

### **Drugs and Supplements**

# Gabapentin (Oral Route)

# **Description and Brand Names**

Drug information provided by: IBM Micromedex

### **US Brand Name**

FusePaq Fanatrex Descriptions

Gabarone

Gralise Gabapentin is used to help control partial seizures (convulsions) in the

Neurontin treatment of epilepsy. This medicine cannot cure epilepsy and will only work to

control seizures for as long as you continue to take it.

Gabapentin is also used in adults to manage a condition called postherpetic neuralgia, which is pain that occurs after shingles.

Gabapentin works in the brain to prevent seizures and relieve pain for certain conditions in the nervous system. It is not used for routine pain caused by minor injuries or arthritis. Gabapentin is an anticonvulsant.

This medicine is available only with your doctor's prescription.

This product is available in the following dosage forms:

- Capsule
- Tablet
- Solution
- Suspension

# **Before Using**

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

### **Allergies**

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

### **Pediatric**

Appropriate studies performed to date have not demonstrated pediatric-specific problems that would limit the usefulness of gabapentin for treating partial seizures in children. However, safety and efficacy have not been established in children younger than 3 years of age.

Appropriate studies have not been performed on the relationship of age to the effects of gabapentin for treating postherpetic neuralgia in children. Safety and efficacy have not been established.

### **Geriatric**

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of gabapentin in the elderly. However, elderly patients are more likely to have unwanted effects (eg, problems with balance or walking, swelling in the feet or legs) and agerelated kidney problems, which may require caution and an adjustment in the dose for patients receiving gabapentin.

### **Breastfeeding**

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

### **Drug Interactions**

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Calcifediol
- Orlistat

Using this medicine with any of the following medicines may cause an increased risk of certain side effects, but using both drugs may be the best treatment for you. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Aluminum Carbonate, Basic
- Aluminum Hydroxide
- Aluminum Phosphate
- Dihydroxyaluminum Aminoacetate
- Dihydroxyaluminum Sodium Carbonate
- Ginkgo
- Magaldrate
- Magnesium Carbonate
- Magnesium Hydroxide
- · Magnesium Oxide
- Magnesium Trisilicate
- Morphine
- Morphine Sulfate Liposome

### Other Interactions

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with food, alcohol, or tobacco.

### **Other Medical Problems**

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- · Depression, history of or
- Mood or mental changes, history of—Use with caution. May make these conditions worse.
- Kidney disease—Use with caution. The effects may be increased because of slower removal of the medicine from the body.

# **Proper Use**

Take this medicine only as directed by your doctor. Do not take more of it, do not take it more often, and do not take it for a longer time than your doctor ordered. To do so may increase the chance of side effects.

This medicine comes with a Medication Guide. Read and follow the instructions carefully. Ask your doctor if you have any questions.

If you are using Gralise® tablets:

- These should be taken with the evening meal.
- Swallow the tablet whole. Do not crush, break, or chew it.

For patients with epilepsy who take gabapentin three times per day, do not allow more than 12 hours to pass between any 2 doses. The medicine works best if a constant amount is in the blood.

Neurontin® capsules, tablets, and solution may be taken with or without food.

You may break the scored Neurontin® tablets into two pieces, but make sure you use the second half of the tablet as the next dose. Do not use the half-tablet if the whole tablet has been cut or broken after 28 days. Ask your doctor or pharmacist if you have any questions.

Swallow the capsule whole with plenty of water. Do not open, crush, or chew it.

Measure the oral liquid using a marked measuring spoon, oral syringe, or medicine cup. The average household teaspoon may not hold the right amount of liquid.

If you take an antacid that contains aluminum or magnesium, wait at least 2 hours before taking gabapentin. Some examples of these antacids are Di-Gel®, Gaviscon®, Gelusil®, Maalox® and Mylanta®.

Only use the brand of this medicine that your doctor prescribed. Different brands may not work the same way.

### **Dosing**

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- For oral dosage forms (capsules, liquid, and tablets):
  - For epilepsy:
    - Adults and children 12 years of age and older—At first, 300 milligrams (mg) three times per day. Your doctor may adjust your dose as needed. However, the dose is usually not more than 2400 mg per day.
    - Children 3 to 11 years of age—Dose is based on body weight and must be determined by your doctor. The starting dose is 10 to 15 milligrams (mg) per kilogram (kg) of body weight per day and divided in 3 doses. Your doctor may adjust your dose as needed.
    - Children younger than 3 years of age—Use and dose must be determined by your doctor.

- For postherpetic neuralgia:
  - Adults— At first, 300 milligrams (mg) as a single dose in the evening. Your doctor may adjust your dose as needed. However, the dose is usually not more than 1800 mg per day.
  - Children—Use and dose must be determined by your doctor.

#### Missed Dose

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

### **Storage**

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

Ask your healthcare professional how you should dispose of any medicine you do not use.

You should store the Neurontin® oral liquid in the refrigerator. Do not freeze.

### **Precautions**

It is very important that your doctor check your progress at regular visits, especially in the first few months if you have epilepsy. This will allow your doctor to see if the medicine is working properly and to decide if you should continue to take it.

