**Study PHN 1**: This 13-week study of 368 patients (275 pregabalin and 93 placebo) compared LYRICA 75, 150, and 300 mg twice daily with placebo. Patients with creatinine clearance (CL\text{cr}) between 30 to 60 mL/min were randomized to 75 mg, 150 mg, or placebo twice daily. Patients with creatinine CL\text{cr} below 30 mL/min were excluded. The efficacy of the maximum recommended dose of LYRICA for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) has been shown to cross the placenta in rats and is present in the milk of lactating rats.

**Study PHN 2**: This 8-week study of 173 patients (89 pregabalin and 84 placebo) compared LYRICA 100 or 200 mg three times a day with placebo. Some patients experienced a decrease in pain as early as Week 1, which persisted throughout the study. Postherpetic Neuralgia (PHN) affects patients 50 years and older and results in chronic pain that is often refractory to current therapies. There is currently no cure for PHN, and most treatments, such as antidepressants, anticonvulsants, and local anesthetics, provide only temporary relief.

**Study DPN 1**: This 5-week study of 337 patients (240 pregabalin and 97 placebo) compared LYRICA 25, 100, or 200 mg three times a day with placebo. The efficacy of the maximum recommended dose of LYRICA for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) has been shown to cross the placenta in rats and is present in the milk of lactating rats. Effects of LYRICA in pregnancy and lactation have not been adequately studied.

**Pharmacokinetics**: LYRICA (pregabalin) capsules are indicated as adjunctive therapy for adult patients with partial onset seizures.

**Clinical Use**: In controlled studies, a higher proportion of patients treated with pregabalin reported blurred vision (6%) than did patients treated with placebo (2%). Ophthalmological Effects: Peripheral edema and weight gain. For patients with preexisting cardiac conditions, this may increase the risk of heart failure. If pregabalin is discontinued this should be done gradually over a minimum of 1 week. As with all AEDs, pregabalin should be withdrawn gradually to minimize the potential of increased seizure frequency in patients with seizure disorders.

**Contraindications**: Pregabalin treatment caused weight gain. In pregabalin controlled clinical trials of up to 13 weeks, a gain of 7% or more over baseline weight was reported more often in patients treated with pregabalin than in those treated with placebo (9.3% vs. 4.3%). Other weight-related adverse reactions included edema, hyperglycemia, and hyperinsulinemia. In standard preclinical in vivo lifetime carcinogenicity studies of pregabalin, an unexpectedly high incidence of hemangiosarcoma was identified in two species (mouse and dog). There was no apparent species selectivity in the incidence of hemangiosarcoma, which was seen at all dose levels, and the frequency was not dose-related. LYRICA is indicated as adjunctive therapy for adult patients with partial onset seizures. In the overall database of controlled trials, 2% of placebo patients and 3% of pregabalin patients discontinued due to peripheral edema.

**Drug Interactions**: Pregabalin treatment caused weight gain. In pregabalin controlled clinical trials of up to 13 weeks, a gain of 7% or more over baseline weight was reported more often in patients treated with pregabalin than in those treated with placebo (9.3% vs. 4.3%). Other weight-related adverse reactions included edema, hyperglycemia, and hyperinsulinemia. In standard preclinical in vivo lifetime carcinogenicity studies of pregabalin, an unexpectedly high incidence of hemangiosarcoma was identified in two species (mouse and dog). There was no apparent species selectivity in the incidence of hemangiosarcoma, which was seen at all dose levels, and the frequency was not dose-related. LYRICA is indicated as adjunctive therapy for adult patients with partial onset seizures. In the overall database of controlled trials, 2% of placebo patients and 3% of pregabalin patients discontinued due to peripheral edema. LYRICA should be administered with food. For patients with preexisting cardiac conditions, this may increase the risk of heart failure. If pregabalin is discontinued this should be done gradually over a minimum of 1 week. As with all AEDs, pregabalin should be withdrawn gradually to minimize the potential of increased seizure frequency in patients with seizure disorders. Contraindications, Warnings, and Precautions, Adverse Reactions, Clinical Use, Pharmacokinetics, Drug Interactions, Administration, and Dosage, Overdosage, Pregnancy, and Lactation, and Foreign Language translations of adverse effects of LYRICA and clinical information differences are included in the text.
PRECAUTIONS

