Patient Information Leaflet (PIL)
GABANET® 100 mg, 300 mg and 400 mg Hard Capsules
Gabapentin

Read all of this leaflet carefully before you start taking this medicine
□ Keep this leaflet. You may need to read it again.
□ If you have any further questions, ask your doctor or your pharmacist.
□ This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
□ If any of the side effects gets serious or if you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What **GABANET** is and what it is used for
2. Before you take **GABANET**
3. How to take **GABANET**
4. Possible side effects
5. How to store **GABANET**
6. Further information.

1. WHAT GABANET IS AND WHAT IT IS USED FOR

GABANET 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 **GABANET** is Gabapentin.
GABANET is used to treat: □ Epilepsy Gabapentin is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and children aged 6 years and above. Gabapentin is indicated as monotherapy in the treatment of partial seizures with and without secondary generalization in adults and adolescents aged 12 years and above.
□ Treatment of peripheral neuropathic pain
Gabapentin is indicated for the treatment of peripheral neuropathic pain such as painful diabetic neuropathy and post-herpetic neuralgia in adults.

2. BEFORE YOU TAKE GABANET

Do not take GABANET if:
□ You are allergic (hypersensitive) to Gabapentin or any of the other ingredients of **GABANET** (Listed in section 6).

Take special care with GABANET:
Talk to your doctor or pharmacist before taking GABANET if:
□ You suffer from kidney problems your doctor may prescribe a different dosing schedule.
□ You are on haemodialysis (to remove waste products because of kidney failure), tell your doctor if you develop muscle pain and/or weakness.
□ You develop signs such as persistent stomach pain, feeling sick and being sick contact your doctor immediately as these may be symptoms of acute pancreatitis (an inflamed pancreas).
□ You have nervous system disorders, respiratory disorders, or you are more than 65 years old, your doctor may prescribe you a different dosing regimen.
□ Gabapentin is associated with respiratory depression without concomitant opioid use.
□ Gabapentin has been associated with severe respiratory depression. Patients with compromised respiratory function, respitatory or neurological disease, renal impairment, concomitant use of CNS depressants and the elderly might be at higher risk of experiencing this severe adverse reaction. Dose adjustment might be necessary in these patients. 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. A small number of people being treated with anti-epileptics such as gabapentin have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
Important information about potentially serious reactions:
A small number of people taking **GABANET** 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 these symptoms to look out for while you are taking **GABANET**.
Read the description of these symptoms in section 4 of this leaflet under 'Contact your doctor immediately if you experience any of the following symptoms after taking this medicine as they can be serious'
Muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown which can be life-threatening and lead to kidney problems. You may also experience discoloration of your urine, and a change in blood test results (notably blood creatine phosphokinase increased). If you experience any of these signs or symptoms, please contact your doctor immediately.
Serious breathing difficulties may occur in patients using gabapentin or pregabalin who have respiratory risk factors. These include use of opioid pain medicines and other drugs that depress the central nervous system, and conditions such as chronic obstructive pulmonary disease that reduce lung function. The elderly are also at higher risk.

Taking other medicines with GABANET:
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. In particular, tell your doctor (or pharmacist) if you are taking or have been recently taking any medicines for convulsions, sleeping disorders, depression, anxiety, or any other neurological or psychiatric problems.
□ Medicines containing opioids such as morphine
If you are taking any medicines containing opioids (such as Morphine), please tell your doctor or pharmacist as opioid may increase the effect of **GABANET**. In addition, combination of **GABANET** with opioids may cause symptoms like sleepiness and/or decrease in breathing.
□ Antacids for indigestion
If **GABANET** and antacids containing aluminium and magnesium are taken at the same time, absorption of **GABANET** from the stomach may be reduced. It is therefore recommended that **GABANET** is taken at the earliest two hours after taking an antacid.
GABANET:
□ Is not expected to interact with other antiepileptic drugs or the oral contraceptive pill.
□ May interfere with some laboratory tests, if you require a urine test tell your doctor or hospital what you are taking.

Take GABANET with food:
GABANET can be taken with or without food.

