

Package leaflet: information for the user

Lyrica 25 mg hard capsules,
Lyrica 50 mg hard capsules,
Lyrica 75 mg hard capsules,
Lyrica 100 mg hard capsules,
Lyrica 150 mg hard capsules,
Lyrica 200 mg hard capsules,
Lyrica 225 mg hard capsules,
Lyrica 300 mg hard capsules
pregabalin

Read carefully the entire leaflet before you take this medicine use because there is important information in for you.

- Keep this leaflet. You might need it later again ..
- you still questions? Then contact your doctor or pharmacist.
- Do not give this medicine to others , because it is onlyprescribed to you . prescribed. The can be harmful to others ,even if they have the same symptoms as you. Do
- you experience one of the side effects listed in the section 4 listed? Or do you get you a side effect that not in this leaflet listed? Then contact your doctor or pharmacist.

Contents of this leaflet

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1. What is Lyrica and what is this medicine usedfor

? Lyrica belongs to the group of medicines used the treatment of epilepsy, neuropathic pain and generalized anxiety disorder (GAD) in adults.

Peripheral and central neuropathic pain: Lyrica is used for the treatment of chronic pain that is caused by nerve damage . Various diseases such as diabetes or shingles diabetes or shingles (shingles) can peripheral neuropathic pain cause. Pain perceptions can be described as hot, burning, throbbing, shooting, stabbing, sharp, cramp, painful, tingling, numb, asleep. Peripheral and central neuropathic pain can also accompanied go with mood swings, sleep disorders, fatigue and can affect the physical and social functioning and the the total quality of life.

Epilepsy: Lyrica is used in the treatment of certain forms of epilepsy in adults adults (partial seizures with or without secondary generalized seizures). Your doctor will prescribe you Lyrica to support the treatment of your epilepsy epilepsy, if your current medications your condition do not under control . You must Lyrica in addition to your current

treatment take . Lyrica is. Lyrica is not intended to be used alone to be used, but must always be used in combination with other anti-epileptics (medications used for epilepsy).

Generalized anxiety disorder: Lyrica is used for the treatment of generalized anxiety disorder (GAD). The symptoms of GAD are long-lasting and excessive anxiety and worry that are difficult to control . GAD can also cause restlessness or a feeling of tension or irritability , or, or can ensure that you you you quickly tired feel, you difficult can concentrate, you nothing more can remember or irritable are, or can muscle tension or sleep disorders cause. This has nothing to do with the stress and the tension in the daily life.

2. When may you this medicine not use or must you extra careful with be?

When may you this medicine not use?

You are allergic to one of the substances in this medicine. These substances can you find in section 6.

When should you be extra careful are with this medicine?

Contact your doctor or pharmacist before you take this medicine.

In some patients who use Lyrica use use, are symptoms reported that indicate an a allergic reaction. These symptoms include swelling of the face, lips, tongue a throat but also widespread skin rash. You must immediately contact contact with your doctor if one of these reactions in you occurs.

In connection with the use of pregabalin reports have been made of serious cutaneous adverse reactions (adverse reactions on the skin), such as the syndrome of Stevens-Johnson and toxic epidermal necrolysis. Stop using pregabalin and seek immediate medical assistance if you experience any symptoms a of the in section 4 described symptoms in connection with these serious skin reactions notice.

- During the use of Lyrica are dizziness and drowsiness occurred, causing the occurrence of accidents (falls) in older patients may increase. Be therefore careful until you accustomed are to the effect that this medicine could possibly have.
- Lyrica can blurred vision or loss of sight of other changes of the visual field cause, of which the most temporary are. You must it immediately to your doctor tell if you changes of your vision notice.
- In certain diabetic patients who gain weight during the treatment with pregabalin may a adjustment of their diabetes medication necessary be.
- Certain side effects such as drowsiness may occur more frequently, because patients with spinal cord injury other medications can use to for example pain or spasticity to treat. These medications have the same side effects as pregabalin and the Severity of these side effects may be increased in concurrent use ..
- are in some patients during the use use of Lyrica reports been of heart failure; mostly were these older patients with heart- and vascular diseases. Before you start with taking of this medicine must you your doctor inform if you in the past suffered have from a heart condition heart condition.
- are are in some patients during the use of Lyrica reports have been of kidney failure. If you during the use of Lyrica notice that you less urinates, must you to your doctor tell since this can improve by stopping the medication tea taking.