ADVERSE REACTIONS

Table 2 lists all adverse events, regardless of causality, occurring in and somnolence. Other reasons for discontinuation from the trials, occurring with greater frequency in the pregabalin group than in the placebo combined pregabalin group for which the incidence was greater in this combined pregabalin group than in the placebo group. In addition, an event is included, Adverse Events Leading to Discontinuation

Adverse Events Leading to Discontinuation

In all controlled and uncontrolled trials across various patient populations during the premarketing development of pregabalin, more than

Adverse events occurring in

PRECAUTIONS

ADVERSE REACTIONS

Table 4 lists all dose-related adverse events, regardless of causality, occurring in at least 2% of all LYRICA-treated

ADVERSE REACTIONS

Controlled Add-On Studies in Epilepsy

In view of dose-dependent adverse events and since LYRICA is eliminated primarily by renal excretion, the dose should be adjusted in patients with

ADVERSE REACTIONS

Nervous System

In controlled clinical studies of LYRICA in neuropathic pain associated with diabetic peripheral neuropathy, 306 patients were 65 to 74 years of age,

ADVERSE REACTIONS

In a double-blind, placebo-controlled clinical trial to assess the effect of pregabalin on sperm motility, 30 healthy male subjects were exposed to pre-

ADVERSE REACTIONS

Hemic and Lymphatic System –

Infrequent: Abnormal dreams, Agitation, Apathy, Aphasia, Circumoral paresthesia, Dysarthria, Hallucinations, Hostility, Hyperalgesia, Hyperesthesia,

ADVERSE REACTIONS

Carbamazepine is often used to prevent seizures in patients with complex partial seizures, which are characterized by impairment of consciousness and

ADVERSE REACTIONS

PRECAUTIONS

Estimated from the exposure to pregabalin (AUC) at the no-effect dose for developmental toxicity in rabbits (500 mg/kg) was associated with a plasma exposure approximately 16 times human exposure at the MRD. A no-effect dose for developmental toxicity in rabbits (500 mg/kg) was associated with a plasma exposure approximately 16 times human exposure at the MRD. A no-effect dose for developmental toxicity in rabbits (500 mg/kg) was associated with a plasma exposure approximately 16 times human exposure at the MRD.

ADVERSE REACTIONS

Therapeutic Plasma Levels and Dose-Dependent Adverse Events

AA 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15

ADVERSE REACTIONS

Adverse events occurring in

ADVERSE REACTIONS

Infrequent: Abnormal dreams, Agitation, Apathy, Aphasia, Circumoral paresthesia, Dysarthria, Hallucinations, Hostility, Hyperalgesia, Hyperesthesia,

ADVERSE REACTIONS

Diplopia 5 7 12 9 4

ADVERSE REACTIONS

Abnormal Gait 1 3 5 4 0

ADVERSE REACTIONS

Face edema 0 1 2 6 2 1

ADVERSE REACTIONS

Weight gain 0 4 4 6 4 0

ADVERSE REACTIONS

Hypersensitivity: Rash (including, but not limited to, rashes, pruritus, urticaria, angioedema, toxic epidermal necrolysis, erythema multiforme, Stevens–Johnson syndrome, and Lyell's syndrome), photosensitivity, and anaphylaxis.

ADVERSE REACTIONS

Abnormal vision 1 0 1 1 0

ADVERSE REACTIONS

Respiratory system

Infrequent: Abnormal dreams, Agitation, Apathy, Aphasia, Circumoral paresthesia, Dysarthria, Hallucinations, Hostility, Hyperalgesia, Hyperesthesia,

ADVERSE REACTIONS

Adverse events occurring in

ADVERSE REACTIONS

Adverse events occurring in

ADVERSE REACTIONS

Weight gain 0 4 4 6 4 0

ADVERSE REACTIONS

Infrequent: Abnormal dreams, Agitation, Apathy, Aphasia, Circumoral paresthesia, Dysarthria, Hallucinations, Hostility, Hyperalgesia, Hyperesthesia,