Pregnancy, breast feeding and fertility:
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking **GABANET.**
Pregnancy:
GABANET 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, particularly when more than one seizure medication is taken at the same time. Therefore, whenever possible, you should try to take only one seizure medication during pregnancy and only under the advice of your doctor.
Contact your doctor immediately if you become pregnant, think you might be pregnant or are planning to become pregnant while taking **GABANET.** Do not suddenly discontinue taking this medicine as this may lead to a breakthrough seizure, which could have serious consequences for you and your baby.
Breast feeding**:**
Gabapentin, the active substance of **GABANET**, is passed on through human milk. Because the effect on the baby is unknown, it is not recommended to breast-feed while using **GABANET.**
Fertility
There is no effect on fertility in animal studies.

Driving and using machines:
GABANET may produce dizziness, drowsiness and tiredness. You should not drive, operate complex machinery or take part in other potentially hazardous activities until you know whether this medication affects your ability to perform these activities.

Important information about some of ingredients of GABANET:
GABANET hard capsules contain lactose (a type of sugar). 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 GABANET

GABANET is for oral use. Gabapentin can be given with or without food and should be swallowed whole with sufficient fluid-intake (e.g. a glass of water).
For all indications a titration scheme for the initiation of therapy is described in Table 1, which is recommended for adults and adolescents aged 12 years and above. Dosing instructions for children under 12 years of age are provided under a separate sub-heading later in this section.

Table 1
Dosing chart- initial titration

Day 1	Day 2	Day 3
300 mg once a day	300 mg twice a day	300 mg three times a day

Discontinuation of gabapentin
In accordance with current clinical practice, if gabapentin has to be discontinued it is recommended this should be done gradually over a minimum of 1 week independent of the indication.
Epilepsy
Epilepsy typically requires long-term therapy. Dosage is determined by the treating physician according to individual tolerance and efficacy.
Adults and adolescents:
In clinical trials, the effective dosing range was 900 to 3600 mg/day. Therapy may be initiated by titrating the dose as described in Table 1 or by administering 300 mg three times a day (TID) on Day 1. Thereafter, based on individual patient response and tolerability, the dose can be further increased in 300 mg/day increments every 2-3 days up to a maximum dose of 3600 mg/day. Slower titration of gabapentin dosage may be appropriate for individual patients. The minimum time to reach a dose of 1800 mg/day is one week, to reach 2400 mg/day is a total of 2 weeks, and to reach 3600 mg/day is a total of 3 weeks. The total daily dose should be divided in three single doses, the maximum time interval between the doses should not exceed 12 hours to prevent breakthrough convulsions.
Children aged 6 years and above:
The starting dose should range from 10 to 15 mg/kg/day and the effective dose is reached by upward titration over a period of approximately three days. The effective dose of gabapentin in children aged 6 years and older is 25 to 35 mg/kg/day. Dosages up to 50 mg/kg/day have been well tolerated in a long-term clinical study. The total daily dose should be divided in three single doses, the maximum time interval between doses should not exceed 12 hours.
It is not necessary to monitor gabapentin plasma concentrations to optimize gabapentin therapy. Further, gabapentin may be used in combination with other antiepileptic medicinal products without concern for alteration of the plasma concentrations of gabapentin or serum concentrations of other antiepileptic medicinal products.
Peripheral neuropathic pain
Adults
The therapy may be initiated by titrating the dose as described in Table 1. Alternatively, the starting dose is 900 mg/day given as three equally divided doses. Thereafter, based on individual patient response and tolerability, the dose can be further increased in 300 mg/ day increments every 2-3 days up to a maximum dose of 3600 mg/day. Slower titration of gabapentin dosage may be appropriate for individual patients. The minimum time to reach a dose of 1800 mg/day is one week, to reach 2400 mg/day is a total of 2 weeks, and to reach 3600 mg/day is a total of 3 weeks.
In the treatment of peripheral neuropathic pain such as painful diabetic neuropathy and post-herpetic neuralgia, efficacy and safety have not been examined in clinical studies for treatment periods longer than 5 months. If a patient requires dosing longer than 5 months for the treatment of peripheral neuropathic pain, the treating physician should assess the patient's clinical status and determine the need for additional therapy.
Instruction for all areas of indication
In patients with poor general health, i.e., low body weight, after organ transplantation etc., the dose should be titrated more slowly, either by using smaller dosage strengths or longer intervals between dosage increases.
Use in elderly patients (over 65 years of age)
Elderly patients may require dosage adjustment because of declining renal function with age (see Table 2). Somnolence, peripheral oedema and asthenia may be more frequent in elderly patients.
Use in patients with renal impairment
Dosage adjustment is recommended in patients with compromised renal function as described in Table 2 and/or those undergoing haemodialysis. Gabapentin 100 mg capsules can be used to follow dosing recommendations for patients with renal insufficiency.