- Some patients who treated were with anti-epileptics such as Lyrica, have thoughts had about self-harm or suicide or have suicidal behavior shown. If you at any time such thoughts has or such behavior shows, contact immediately your doctor.
- When Lyrica is taken with other medications that constipation can cause (such as some types painkillers), it is possible that gastrointestinal problems occur (e.g.. constipationblocked or paralyzed intestine intestine). Tell the your doctor if you constipation have, especially if you sensitive to this problem are.
- Tell the your doctor before you start with the use of this medicine if you ever abused have made or dependent have been of alcohol, medications on prescription or illegal drugs; this can mean that you have a greater risk of becoming dependent on become of Lyrica.
- There are cases of seizures/convulsions (convulsions) reported during the use of Lyrica or shortly after the stop with Lyrica. Contact your doctor if a seizure occurs in you ..
- are cases of reduced brain function brain function encephalopathyencephalopathy) reported in a number of patients who used Lyrica used. These patients had also other conditions. Tell it your doctor if you in the past suffered from had of serious conditions, such as for example liver or kidney diseases.
- There have been reports of from breathing difficulties. If you suffer from nervous system disorders
- nervous system disordersrespiratory system disorders respiratory system disorderskidney dysfunction or if you are older than 65 years ,your doctor may give you a one other dosing schedule prescribe. Contact your doctor if you have difficulty breathing breathing or a shallow breathing experience.

Dependence

Some people can of Lyrica dependent become (a need to continue medication to continue taking). They can withdrawal symptoms experience when they stop taking the use of Lyrica (see section 3, "How to use this medicine ?"and "If you stop using this medicine "). If you feel thismedicine yourself there concerns about makes that you from Lyrica dependent can become, it is important that you your doctor consults.

If you one of the next symptoms notices during the taking of Lyrica, can this a sign be that you dependent have become:

- You must the medication longer take than recommended by your prescriber
- You feel the feeling that you need to take than the recommended dose
- You use the medication for other reasons than prescribed
- You have repeated, failed attempts made to stop stop with or control to get over the use of the medication
- When you stop taking the medication you feel not well yourself not good, and you feel better as soon as you take the medicine again If you notice

any of these symptoms , contact yourdoctor to discuss it best treatment plan for you to discuss, including when it a suitable time to to stop and how you this in a safe way must do.

Children and adolescents up to 18 years

The safety and efficacy in children and adolescents (up to the age from 18 years) are not established. Lyrica should therefore not be used in this age group.

Do you take other medications?

Used you besides Lyrica any other medications, have you that recently done or is there a possibility that you in the near future other medications will use? Inform that then your doctor or pharmacist. That applies also to medications where you no prescription for needed have.

Lyrica and certain other medicines can each other influence (interaction). With intake with certain other medications that a sedative effect have (including opioids), can Lyrica these effects enhance, which can lead to respiratory arrest, coma and death. Dizziness, drowsiness and decreased concentration may worsen if Lyrica is used with medications administered that:

- oxycodone (used as painkiller)
- lorazepam (used for the treatment of anxiety) or
- alcohol contain.

Lyrica can simultaneously with oral contraceptives are used.

What should you pay attention to with food, drink and alcohol?

Lyrica capsules may with or without food be taken.

The is recommended not alcohol to drink during the use of Lyrica.

Pregnancy and breastfeeding

Lyrica should not during the pregnancy of during the breastfeeding be used, unless your doctor decides otherwise. The use of pregabalin during the first 3 months of the pregnancy can birth defects cause in the unborn child for which a medical treatment necessary is. From a study involving data were assessed of women from Northern-European countries who during the first 3 months of the pregnancy pregabalin had taken, pale that 6 out of the 100 babies such birth defects showed. Among women who during the study not with pregabalin were treated, were that 4 out of 100 babies. Malformations of the face (cleft lip, jaw and/or palate), the eyes, the nervous system (including the brain), kidneys and reproductive organs were reported.

Women who can become pregnant ,must use effective contraception use. Are you pregnant, do you think you are pregnant to be, do you want to become pregnant or are you breastfeeding ? Then contact your doctor or pharmacist before physician or pharmacist before you this medicine used.

Driving ability and the use of machines

The use of Lyrica can lead to dizziness, drowsiness and reduced concentration. You must not operate vehicles , operate machinery, handle or other hazardous activities perform, until it is clear whether this medication your ability to aforementioned tasks out to perform, whether or not affects.

Lyrica contains lactose monohydrate

Consult your doctor before you this medicine take, if your doctor has told you that you certain sugars cannot tolerate ..

contains sodium This

This medicine contains less than 1 mmol sodium (23 mg) per hard capsule, which means that it is essentially 'sodium-free'. How

3. do you use this medicine?

Use this medicine always exactly as your doctor or pharmacist told you that .. you are unsure about the correct use? Then contact your doctor or pharmacist. Take not more of the medication than prescribed to you by.