ADVERSE REACTIONS

Abnormal Gait 1 3 5 4 0

ADVERSE REACTIONS

Face edema 0 1 2 6 2 1

ADVERSE REACTIONS

Respiratory system

Infrequent: Abnormal dreams, Agitation, Apathy, Aphasia, Circumoral paresthesia, Dysarthria, Hallucinations, Hostility, Hyperalgesia, Hyperesthesia,

ADVERSE REACTIONS

Diplopia 5 7 12 9 4

ADVERSE REACTIONS

Abnormal Gait 1 3 5 4 0

ADVERSE REACTIONS

Face edema 0 1 2 6 2 1

ADVERSE REACTIONS

Weight gain 0 4 4 6 4 0

ADVERSE REACTIONS

Respiratory system

Infrequent: Abnormal dreams, Agitation, Apathy, Aphasia, Circumoral paresthesia, Dysarthria, Hallucinations, Hostility, Hyperalgesia, Hyperesthesia,
Read the Patient Information that comes with LYRICA before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition or treatment. If you have any questions about LYRICA, ask your doctor or pharmacist.

What is the most important information I should know about LYRICA?

1. LYRICA may cause dizziness and sleepiness.
   - Do not drive a car, work with machines, or do other dangerous activities until you know how LYRICA affects how alert you are. Ask your doctor when it is okay to do these activities.

2. LYRICA may cause problems with your eyesight, including blurry vision.
   - Call your doctor if you have any changes in your eyesight.

What is LYRICA?

LYRICA is a prescription medicine used in adults, 18 years and older, to treat:

• pain from damaged nerves (neuropathic pain) that happens with diabetes
• pain from damaged nerves (neuropathic pain) that follows healing of shingles (a painful rash that comes after a herpes zoster infection)
• partial seizures when taken together with other seizure medicines

Pain From Damaged Nerves (neuropathic pain).

Diabetes and shingles can damage your nerves. Pain from damaged nerves may feel sharp, burning, tingling, shooting, or numb. If you have diabetes, the pain can be in your arms, hands, fingers, legs, feet, or toes. If you have shingles, the pain is in the area of your rash. You may experience this kind of pain even with a very light touch. LYRICA can help relieve the pain. Some people taking LYRICA had less pain by the end of the first week of LYRICA therapy. LYRICA may not work for everyone. LYRICA has not been studied for nerve pain in children under 18 years of age.

Partial Seizures

Partial seizures start in one part of the brain. A seizure can make you fearful, confused, or just feel “funny.” You may smell strange smells. A seizure may cause your arm or leg to jerk or shake. It can spread to other parts of your brain, make you pass out, and cause your whole body to start jerking.

LYRICA can lower the number of seizures for people who are already taking seizure medicine. LYRICA has not been studied for partial seizures in children under 18 years of age.

Who Should Not Take LYRICA?

Do not take LYRICA if you are allergic to any of its ingredients. The active ingredient is pregabalin. See the end of this leaflet for a complete list of ingredients in LYRICA.

What should I tell my doctor before taking LYRICA?

Tell your doctor about all your medical conditions, including if you:

• have any kidney problems or get kidney dialysis
• have heart problems including heart failure
• have a bleeding problem or a low blood platelet count
• are pregnant or plan to become pregnant. It is not known if LYRICA may harm your unborn baby. You and your doctor will have to decide if LYRICA is right for you while you are pregnant.
• are breastfeeding. It is not known if LYRICA passes into breast milk and if it can harm your baby. You and your doctor should decide whether you should take LYRICA or breastfeed, but not both.

Tell your doctor about all the medicines you take including prescription or non-prescription medicines, vitamins or herbal supplements. LYRICA and other medicines may affect each other. Especially tell your doctor if you take:

• rosiglitazone (Avandia®) or pioglitazone (Actos®) for diabetes. You may have a higher chance of weight gain or swelling if these medicines are taken with LYRICA. See "What are the possible side effects of LYRICA?"
• any narcotic pain medicine (such as oxycodone), tranquilizers or medicines for anxiety (such as lorazepam). You may have a higher chance for dizziness and sleepiness if these medicines are taken with LYRICA. See "What is the most important information I should know about LYRICA?"
• any medicines that make you sleepy

Know all the medicines you take. Keep a list of them with you to show your doctor and pharmacist each time you get a new medicine.