Table 2
Dosage of Gabapentin in Adults Based on Renal Function

Creatinine Clearance (ml/min)	Total Daily Dose[a] (mg/day)
80	900 - 3600
50 - 79	600 - 1800
30 - 49	300 - 900
15 - 29	150[b] - 600
<15[c]	150[b] - 300

a Total daily dose should be administered as three divided doses. Reduced dosages are for patients with renal impairment (creatinine clearance < 79 ml/min).
b To be administered as 300 mg every other day.
c For patients with creatinine clearance <15 ml/min, the daily dose should be reduced in proportion to creatinine clearance (e.g., patients with a creatinine clearance of 7.5 ml/min should receive one-half the daily dose that patients with a creatinine clearance of 15 ml/min receive).
Use in patients undergoing haemodialysis
For anuric patients undergoing haemodialysis who have never received gabapentin, a loading dose of 300 to 400 mg, then 200 to 300 mg of gabapentin following each 4 hours of haemodialysis, is recommended. On dialysis-free days, there should be no treatmentwith gabapentin.
For renally impaired patients undergoing haemodialysis, the maintenance dose of gabapentin should be based on the dosing recommendations found in Table 2. In addition to the maintenance dose, an additionnal 200 to 300 mg dose following each 4-hour haemodialysis treatment is recommended.
Method of administration
GABANET is for oral use. Always swallow the capsules with plenty of water. Continue taking **GABANET** until your doctor tells you to stop.
If you take more GABANET than you should:
Higher than recommended doses may result in an increase in side effects including loss of consciousness, dizziness, double vision, slurred speech, drowsiness and diarrhoea. Call your doctor or go to the nearest hospital emergency unit immediately if you take more **GABANET** than your doctor prescribed. Take along any capsules or tablets that you have not taken, together with the container and the label so that the hospital can easily tell what medicine you have taken.
If you forget to take GABANET:
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 dose.
If you stop taking GABANET:
Do not stop taking **GABANET** 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 **GABANET** 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, **GABANET** can cause side effects, although not everybody gets them:
Contact your doctor immediately if you experience any of the following symptoms after taking this medicine as they can be serious:
□ Severe skin reactions that require immediate attention, swelling of the lips and face, skin rash and redness and/or hair loss (these may be symptoms of a serious allergic reaction)
□ Persistent stomach pain, feeling sick and being sick as these may be symptoms of acute pancreatitis (an inflamed pancreas)
□ Breathing problems, which if severe you may need emergency and intensive care to continue breathing normally
□ **GABANET** 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 hospitalized or to stop **GABANET**. Call your doctor right away if you have any of the following symptoms:
□ 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 symptoms may be the first signs of a serious reaction. A doctor should examine you to decide if you should continue taking **GABANET**.
If you are on haemodialysis, tell your doctor if you develop muscle pain and/or weakness.
Other side effects include:
Very common: (may affect more than 1 in 10 people)
□ Viral infection □ Feeling drowsy, dizziness, lack of coordination □ Feeling tired, fever
Common: (may affect up to 1 in 10 people)
□ Pneumonia, respiratory infections, urinary tract infection,inflammation of the ear or other infections
□ Low white blood cell counts □ Anorexia, increased appetite
□ Anger towards others, confusion, mood changes, depression, anxiety, nervousness, difficulty with thinking
□ Convulsions, jerky movements, difficulty with speaking, loss of memory, tremor, difficulty sleeping, headache, sensitive skin, decreased sensation (numbness), difficulty with coordination, unusual eye movement, increased, decreased or absent reflexes
□ Blurred vision, double vision □ Vertigo
□ High blood pressure, flushing or dilation of blood vessels □ Difficulty breathing, bronchitis, sore throat, cough, dry 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 (impotence)
□ Swelling in the legs and arms, difficulty with walking, weakness, pain, feeling unwell, flu-like symptoms
□ Decrease in white blood cells, increase in weight
□ Accidental injury, fracture, abrasion
Additionally in clinical studies in children, aggressive behavior and jerky movements were reported commonly.
Uncommon: (may affect more than 1 in 100 people)
□ Agitation (a state of chronic restlessness and unintentional and purposeless motions)
□ Allergic reactions such as hives
□ Decreased movement □ Racing heartbeat
□ Difficulty swallowing
□ Swelling that may involve the face, trunk and limbs □ Abnormal blood test results suggesting problems with the liver □ Mental impairment □ Fall
□ Increase in blood glucose levels (most often observed in patients with diabetes)
Rare: (may affect up to 1 in 1000 people)
□ Decrease in blood glucose levels (most often observed in patients with diabetes)
□ Loss of consciousness □Trouble breathing, shallow breaths (respiratory depression)
After marketing GABANET the following side-effects have been reported:
□ Decreased platelets (blood clotting cells)
□ Hallucinations
□ Problems with abnormal movements such as writhing, jerking movements and stiffness
□ Ringing in the ears □ A group of side effects that could include swollen lymph nodes (isolated small raised lumps under the skin), fever, rash, and inflammation of liver occurring together
□ Yellowing of the skin and eyes (jaundice), inflammation of the liver □ Acute kidney failure, incontinence
□ Increased breast tissue, breast enlargement
□ Adverse events following the abrupt discontinuation of gabapentin (anxiety, difficulty sleeping, feeling sick, pain, sweating), chest pain
□ Breakdown of muscle fibres (rhabdomyolysis)
□ Change in blood test results (creatine phosphokinase increased) □ Problems with sexual functioning including inability to achieve a sexual climax, delayed ejaculation □ Low blood sodium level □ Anaphylaxis (serious, potentially life threatening allergic reaction including difficulty breathing, swelling of the lips, throat, and tongue, and hypotension requiring emergency treatment)