Your doctor will determine which dose for u suitable is.

Lyrica is exclusively intended for oral use.

Peripheral and central neuropathic pain, epilepsy or generalized anxiety disorder:

- Take the number capsules that by your doctor is prescribed.
- The dosage is adjusted to you and your condition and will in the general range between 150 and 600 mg per day.
- Your doctor will tell you that you either twice or three times per day Lyrica must take. For twice per day take you Lyrica once in the morning and once in the evening in, every day at approximately the same time. For three times per day take Lyrica once in the morning, once in the afternoon in once 's evening in, every day at approximately the same time.

If you have the impression that the effect of Lyrica is too strong or to weak is, light than your doctor or Pharmacist in.

If you an older patient are (older than 65 years), must you take Lyrica in the usual dosage in take, except if you have with your kidneys have.

It is possible that your doctor you a other dosing schedule and/or other dosage prescribes if you have kidney problems ..

whole with water. Take Lyrica until

Take Lyrica until your doctor tells that you can stop.

Have you too much of this medicine used?

Contact your doctor or go to the nearest Emergency Department of a hospital. Take your box or bottle with Lyrica capsules with you. You may feel drowsy, confused, distressed or restless feel after you too much Lyrica have taken. Epileptic seizures and unconsciousness (coma) have also been reported.

Have you forgotten this medicine to use?

It is important to your Lyrica capsules every day regularly at the same time each to take. If you have forgotten a dose to take , do this as soon as possible as you think of it , unless it is except if the time is for your next dose. In that case take you simply the next dose in. Do not take a double dose to a missed dose in to catch up.

If you stop using use of this medicine

Do not suddenly stop taking Lyrica. If you want to stop with the taking of Lyrica, discuss this first with your doctor. He or she will tell you how to do this. If your treatment is discontinued, must this gradually happen over a period of at least 1 week. You must know that there with u certain side effects, so-called withdrawal symptoms, may occur after the discontinuation of a short- or long-term treatment with Lyrica. These side effects exist of: insomnia, headache, nausea, feeling anxious ,diarrhea ,flu-like symptoms ,seizures //convulsions (convulsions), nervousness, depression, thoughts of self-harm or suicide, pain, sweating and dizziness. These side effects may occur more frequently or become more severe if you have used Lyrica for a longer period of time . If you experiencewithdrawal symptoms withdrawal symptoms receives, must you contact contact with your doctor.

Do you any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medication can also this medication side effects have, although not everyone gets them tea experience.

Side effects that very often, in more than 1 in 10 people, occur

- dizziness, drowsiness, headache

Side effects that often, in less than 1 in 10 people, occur

- increased appetite
- feeling of euphoria, confusion, disorientation (disorientation), reduced sexual interest, irritability
- attention disorders, clumsiness, memory disorder, memory loss, uncontrolled tremors or shaking, speech disorders, tingling sensation, numbness, drowsiness/ sleepiness (sedation), somnolence (lethargy), insomnia, fatigue, you feel abnormally blurred
- vision see, double vision
- dizziness, problems with balance, falls
- dry mouth, constipation, vomiting, flatulence, diarrhea, nausea, bloated abdomen
- erectile dysfunction
- swelling of the body including the limbs
- a drunk feeling having, abnormal way of walking
- weight gain
- muscle cramp, pain in the joints, back pain, pain in the limbs (arms and/or legs)
- sore throat

Side effects that sometimes, in less than 1 in 100 people, occur

- loss of appetite, weight loss, lowering of blood sugar, increase in blood sugar
- changed self-awareness, restlessness, depression, agitation, mood changes, difficulty finding words , hallucinations, hallucinations, abnormal dreams, panic attacks, indifference, aggression, excessive cheerfulness, mental decline, problems with thinking, increased sexual interest, problems with sexual functioning including the difficulty reaching a sexual climax, delayed ejaculation (ejaculation)•

- changes in the vision, unusual eye movements, changes in the vision including tunnel vision (restricted visual field), flashes of light, spastic movements, decreased reflexes, hyperactivity, dizzy become upon standing, sensitive skin, loss of taste, burning sensation, tremors at move, decreased consciousness, loss of consciousness, fainting, increased sensitivity to sound, feeling not well feel
 - dry eyes, swollen eyes, eye pain, weak eyes, watery eyes, irritated eyes
 - arrhythmias, accelerated heart rate, low blood pressure, high blood pressure, changes in the heart rate, reduced function of the heart
 - flushing, hot flashes
 - breathing difficulties, dry nose, congested nose
 - increased saliva production, heartburn, numb around the mouth sweating
 - sweating rash skin rash cold cold chills, fever
 - muscle spasms, joint swelling, muscle stiffness, pain including muscle pain, pain in the neck
 - pain in the chest
 - difficult or painful urination, incontinence
 - weakness, thirst, tight sensation on the chest
 - changes in blood- and liver test results (increase of creatine phosphokinase, alanine aminotransferase and aspartate-aminotransferase in the blood, decrease in the number of platelets in the blood, deficiency of white blood cells that itself in in increased sensitivity to infections (neutropenia), more creatinine in the blood, less potassium in the blood)
 - hypersensitivity, swollen face, itching, skin rash with severe itching and formation of bumps (hives), runny nose, nosebleed, coughing, snoring
 - painful menstruations
 - cold hands and feet

