Gabapentin Mylan 600 mg
Gabapentin Mylan 800 mg
Tablets
7505xxxx

Gabapentin Mylan 600 mg
Gabapentin Mylan 800 mg
Tablets
7505xxxx

Package Leaflet: Information for the patient

Gabapentin Mylan 600 mg Tablets
Gabapentin Mylan 800 mg Tablets

(gabapentin)

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

1. What Gabapentin Mylan is and what it is used for

Gabapentin belongs to a group of medicines used to treat epilepsy and peripheral neuropathic pain (long lasting pain caused by damage to the nerves).

The active ingredient in Gabapentin Mylan is gabapentin.

Epilepsy: Gabapentin Mylan is used to treat various forms of epilepsy (seizures that are initially limited to certain parts of the brain, whether the seizure spreads to other parts of the brain or not). Your doctor will prescribe this medicine for you to help treat your epilepsy when your current treatment is not fully controlling your condition. You should take Gabapentin Mylan in addition to your current treatment unless told otherwise. Gabapentin Mylan can also be used on its own to treat adults and children over 12 years of age.

Peripheral neuropathic pain: Gabapentin Mylan is used to treat long lasting pain caused by damage to the nerves. A variety of different diseases can cause peripheral (primarily occurring in the legs and/or arms) neuropathic pain, such as diabetes or shingles. Pain sensations may be described as hot, burning, throbbing, shooting, stabbing, sharp, cramping, aching, tingling, numbness, pins and needles etc.

2. What you need to know before you take Gabapentin Mylan

Do not take Gabapentin Mylan:
- if you are allergic to gabapentin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Gabapentin Mylan:
- if you suffer from kidney problems - your doctor may prescribe a different dosing schedule
- if you are on haemodialysis (to remove waste products because of kidney failure) - tell your doctor if you develop muscle pain and/or weakness.

Cases of abuse and dependence have been reported for gabapentin. Talk to your doctor if you have a history of abuse or dependence.

During treatment
If you develop signs such as persistent stomach pain, feeling sick and being sick contact your doctor immediately as these may be signs of acute pancreatitis (an inflamed pancreas).

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

Increase in seizures or new types of seizure have been seen in some people taking gabapentin. Talk to your doctor or pharmacist if you notice a change to your condition.

If you experience any signs such as feeling dizzy and drowsy (which could increase accidental injury), confusion, loss of consciousness and reduced mental state while taking gabapentin, talk to you doctor or pharmacist for advice.

Important information about potentially serious reactions
A small number of people taking gabapentin get an allergic reaction or potentially serious skin reaction, which may develop into more serious problems if they are not treated. You need to know the signs to look out for while you are taking this medicine.

Read the description of these signs in section 4 of this leaflet under 'Stop taking this medicine and contact your doctor **immediately** or go to the nearest hospital casualty department straight away if you experience any of the following signs after taking this medicine as they can be serious'.

Other medicines and Gabapentin
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Medicine containing opioids such as morphine
If you are taking any medicines containing opioids (such as morphine), please tell your doctor or pharmacist as opioids may increase the effect of gabapentin. In addition, combination of gabapentin with opioids may cause symptoms like sleepiness and/or decrease in breathing.

Antacids for indigestion
If gabapentin and antacids containing aluminium and magnesium are taken at the same time, absorption of gabapentin from the stomach may be reduced. It is therefore recommended that Gabapentin Mylan is taken at least two hours after taking an antacid.

This medicine:
- is not expected to interact with other antiepileptic medicines or oral contraceptive pills containing norethindrone or ethinyl estradiol
- may interfere with some laboratory tests - if you require a urine test tell your doctor or hospital what you are taking.

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.

Pregnancy
Gabapentin Mylan should not be taken during pregnancy, unless you are told otherwise by your doctor. Effective contraception must be used by women of child-bearing potential.

There have been no studies specifically looking at the use of gabapentin in pregnant women, but other medications used to treat seizures have reported an increased risk of harm to the developing baby (foetus), particularly when more than one seizure medication is taken at the same time. Therefore, whenever possible and only under advice of your doctor, you should try to take only one seizure medication during pregnancy.

Do not suddenly stop taking this medicine as this may lead to breakthrough seizure, which could have serious consequences for you and your baby.

Breast-feeding
Gabapentin passes into human milk. Because the effect on the nursing newborn is unknown, it is not recommended to breast-feed your baby while taking this medicine.

Driving and using machines
Gabapentin Mylan may cause dizziness, drowsiness and tiredness. You should not drive, operate machinery or engage in other potentially hazardous activities until you know whether this medication affects your ability to perform these activities.

3. How to take Gabapentin Mylan

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

Your doctor will determine what dose is appropriate for you.

If you have the impression that the effect of Gabapentin Mylan is too strong or too weak, talk to your doctor or pharmacist.

