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Perampanel

pronounced as (per am' pa nel)

IMPORTANT WARNING:

People who have taken perampanel have developed serious or life-threatening changes in their mental health and behavior, especially increased hostility or aggression toward others. Tell your doctor if you have or have ever had any type of mental illness or aggressive behavior. However, you should know that it is possible to develop these changes in mental health and behavior while taking perampanel even if you have never had any problems with mental health or behavior in the past. You, your family, or your caregiver should call your doctor right away if you experience any changes in mood, behavior, or personality during your treatment with perampanel or for up to a month after stopping your treatment. Your doctor will monitor your mental health closely during your treatment with perampanel, especially when you begin taking this medication and any time that your dose is changed. If you experience any of the following symptoms, call your doctor immediately: aggression, hostility, anger, anxiety, irritability, suspicious or distrustful behavior, confusion, memory problems, and thinking about harming or killing others or threatening or trying to do so. Your doctor may decrease your dose or stop your medication.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with perampanel and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) or the manufacturer's website to obtain the Medication Guide.

Talk to your doctor about the risks of taking perampanel.

Why is this medication prescribed?

Perampanel is used to treat certain types of partial onset seizures (seizures that involve only one part of the brain) in adults and children 4 years of age and older. It is also used in combination with other medications to treat certain types of primary generalized tonic-clonic seizures (formerly known as a grand mal seizure; seizure that involves the entire body) in adults and children 12 years of age or older.

Perampanel is in a class of medications called anticonvulsants. It works by decreasing abnormal electrical activity in the brain.

How should this medicine be used?

Perampanel comes as a tablet and as an suspension (liquid) to take by mouth. It is usually taken once a day at bedtime. Take perampanel at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take perampanel exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Shake the suspension well before each use to mix the medication evenly.

Always use the oral (by mouth) dosing syringe that comes with perampanel suspension to prepare and measure your dose. Do not use a household spoon to measure your dose.

Your doctor will probably start you on a low dose of perampanel and gradually increase your dose, not more than once every week.

Perampanel may be habit forming. Do not take a larger dose, take it more often, or take it for a longer period of time than prescribed by your doctor.

Perampanel may help control your condition but does not cure it. Do not stop taking perampanel without talking to your doctor. If you suddenly stop taking perampanel, your seizures may become worse. Your doctor will probably decrease your dose gradually.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking perampanel,

- tell your doctor and pharmacist if you are allergic to perampanel, any other medications, or any of the ingredients in perampanel tablets or oral suspension. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: antidepressants; barbiturates such as phenobarbital and secobarbital (Seconal); medications for allergies, anxiety, cough and cold, mental illness, and pain; medications for seizures such as carbamazepine (Carbatrol, Tegretol, Equetro), oxcarbazepine (Trileptal, Oxtellar), phenytoin (Dilantin, Phenytek), primidone (Mysoline), and topiramate (Topamax); rifampin (Rifadin); sedatives; sleeping pills; and tranquilizers. Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with perampanel, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- you should know that perampanel may decrease the effectiveness of hormonal contraceptives (birth control pills, patches, rings, or implants) that contain levonorgestrel. Use another form of birth control

while taking perampanel and for 1 month after your final dose. Ask your doctor or pharmacist if you are not sure if your birth control contains levonorgestrel.

- tell your doctor what herbal products you are taking, especially St. John's wort.
- tell your doctor if you drink or have ever drunk large amounts of alcohol, if you use or have ever used street drugs, or if you have over-used prescription medications. Also tell your doctor if you have or have ever had kidney or liver disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while taking perampanel, call your doctor.
- you should know that perampanel may cause dizziness, drowsiness, and problems with coordination and balance. This may increase the risk of falls that can cause serious injury, especially if you are elderly. Do not drive a car, operate machinery, or participate in activities requiring alertness or coordination until you know how this medication affects you.
- ask your doctor about the safe use of alcoholic beverages while you are taking perampanel. Alcohol can make the side effects from perampanel worse.
- you should know that your mental health may change in unexpected ways and you may become suicidal (thinking about harming or killing yourself or planning or trying to do so) while you are taking perampanel. A small number of adults and children 5 years of age and older (about 1 in 500 people) who took anticonvulsants like perampanel to treat various conditions during clinical studies became suicidal during their treatment. Some of these people developed suicidal thoughts and behavior as early as 1 week after they started taking the medication. There is a risk that you may experience changes in your mental health if you take an anticonvulsant medication such as perampanel, but there may also be a risk that you will experience changes in your mental health if your condition is not treated. You and your doctor will decide whether the risks of taking an anticonvulsant medication are greater than the risks of not taking the medication. You, your family, or your caregiver should call your doctor right away if you experience any of the following symptoms: panic attacks; agitation or restlessness; new or worsening irritability, anxiety, or depression; acting on dangerous impulses; difficulty falling asleep or staying asleep; aggressive, angry, or violent behavior; mania (frenzied, abnormally excited mood); talking or thinking about wanting to hurt yourself or end your life; or any other unusual changes in behavior or mood. Be sure that your family or caregiver knows which symptoms may be serious so they can call the doctor if you are unable to seek treatment on your own.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one. If you miss more than one dose, contact your doctor.

What side effects can this medication cause?

Perampanel may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- dizziness or a sense of spinning
- drowsiness

- constipation
- nausea
- vomiting
- headache
- tiredness
- weight gain
- irritability
- weakness
- problems with coordination
- muscle, back, or joint pain
- decreased sense of touch or sensation
- blurred or double vision

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING and SPECIAL PRECAUTIONS sections, stop taking perampanel and call your doctor immediately or get emergency medical treatment:

- rash; hives; fever or swollen glands; swelling of your face or legs; shortness of breath; yellow of skin or eyes; or dark urine

Perampanel may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Do not freeze the suspension. Discard any unused suspension 90 days after first opening the bottle.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the

best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- dizziness
- unusual changes in behavior or mood
- agitation
- aggressive behavior

What other information should I know?

Keep all appointments with your doctor.

Do not let anyone else take your medication. Perampanel is a controlled substance. Prescriptions may be refilled only a limited number of times; ask your pharmacist if you have any questions.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Fycompa[®]

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