These may be cause serious allergic reactions that may involve multiple organs, such as your liver or kidneys. Check with your doctor right away if you or your child have more than one of the following symptoms: fever, rash, swollen, painful, or tender lymph glands in the neck, armpit, or groin, unusual bleeding or bruising, or yellow eyes or skin.

Gabapentin may cause vision changes, clumsiness, unsteadiness, dizziness, drowsiness, sleepiness, or trouble with thinking. Make sure you know how you react to this medicine before you drive, use machines, or do anything else that could be dangerous if you are not alert, well-coordinated, or able to think or see well. If these side effects are especially bothersome, check with your doctor.

This medicine may cause some people to be agitated, irritable, or display other abnormal behaviors, such as feeling sad or hopeless, getting upset easily, or feeling nervous, restless, or hostile. It may also cause some people to have suicidal thoughts and tendencies or to become more depressed. If you, your child, or your caregiver notice any of these side effects, tell your doctor right away.

This medicine will add to the effects of alcohol and other CNS depressants (medicines that make you drowsy or less alert). Some examples of CNS depressants are antihistamines or medicine for hay fever, allergies, or colds, sedatives, tranquilizers, or sleeping medicines, prescription pain medicine or narcotics, other medicines for seizures (eg, barbiturates), muscle relaxants, or anesthetics, including some dental anesthetics. Check with your medical doctor or dentist before taking any of the above while you or your child are using gabapentin.

Do not stop using gabapentin without checking with your doctor. Stopping the medicine suddenly may cause seizures. Your doctor may want you or your child to gradually reduce the amount you are taking before stopping it completely.

Make sure any doctor or dentist who treats you knows that you are using this medicine. This medicine may affect the results of certain medical tests.

Do not take other medicines unless they have been discussed with your doctor. This includes prescription or nonprescription (over-the-counter [OTC]) medicines and herbal or vitamin supplements.

### **Side Effects**

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

#### More common

- · Clumsiness or unsteadiness
- continuous, uncontrolled, back-and-forth, or rolling eye movements

#### More common in children

- Aggressive behavior or other behavior problems
- anxiety
- concentration problems and change in school performance
- crying
- depression
- false sense of well-being
- hyperactivity or increase in body movements
- · rapidly changing moods
- reacting too quickly, too emotional, or overreacting
- restlessness
- suspiciousness or distrust

#### Less common

- · Black, tarry stools
- chest pain
- chills
- cough
- depression, irritability, or other mood or mental changes
- fever
- loss of memory
- · pain or swelling in the arms or legs
- · painful or difficult urination
- · shortness of breath
- sore throat
- sores, ulcers, or white spots on the lips or in the mouth
- swollen glands
- · unusual bleeding or bruising
- unusual tiredness or weakness

#### Incidence not known

- · Abdominal or stomach pain
- · blistering, peeling, or loosening of the skin
- clay-colored stools
- coma
- confusion
- convulsions
- · dark urine
- decreased urine output
- diarrhea
- dizziness
- fast or irregular heartbeat
- headache
- increased thirst
- itching or skin rash
- joint pain
- large, hive-like swelling on the face, eyelids, lips, tongue, throat, hands, legs, feet, or sex organs
- · loss of appetite
- muscle ache or pain

- nausea
- red skin lesions, often with a purple center
- · red, irritated eyes
- unpleasant breath odor
- · vomiting of blood
- · yellow eyes or skin

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

#### More common

- Blurred vision
- · cold or flu-like symptoms
- delusions
- dementia
- hoarseness
- lack or loss of strength
- · lower back or side pain
- swelling of the hands, feet, or lower legs
- trembling or shaking

#### Less common or rare

- Accidental injury
- appetite increased
- · back pain
- bloated or full feeling
- · body aches or pain
- burning, dry, or itching eyes
- · change in vision
- change in walking and balance
- · clumsiness or unsteadiness
- congestion
- constipation
- · cough producing mucus
- decrease in sexual desire or ability

- · difficulty with breathing
- · dryness of the mouth or throat
- earache
- excess air or gas in the stomach or intestines
- · excessive tearing
- eye discharge
- · feeling faint, dizzy, or lightheadedness
- feeling of warmth or heat
- flushed, dry skin
- flushing or redness of the skin, especially on the face and neck
- frequent urination
- · fruit-like breath odor
- · impaired vision
- incoordination
- increased hunger
- · increased sensitivity to pain
- increased sensitivity to touch
- increased thirst
- indigestion
- noise in the ears
- pain, redness, rash, swelling, or bleeding where the skin is rubbed off
- passing gas
- · redness or swelling in the ear
- redness, pain, swelling of the eye, eyelid, or inner lining of the eyelid
- · runny nose
- sneezing
- sweating
- tender, swollen glands in the neck
- tightness in the chest
- tingling in the hands and feet
- · trouble sleeping
- trouble swallowing
- · trouble thinking
- twitching
- unexplained weight loss

- voice changes
- vomiting
- weakness or loss of strength
- · weight gain

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

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