Peripheral Neuropathic Pain:

Adults:
Take the number of tablets as instructed by your doctor. Your doctor will usually build up your dose gradually.
The recommended starting dose will generally be between 300 mg and 900 mg each day. Thereafter, the dose may be increased stepwise up to a maximum of 3600 mg each day and your doctor will tell you to take this in 3 divided doses, i.e. once in the morning, once in the afternoon and once in the evening.

Epilepsy:

Use in adults and adolescents:
Take the number of tablets as instructed. Your doctor will usually build up your dose gradually. The starting dose will generally be between 300 mg and 900 mg each day. Thereafter, the dose may be increased stepwise up to a maximum of 3600 mg each day and your doctor will tell you to take this in 3 divided doses, i.e. once in the morning, once in the afternoon and once in the evening.

Use in children aged 6 years and above:
The dose to be given to your child will be decided by your doctor as it is calculated against the child's weight. The treatment is started with a low initial dose, which is gradually increased over a period of approximately 3 days.
The recommended dose to control epilepsy is 25-35 mg/kg/day. It is usually given in 3 divided doses, by taking the tablets each day, usually once in the morning, once in the afternoon and once in the evening.

Gabapentin is not recommended for use in children below 6 years of age.

Older patients
If you are an elderly patient (over 65 years of age), you should take this medicine normally except if you have problems with your kidneys.

If you have kidney problems or are receiving haemodialysis
Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys or are undergoing haemodialysis.

Method and route of administration
Gabapentin Mylan is for oral use.

You should swallow the tablets whole with plenty of water. The tablet can be divided into equal doses.

This medicine may be taken with or without food.

Continue taking this medicine until your doctor tells you to stop.

If you take more Gabapentin Mylan than you should
If you or someone else accidentally takes too many tablets, or if you think a child has swallowed any, contact your doctor or go to your nearest hospital emergency department immediately. Take along any tablets that are left, the container and the label so that the hospital can easily tell what medicine you have taken. Signs of an overdose include dizziness, double vision, slurred speech, loss of consciousness, drowsiness and mild diarrhoea.

If you forget to take Gabapentin Mylan
If you forget to take a dose, 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 tablet.

Description	Gabapentin 600 mg,800 mg all			Date: 24 JAN 2017		Time: 10:59	
Component Type	Leaflet	Pharma Code	TBC	No. of colours	1	Page Count	1/2
Affiliate Item Code	1088311	SAP No.	NA	Colours	Black		
Superceded Affiliate Item Code	745305	Vendor Job No.	300432				
TrackWise PR No.	1088311	Trackwise Proof No.	3	Non-Print Colours	Codes		
MA No.	NA	Client Market	United Kingdom	Equate CMYK with			
Packing Site/Printer	NA	Keyline/Drawing No.	NA				
Supplier Code	NA	Barcode Info	NA	Main Font	Myriad Pro	Body Text Size	10.5 pt
				Dimensions	272 x 400 mm	Min Text Size used	9 pt
Sign-offs							
							v2/Oct 2016

If you stop taking Gabapentin Mylan
Do not stop taking this medicine unless your doctor tells you to. If your treatment is stopped it should be done gradually over a minimum of 1 week. If you stop taking gabapentin suddenly or before your doctor tells you, there is an increased risk of seizures.

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.

Stop taking this medicine and contact your doctor immediately or go to the nearest hospital casualty department straight away if you experience any of the following signs after taking this medicine as they can be serious:

Common (may affect up to 1 in 10 people):
- serious chest infection which may cause fever, chills, shortness of breath, cough, phlegm and occasionally blood (pneumonia)
- fits (convulsions).

Not known (frequency cannot be estimated from the available data):
- anaphylaxis (serious, potentially life threatening allergic reaction including difficulty breathing, swelling of the lips, throat, and tongue, and hypotension requiring emergency treatment)
- severe skin reactions that require immediate attention such as swelling of the lips and face, skin rash and redness (these may be signs of a serious allergic reaction)
- persistent stomach pain that spreads to the back, feeling sick and being sick as these may be signs of acute pancreatitis (an inflamed pancreas)
- potentially life-threatening skin rashes (Stevens-Johnson syndrome) appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). The rash may progress to widespread blistering or peeling of the skin
- a severe condition of the skin (Erythema multiforme) that may affect the mouth and other parts of the body signs include red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body. The spots may blister or may progress to form raised, red, pale-centred marks. Those affected may have fever, sore throat, headache and/or diarrhoea
- kidney disease leading to passing less urine than usual, feeling or being sick, or confused (acute kidney failure)
- destruction of muscle fibres associated with muscle cramps, muscle pain, fever and red-brown discoloration of the urine (rhabdomyolysis).

  Gabapentin may cause a serious or life-threatening allergic reaction that may affect your skin or other parts of your body such as your liver or blood cells. You may or may not have rash when you get this type of reaction. It may cause you to be hospitalised or to stop this medicine.

  Call your doctor right away if you have any of the following signs:
  - skin rash
  - itchy, lumpy, skin rash (hives)
  - fever
  - swollen glands that do not go away
  - swelling of your lip and tongue
  - yellowing of your skin or of the whites of the eyes
  - unusual bruising or bleeding
  - severe fatigue or weakness
  - unexpected muscle pain
  - frequent infections.