Tell your doctor if you plan to father a child. Animal studies showed that pregabalin, the active ingredient in LYRICA, made male animals less fertile. Also, in animal studies, birth defects occurred in the offspring of male animals who were treated with pregabalin. It is not known if these effects would happen in people.

How should I take LYRICA?

• Take LYRICA exactly as prescribed. Your doctor may adjust your dose during treatment. Do not change your dose without talking to your doctor.
• Do not stop taking LYRICA suddenly without talking to your doctor. If you stop taking LYRICA suddenly, you may have headaches, nausea, diarrhea or trouble sleeping. Talk with your doctor about how to slowly stop LYRICA.
• LYRICA is usually taken 2 or 3 times a day, depending on your medical condition. Your doctor will tell you how much to take and when to take it. Take LYRICA at the same times each day.
These are not all the side effects of LYRICA. For more information, ask your doctor or pharmacist.

How should I store LYRICA?
• Store LYRICA at room temperature, 59 to 86 ºF (15 to 30 ºC) in its original package.
• Safely throw away LYRICA that is out of date or no longer needed.
• Keep LYRICA and all medicines out of the reach of children.

General information about LYRICA
Medicines are sometimes prescribed for conditions other than those listed in patient information leaflets. Do not use LYRICA for a condition for which it was not prescribed. Do not give LYRICA to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about LYRICA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about LYRICA that is written for health professionals.

You can also visit the LYRICA website at www.LYRICA.com or call 1-866-4LYRICA.

What are the ingredients in LYRICA?
Active ingredient: pregabalin
Inactive ingredients: lactose monohydrate, cornstarch, talc; Capsule shell: gelatin and titanium dioxide; Orange capsule shell: red iron oxide; White capsule shell: sodium lauryl sulfate, colloidal silicon dioxide.
Colloidal silicon dioxide is a manufacturing aid that may or may not be present in the capsule shells.
Imprinting ink: shellac, black iron oxide, propylene glycol, potassium hydroxide.

LYRICA may be taken with or without food.
• If you miss a dose by a few hours, take it as soon as you remember. If it is close to your next dose, just take LYRICA at your next regular time. Do not take two doses at the same time.
• If you take too much LYRICA, call your doctor or poison control center or go to the nearest emergency room right away.

What Should I Avoid While Taking LYRICA?
• Do not drive a car, work with machines, or do other dangerous activities until you know how LYRICA affects how alert you are. See “What is the most important information I should know about LYRICA?”
• Do not drink alcohol while taking LYRICA. LYRICA and alcohol can affect each other and increase side effects such as sleepiness and dizziness. This can be dangerous.

Do not take other medicines without talking to your doctor. Other medicines include prescription and non-prescription medicines, vitamins, and herbal supplements. LYRICA and other medicines may affect each other and increase the side effects of sleepiness and dizziness. Be especially careful about medicines that make you sleepy (such as sleeping pills, anxiety medicines, tranquilizers and some antihistamines, pain relievers and seizure medicines).

What are the possible side effects of LYRICA?
LYRICA may cause side effects including:
• dizziness and sleepiness. See “What is the most important information I should know about LYRICA?”
• eyegight problems. See “What is the most important information I should know about LYRICA?”
• weight gain and swelling of the hands and feet (edema). Weight gain may affect the management of diabetes. Weight gain and swelling can also be a serious problem for people with heart problems.
• unexplained muscle problems, such as muscle pain, soreness, or weakness. If you develop these symptoms, especially if you also feel sick and have a fever, tell your doctor right away.

The most common side effects of LYRICA are:
• dizziness
• blurry vision
• weight gain
• sleepiness
• trouble concentrating
• swelling of hands and feet
• dry mouth

LYRICA caused skin sores in animals. Although skin sores were not seen in studies in people, if you have diabetes, you should pay extra attention to your skin while taking LYRICA and tell your doctor of any sores or skin problems.

LYRICA may cause some people to feel “high.” Tell your doctor, if you have abused prescription medicines, street drugs, or alcohol in the past. Tell your doctor about any side effect that bothers you or that does not go away.

Avandia is a registered trademark of GlaxoSmithKline.
Actos is a registered trademark of Takeda Chemicals Industries, Ltd. and used under license by Takeda Pharmaceuticals of America, Inc. and Eli Lilly and Co.
Store at 25ºC (77ºF); excursions permitted to 15-30ºC (59-86ºF) [see USP Controlled Room Temperature].

