

PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before you start taking NEURONTIN. It contains important information about your treatment. If you have any questions, or if you are not sure about anything, ask your doctor or pharmacist.

SCHEDULING STATUS: **S3**

PROPRIETARY NAME AND DOSAGE FORM:

NEURONTIN® 100 (capsules)

NEURONTIN® 300 (capsules)

NEURONTIN® 400 (capsules)

NEURONTIN® 600 (tablets)

NEURONTIN® 800 (tablets)

WHAT DOES NEURONTIN CONTAIN?

The active ingredient of NEURONTIN is gabapentin.

NEURONTIN capsules contain sugar:

Each NEURONTIN 100 capsule contains 14,25 mg lactose monohydrate.

Each NEURONTIN 300 capsule contains 42,75 mg lactose monohydrate.

Each NEURONTIN 400 capsule contains 57,00 mg lactose monohydrate.

NEURONTIN tablets are sugar free.

Excipients:

Each capsule contains lactose monohydrate, maize starch and talc. The capsule shells consist of gelatine, water, sodium laurylsulphate and the colourants titanium dioxide, yellow iron oxide (300 mg and 400 mg only) and red iron oxide (400 mg only). The printing ink consists of shellac and the colourants titanium dioxide and indigocarmine Al salt.

Each tablet contains poloxamer 407, copolyvidone K, maize starch and magnesium stearate. The film-coating consists of talc, hydroxypropylcellulose and purified water. The polishing agent is candelilla wax.

WHAT IS NEURONTIN USED FOR?

NEURONTIN is used to treat various forms of epilepsy. Your doctor will prescribe NEURONTIN for you to help treat your epilepsy when your current treatment is not fully controlling your condition or where your current treatment is causing problems such as side effects. You should only take NEURONTIN in addition to your current treatment unless told otherwise.

BEFORE USING NEURONTIN:

Do not take NEURONTIN:

- If you are allergic (hypersensitive) to NEURONTIN or any of its ingredients.
- If you are pregnant, trying to become pregnant or breastfeeding.
- If you suffer from kidney problems.

Take special care with NEURONTIN:

- If you are taking other medicines (see section 'Taking other medicines').

Taking other medicines with NEURONTIN:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of NEURONTIN with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

- NEURONTIN is not expected to interact with other anti-epileptic medicines or with the oral contraceptive.
- If NEURONTIN and antacids containing aluminium and magnesium are taken at the same time, the absorption of NEURONTIN from the stomach may be reduced. It is recommended that NEURONTIN be taken about two hours before or after antacid administration.

Pregnancy:

You should not take NEURONTIN while you are pregnant.

The safety of taking NEURONTIN during pregnancy is not known.

Breastfeeding:

You should not take NEURONTIN while you are breastfeeding.

Driving and using machines:

Special care should be taken when driving, operating machinery or performing any hazardous tasks.

NEURONTIN may cause dizziness, drowsiness and tiredness.

Important information about some of the ingredients of NEURONTIN:

If you have been told by your doctor that you have an intolerance to some sugars such as lactose, contact your doctor before taking NEURONTIN.

HOW TO TAKE NEURONTIN:

Always take NEURONTIN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adults and children over 12 years:

The usual dose is 900 – 1800 mg each day in 3 divided doses i.e. in the morning, at midday and at night.

Elderly:

Elderly patients may need their dosage adjusted by their doctor.

NEURONTIN can be taken with or without food. Always swallow the capsules or tablets with plenty of water.

Do not alter the dose yourself without your doctor's advice. Do not stop taking the capsules or tablets unless told to do so by your doctor.

What if you take too many NEURONTIN capsules or tablets?

These are the possible signs and symptoms of overdose: dizziness, double vision, slurred speech, drowsiness, tiredness and mild diarrhoea.

Call your doctor immediately if you take more capsules or tablets than you should. If you cannot call your doctor go to the nearest hospital or poison control centre at once. Take along any capsules or tablets that are left, the container and the label so that the doctor can identify the medicine you are taking.

What if you forget to take your NEURONTIN capsules or tablets?

If you forget to take a tablet, just take one tablet the following day at the usual time. If you forget to take your medicine for more than one week, call your doctor before taking any more medicine.

POSSIBLE SIDE EFFECTS:

NEURONTIN can cause side effects.

- The most common side effects are dizziness, tiredness.
- Less common side effects include drowsiness, nausea, diarrhoea, unusual eye movement, tremor, memory loss, anxiety, constipation, weight gain, sore throat, rhabdomyolysis (general weakness, muscle ache/stiffness, decreased urine production).

Some additional side effects that may occur when you stop taking your NEURONTIN medication are headache, pain, confusion, sweating and panic attacks or agitation.

Not all side effects reported for NEURONTIN are included in this leaflet.

Also, tell your doctor if any other effects occur while you are taking NEURONTIN.

If you develop a rash or other signs or symptoms of hypersensitivity such as fever or enlargement of lymph nodes, you should tell your doctor immediately as this may be an indication of a serious medical event.

STORING AND DISPOSING OF NEURONTIN:

Keep all medicines out of reach and sight of children. Store in a cool, dry place (at or below 25 °C).

Do not use NEURONTIN after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Return all unused medicine to your pharmacist. DO NOT dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION:

Blister packs of 100 capsules or tablets.

IDENTIFICATION:

NEURONTIN 100: White, opaque, hard gelatine capsules imprinted in blue ink with "NEURONTIN 100 mg" on the cap and "PD" on the body.

NEURONTIN 300: Pale yellow, opaque, hard gelatine capsules imprinted in grey ink with "NEURONTIN 300 mg" on the cap and "PD" on the body.

NEURONTIN 400: Orange, opaque, hard gelatine capsules imprinted in grey ink with "NEURONTIN 400

mg” on the cap and “PD” on the body.

NEURONTIN 600: White, elliptical film-coated tablet with bisecting score on both sides, debossed with “NT” and “16” on one side.

NEURONTIN 800: White, elliptical film-coated tablet with bisecting score on both sides, debossed with “NT” and “26” on one side.

REGISTRATION NUMBERS:

NEURONTIN 100 capsules: 27/2.5/0598

NEURONTIN 300 capsules: 27/2.5/0599

NEURONTIN 400 capsules: 27/2.5/0600

NEURONTIN 600 tablets: 35/2.5/0099

NEURONTIN 800 tablets: 35/2.5/0100

NAME AND BUSINESS ADDRESS OF HOLDER OF THE CERTIFICATE:

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