

## Patient Information Leaflet (PIL)

### Neuroplex® 300 mg Capsules Neuroplex® 400 mg 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 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 this leaflet, please tell your doctor or pharmacist.

#### In this leaflet:

1. What **Neuroplex** is and what it is used for
2. Before you use **Neuroplex**
3. How to take **Neuroplex**
4. Possible side effects
5. How to store **Neuroplex**
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#### 1. What **Neuroplex** is and what it is used for

The name of your medicine is **Neuroplex** 300 mg or 400 mg capsules.

**Neuroplex** belongs to a group of medicines used:

- To treat epilepsy.
- To relieve long lasting pain caused by damage to the nerves (peripheral neuropathic pain).

**To treat epilepsy:** **Neuroplex** is used to treat various forms of epilepsy in adults and children over 6 years old.

Your doctor will prescribe **Neuroplex** if your current treatment is no longer fully controlling your epilepsy.

You should take **Neuroplex** in addition to your current treatment.

If your doctor considers that it is necessary, **Neuroplex** can also be used on its own.

**To relieve peripheral neuropathic pain:** Peripheral neuropathic pain is a long lasting pain caused by damage to the nerves.

A variety of different diseases can cause this type of pain (primarily occurring in the legs and/or arms), such as diabetes (high blood sugar) or shingles (disease caused by the varicella virus). These pains may be felt as hot, burning, throbbing, shooting, stabbing, sharp, cramping, aching, tingling, numbness, pins and needles etc.

**Neuroplex** is used to treat these long lasting pains.

#### 2. Before you take **Neuroplex**

##### Do not take **Neuroplex**

- If you are allergic (hypersensitive) to gabapentin or any of the other ingredients of **Neuroplex**.

##### Warnings and precautions:

##### Respiratory depression:

Gabapentin has been associated with severe respiratory depression. Patients with compromised respiratory function, respiratory 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 adjustments might be necessary in these patients.

##### Take special care with **Neuroplex**

- If you suffer from kidney problems your doctor may prescribe a different dosing schedule.

- If you are on hemodialysis (to remove waste products because of kidney failure), tell your doctor if you develop muscle pain and/or weakness.

If 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).

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 **Neuroplex** 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 **Neuroplex**.

##### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

##### Medicines containing morphine

If you are taking any medicines containing morphine, please tell your doctor or pharmacist as morphine may increase the effect of **Neuroplex**.

##### Antacids for indigestion

If **Neuroplex** and antacids containing aluminium and magnesium are taken at the same time, absorption of **Neuroplex** from the stomach may be reduced. It is therefore recommended that **Neuroplex** is taken at the earliest two hours after taking an antacid.

##### Neuroplex:

- 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.

##### Taking **Neuroplex** with food and drink

**Neuroplex** can be taken with or without food.

##### Pregnancy

**Neuroplex** 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 **Neuroplex**. 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 **Neuroplex**, is passed on through human milk. Because the effect on the baby is unknown, it is not recommended to breast-feed while using **Neuroplex**.

Ask your doctor or pharmacist for advice before taking any medicine.

##### Driving and using machines

**Neuroplex** 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 the ingredients of **Neuroplex**

**Neuroplex** 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 **Neuroplex**

Always take **Neuroplex** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

##### Dosage

Your doctor will determine what dose is appropriate for you.

##### If you take **Neuroplex** to relieve peripheral neuropathic pain:

Take the number of capsules as instructed by your doctor. 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 progressively up to a maximum of 3600 mg each day. Your doctor will tell you to take the dose in 3 divided doses, i.e. once in the morning, once in the afternoon and once in the evening.

##### If you take **Neuroplex** to treat your epilepsy:

##### Adults and adolescents over 12 years old:

Take the number of capsules as instructed by your doctor.

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 progressively up to a maximum of 3600 mg each day. Your doctor will tell you to take the dose in 3 divided doses, i.e. once in the morning, once in the afternoon and once in the evening.

##### Children aged 6 years old and older:

The dose to be given to your child will be decided by your doctor as it is calculated against your child's weight. The treatment is started with a low initial dose which is gradually increased over a period of approximately 3 days.

The usual dose to control epilepsy is 25-35 mg/kg/day.

It is usually given in 3 divided doses, by taking the capsule(s) each day, usually once in the morning, once in the afternoon and once in the evening.

**Neuroplex** is not recommended for use in children under 6 years old.

##### Particular groups of patients

If you have problems with your kidneys (because of a renal failure due to your age or a disease), your doctor may prescribe a different dosing schedule and/or dose.

If you are an elderly patient (over 65 years old), you should take **Neuroplex** as indicated (except if you have problems with your kidneys).

##### Route of administration

Always swallow the capsules whole with plenty of water.

##### Duration of treatment

Continue taking **Neuroplex** until your doctor tells you to stop. You should not stop taking this medicine without medical advice.

##### If you take more **Neuroplex** 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 diarrhea. Call your doctor or go to the nearest hospital emergency unit immediately if you take more **Neuroplex** than your doctor prescribed. Take along any capsules 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 **Neuroplex**

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 **Neuroplex**

Do not stop taking **Neuroplex** 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 **Neuroplex** 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, **Neuroplex** 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).
- **Neuroplex** 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 **Neuroplex**. 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 **Neuroplex**.

If you are on hemodialysis, tell your doctor if you develop muscle pain and/or weakness.

Other side effects include:

##### Very common side effects (which may affect more than 1 person in 10):

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

##### Common side effects (which may affect more than 1 person in 100):

- 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, diarrhea, 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 behaviour and jerky movements were reported commonly.

##### Uncommon side effects (which may affect more than 1 person in a 1000):

- Allergic reactions such as hives.
- Decreased movement.
- Racing heartbeat.
- Swelling that may involve the face, trunk and limbs.
- Abnormal blood test results suggesting problems with the liver.

##### Rare (may affect less than 1 person in 1000):

- Respiratory depression.
- **Since introduction to the market 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).
  - Blood glucose fluctuations in patients with diabetes.

**If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

#### 5. How to store **Neuroplex**

Keep at room temperature (15-30°C).

Do not use beyond the expiry date or if the product shows any sign of deterioration.

#### 6. Further information

##### What **Neuroplex** contains:

**Neuroplex 300 mg:** Each capsule contains: Gabapentin 300 mg.  
**Neuroplex 400 mg:** Each capsule contains: Gabapentin 400 mg.  
Excipients: Lactose monohydrate, pregelatinized starch, talc.

##### Presentations:

Packs of 50 Capsules.  
Hospital packs are available.

® is a trademark.

##### THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists.



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