reflexes.
- Blurred vision, double vision, unusual eye movement
- Vertigo (a sensation of spinning)
- High blood pressure, flushing or dilation of blood vessels
- Difficulty breathing, bronchitis, sore throat, cough, dry or runny nose
- Vomiting (being sick), nausea (feeling sick), problems with teeth, inflamed gums, diarrhoea, stomach pain, indigestion, constipation, dry mouth or throat, flatulence
- Facial swelling, bruises, rash, itch, acne
- Joint pain, muscle pain, back pain, twitching
- Difficulties with erection
- Swelling in the legs and arms, difficulty with walking, weakness, pain, feeling unwell, flu-like symptoms
- Accidental injury, fracture, abrasion

**Uncommon side-effects** (affects more than 1 person in 1000)

- Decreased movement
- Swelling that may involve the face, trunk and limbs
- Allergic reaction such as hives
- Fall
- abnormal blood test results suggesting problems with the liver or increases in blood creatine phosphokinase
- Racing heartbeat
- Mental impairment

- Increase in blood glucose levels (most often observed in patients with diabetes)

#### **Rare**

- Loss of consciousness
- Decrease in blood glucose levels (most often observed in patients with diabetes)

#### **Frequency of the following adverse reaction is unknown**

- Ringing in the ears
- Inflammation of the pancreas
- Inflammation of the liver, yellowing of the skin and eyes
- Hallucinations
- Problems with abnormal movements such as writhing, jerking movements and stiffness
- Acute kidney failure
- Incontinence
- Increased breast tissue, breast enlargement
- Sexual dysfunction (including changes in your libido, ejaculation disorders and inability to orgasm)
- decreased in blood sodium levels
- Blood glucose fluctuations in patients with diabetes
- Adverse events following the abrupt discontinuation of gabapentin, anxiety, difficulty sleeping, feeling sick, pain, sweating, chest pain
- Side effects occurring together that may include swollen lymph nodes (isolated small raised lumps under the skin), fever, rash and inflammation of the liver
- Decreased platelets (blood clotting cells)
- Muscle damage and twitching
- Breakdown of muscle fibers (rhabdomyolysis)

Additionally in clinical studies in children, aggressive behaviour and jerky movements were reported commonly. Do not be alarmed by this list of side effects, most people take gabapentin without any problems.

#### **Reporting of side effects**

If you get any side effects, talk to your 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](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Gabapentin**

#### **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**

Do not use this after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

Do not throw away any medications via waste water or house hold 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 Gabapentin Athlone looks like and contents of the pack**

The name of your medicine is Gabapentin Athlone. Gabapentin Athlone hard capsules are available in three strengths:

Gabapentin Athlone 100mg Capsules are opaque white hard gelatin capsules marked with GABA 100mg.

Gabapentin Athlone 300mg Capsules are opaque yellow hard gelatin capsules marked with GABA 300mg.

Gabapentin Athlone 400mg Capsules are opaque orange hard gelatin capsules marked with GABA 400mg.

Gabapentin Athlone Capsules also contain the inactive ingredients: lactose monohydrate, maize starch, talc and gelatin.

The 100mg capsules contain the colouring titanium dioxide (E171)

The 300mg capsules contain the colourings titanium dioxide (E171) and yellow iron oxide (E172)

The 400mg capsules contain the colourings titanium dioxide (E171), red iron oxide (E172) and yellow iron oxide (E172).

The printing ink contains: shellac, black iron oxide (E172), soya lecithin and antifoam.

Gabapentin Athlone Capsules are available in blister packs containing 100 capsules, with each blister strip containing 10 capsules.

**Marketing authorisation holder and manufacturer**

Athlone Pharmaceuticals Limited, Ballymurray, Co. Roscommon, Ireland

**Distributed by:**

Kent Pharmaceuticals Limited, Wotton Road, Ashford, Kent, TN23 6LL, U.K.

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