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

Other possible side effects
Very common (may affect more than 1 in 10 people):
- viral infection
- feeling drowsy, dizziness, lack of coordination
- feeling tired.

Common (may affect up to 1 in 10 people):
- urinary tract infection, inflammation of the ear or other infections
- loss of appetite, increased appetite
- anger towards others, confusion, mood swings, depression, anxiety, nervousness, difficulty with thinking
- jerky movements, difficulty with speaking, loss of memory, shaking, difficulty sleeping, headache, numbness, tingling or pins and needles, decreased sensation, difficulty with coordination
- rapid unusual eye movement, increased, decreased or absent reflexes
- blurred vision, double vision
- spinning sensation (vertigo)
- high blood pressure, flushing or dilation of blood vessels
- shortness of breath, chest infection (bronchitis), sore throat and discomfort when swallowing, cough, runny or blocked nose
- vomiting (being sick), nausea (feeling sick), problems with teeth, inflamed gums, diarrhoea, stomach pains, indigestion, constipation, dry mouth or throat, wind
- facial swelling, bruises, acne
- joint pain, muscle pain, back pain, twitching
- difficulty getting or maintaining an erection
- swelling in the legs and arms, difficulty with walking, pain, generally feeling unwell, flu-like symptoms
- increase in weight
- accidental injuries, such as broken bones, scratches or bruises.

Uncommon (may affect up to 1 in 100 people):
- unusually reduced or slow body movement
- racing heartbeat
- swelling that may involve the trunk
- abnormal blood test results suggesting problems with the liver
- fall
- difficulty with thinking
- high blood sugar (most often observed in patients with diabetes)
- agitation (a state of chronic restlessness and unintentional and purposeless motions).

Rare (may affect up to 1 in 1,000 people):
- low blood sugar (most often observed in patients with diabetes
- loss of consciousness.

Not known (frequency cannot be estimated from the available data):
- sensing things that are not real (hallucinations)
- problems with abnormal movements such as writhing, jerking movements and stiffness affecting the eyes, head, neck and body
- ringing in the ears
- hair loss
- problems with sexual functioning including changes in sex drive, inability to reach a sexual climax, delayed ejaculation
- uncontrolled passing of urine
- increased breast tissue, breast enlargement in males
- signs of withdrawal (anxiety, difficulty sleeping, feeling sick, pain, sweating), chest pain
- change in blood test results (increase in creatine phosphokinase)
- low levels of sodium in the blood.

Additional side effects in children
Aggressive behaviour was commonly reported.

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 at: 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 Mylan

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 after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

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 Gabapentin Mylan contains:
- The active substance is gabapentin.
- Each tablet contains 600 mg gabapentin.
- Each tablet contains 800 mg gabapentin.
- The other ingredients are hydroxypropylcellulose, mannitol, poloxamer, crospovidone, talc, magnesium stearate

What Gabapentin Mylan look like and contents of the pack
Gabapentin Mylan 600 mg Tablets: White to off-white, oval, biconvex, uncoated, beveled edged tablets debossed with "MYLAN" on one side and "G" to the left of the score and "24" to the right of the score on the other side.

Gabapentin Mylan 800 mg Tablets: White to off-white, oval, biconvex, uncoated, beveled edged tablets debossed with "MYLAN" on one side and "G" to the left of the score and "25" to the right of the score on the other side.

Packs of 20, 30, 45, 50, 90 and 100 tablets are packed in white opaque HDPE bottle with white opaque polypropylene (PP) cap containing desiccant (silica gel).

Packs of 20, 30, 45, 50, 60, 90, 100, 200, 250 and 500 are packed in OPA/Al/PVC blister.

Packs of 90 x 1 and 500 x 1 tablets are supplied as OPA/Al/PVC perforated unit dose blister.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturers:
Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland
Mylan Hungary Kft, H-2900 Komárom, Mylan utca 1, Hungary

This leaflet was last revised in January 2017

CODE No.: MH/DRUGS/25/NKD/89 1088311

Description	Gabapentin 600 mg,800 mg all			Date: 24 JAN 2017		Time: 10:59	
Component Type	Leaflet	Pharma Code	TBC	No. of colours	1	Page Count	2/2
Affiliate Item Code	1088311	SAP No.	NA	Colours	Black		
Superceded Affiliate Item Code	745305	Vendor Job No.	300432				
TrackWise PR No.	1088311	Trackwise Proof No.	3	Non-Print Colours	Codes		
MA No.	NA	Client Market	United Kingdom	Equate CMYK with			
Packing Site/Printer	NA	Keyline/Drawing No.	NA				
Supplier Code	NA	Barcode Info	NA	Main Font	Myriad Pro	Body Text Size	10.5 pt
				Dimensions	272 x 400 mm	Min Text Size used	9 pt
Sign-offs							
							v2/Oct 2016