5. HOW TO STORE GABANET

□ Keep out of the reach and sight of children.
□ Do not store above 30 °C, protected from humidity.
□ Do not use **GABANET** after the expiry date which is stated on the carton and on the blister, after (EXP).Date.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What GABANET contains:
The active substance is Gabapentin. Each **GABANET 100, 300 and 400** hard capsule contains 100mg, 300mg and 400 mg of Gabapentin respectively.
The other ingredients:
□ **GABANET 100:** lactose anhydrous, maize starch, purified talc, empty hard gelatin capsule size (3) white opaque / white opaque.
□ **GABANET 300:** lactose anhydrous, maize starch, purified talc, empty hard gelatin capsule size (1) buff opaque and buff opaque.
□ **GABANET 400:** lactose anhydrous, maize starch, purified talc, empty hard gelatin capsule size (0) orange opaque and orange opaque.

What GABANET looks like and contents of the pack:
□ **GABANET 100** capsules are cylindrical hard gelatin composed of white opaque body printed with 'Gabanet 100®' and white opaque cap filled with white powder.
□ **GABANET 300** capsules are cylindrical hard gelatin composed of buff body printed with 'Gabanet 300®' and buff cap filled with white to off white powder.
□ **GABANET 400** capsules are cylindrical hard gelatin composed of orange body printed with 'Gabanet 400®' and orange cap filled with white to off white powder.
□ Boxes of 48 blistered Capsule of **GABANET 100**.
□ Boxes of 48 blistered Capsule of **GABANET 300.**
□ Boxes of 48 blistered Capsule of **GABANET 400**.

Health care professionals and patients are encouraged to report adverse events or side effects to JFDA by using:
Email: jpc@jfda.jo
Website: www.jfda.jo
Mobile application: (Jordan fda)
Yellow card form.

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THIS IS A MEDICAMENT
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament
- The doctor and the pharmacist are experts in medicine.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicaments out of the reach of children.

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COUNCIL OF ARAB HEALTH MINISTERS UNION OF ARAB PHARMACISTS
Prescribing Information Available Upon Request

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