Each capsule contains 50 mg pregabalin.

DOSAGE AND USE

See accompanying prescribing information.

Each capsule contains 50 mg pregabalin. 

Manufactured by:
Pfizer Pharmaceuticals LLC
Vega Baja, PR 00694

Rx only
Each capsule contains 75 mg pregabalin.

**DOSAGE AND USE**

See accompanying prescribing information.
Rx only

Store at 25ºC (77ºF); excursions permitted to 15-30ºC (59-86ºF) [see USP Controlled Room Temperature].

Each capsule contains 50 mg pregabalin.

DOSAGE AND USE

See accompanying prescribing information.

Manufactured by:
Pfizer Pharmaceuticals LLC
Vega Baja, PR 00694

Distributed by:
Pfizer Inc, NY, NY 10017
U.S. Pharmaceuticals

NDC 63539-510-00

Rx only
Store at 25°C (77°F); excursions permitted to 15–30°C (59–86°F) (see USP Controlled Room Temperature).

Dispense in tight containers (USP).

DOSAGE AND USE
See accompanying prescribing information.

Each capsule contains 300 mg pregabalin.

Manufactured by:
Pfizer Pharmaceuticals LLC
Vega Baja, PR 00604
Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) see USP Controlled Room Temperature.

Dispense in tight containers (USP).

DOSAGE AND USE
See accompanying prescribing information.

Each capsule contains 225 mg pregabalin.

Manufactured by Pfizer Pharmaceuticals LLC
Vega Baja, PR 00694

Rx only
Store at 25°C (77°F); excursions permitted to 15–30°C (59–86°F) (see USP Controlled Room Temperature). Dispense in tight containers (USP).

**Dosage and Use**

See accompanying prescribing information.

Each capsule contains 200 mg pregabalin.

Manufactured by Pfizer Pharmaceuticals LLC, Vega Baja, PR 00694
Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) under USP Controlled Room Temperature.

Dispense in tight containers (USP).

**Dosage and Use**

See accompanying prescribing information.

Each capsule contains 150 mg pregabalin.

Manufactured by:

Pfizer Pharmaceuticals LLC
Vega Baja, PR 00694

**Lynica™**

(pregabalin) capsules

150 mg

Rx only
DOSAGE AND USE
See accompanying prescribing information.

Manufactured by:
Pfizer Pharmaceuticals LLC
Vega Baja, PR 00694

Each capsule contains 100 mg pregabalin.

Dispense in tight containers (USP).

DOSAGE AND USE
See accompanying prescribing information.

Each capsule contains 100 mg pregabalin.

Manufactured by:
Pfizer Pharmaceuticals LLC
Vega Baja, PR 00694

Distributed by:
Division of Pfizer Inc, NY, NY 10017

Parke-Davis

(pregabalin) capsules

Lyrica

100 mg

90 Capsules

MDC 0071-0770-08
Rx only

Store at 25 ºC (77 ºF); excursions permitted to 15- 30 ºC (59 - 86 ºF) [see USP Controlled Room Temperature].
DOSAGE AND USE
See accompanying prescribing information.
Manufactured by: Pfizer Pharmaceuticals LLC
Vega Baja, PR 00694
Each capsule contains 75 mg pregabalin
Rx only
Distributed by Division of Pfizer Inc, NY, NY 10017
Parke-Davis (pregabalin) capsules
Lyrica™
75 mg
NDC 0071-1014-68
90 Capsules
Store at 25° C (77° F); excursions permitted to 15-30° C (59-86° F) [see USP Controlled Room Temperature].
Dispense in tight containers (USP)
DOSAGE AND USE

See accompanying prescribing information.

Manufactured by:
Pfizer Pharmaceuticals LLC
Vega Baja, PR 00694

Each capsule contains 50 mg pregabalin.
DOSAGE AND USE
See accompanying prescribing information.
Each capsule contains 25 mg pregabalin.
Manufactured by Pfizer Pharmaceuticals LLC
Vega Baja, PR 00694

Store at 25°C (77°F);
excursions permitted to 15-30°C (59-86°F)
[see USP Controlled Room Temperature].