Side effects that rarely, in less than 1 in 1,000 people, occur

- abnormal sense of smell, movement of the vision as soon as the head is moved, change
- in perception of depth, glare, loss of sight
- dilate of the pupils, cross-eyed look
- cold sweat, tightness in the throat, swollen tongue inflammation
- of the pancreas problems
- with swallowing swallow
- slow or decreased movement of the body
- problems with writing
- fluid retention in the (lower)abdomen
- fluid retention in the lungs
- seizures/convulsions (seizures)
- changes in the ECG (electrocardiogram) that correspond with disturbances of the
- heartbeat
- muscle damage
- spontaneous discharge from the breasts, abnormal breast growth, breast development in men
- disturbed menstrual pattern (irregular menstruations)
- reduced function of your kidneys (kidney failure), reduced excretion of urine, not able to urinate (urinary retention)
- decrease in the number white blood cells

- inappropriate behavior, suicidal behavior, suicidal thoughts
- allergic reactions, including possibly: difficulty breathing, inflamed eyes (keratitis) and severe reactions of the skin with characteristics: reddish, non-elevated, disc-shaped or circular spots on the trunk, often with blisters in the center of them, skin peeling, ulcers in and around the mouth, throat, nose or on the genitals and eyes; this severe skin rash is possibly preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis), jaundice
- (yellowing of skin and eyes)
- parkinsonism, that are symptoms that resemble disease of Parkinson appear, such as trembling, difficulty having with moving (bradykinesia) and stiff muscles

Side effects that very rarely, in less than 1 in 10,000 people, occur

- liver failure
- hepatitis (liver inflammation).

Not known: frequency can with the available data not be determined

- Dependent become of Lyrica ('drug dependence').

You must know that there in you certain side effects, so-called withdrawal symptoms, may occur after stopping treatment with a short- or long-term treatment with Lyrica (see "If you stop with the use of this medicine).

You must immediately seek medical advice if you notice that your tongue or face begins on to swell or if your skin red becomes and there blistering or peeling begins on to occur.

Certain side effects such as drowsiness may occur more frequently, because patients with spinal cord injury other medications may use for example pain of spasticity to treat. These medications have the same side effects as pregabalin and the severity of these side effects can increase are with simultaneous use.

The following side effect is reported after this medicine on the market is brought: difficulty with breathing, shallow breathing.

Report side effects of side effects

Do you experience side effects, contact your doctor or pharmacist. This applies also to possible side effects that are not in this leaflet. You can report side effects also directly via the national reporting system as stated in in appendix V. By side effects to report, you can help us obtain more information about the safety of this medication medication.

5. How do you store this medicine? Keep out of sight and reach of children. Do not use.

medication after the expiry date. the expiry date. You can find it on the box or the bottle after EXP. There is a month and a year. The last day of the month is the expiry date.

For this medicine there are no special storage conditions.

Do not flush medicines down the sink or the toilet and throw them not in the trash can. Ask your pharmacist what to do with medicines you should do not use anymore. If you medicines on the correct way disposes are they in a a responsible way destroyed and enter they not into the environment end up.

6. Contents of the packaging and other information

Which substances are in this medicine?

The active substance in this medicine is pregabalin. Each hard capsule contains 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg or 300 mg pregabalin.

The other ingredients in this product are: lactose monohydrate, corn starch, talc, gelatin, titanium dioxide (E171), sodium lauryl sulfate, anhydrous colloidal silicon dioxide, black ink (which shellac, iron oxide black (E172), propylene glycol and potassium hydroxide contains) in water.

The 75 mg, 100 mg, 200 mg, 225 mg and 300 mg capsules contain also red iron oxide (E172).

What does Lyrica look like and how much is in a package?

25 mg capsules	White hard capsules, with imprint "VTRS" on the upper part and "PGN 25" on the lower part of the capsule
50 mg capsules	White hard capsules, with imprint "VTRS" on the upper part and "PGN 50" on the lower part of the capsule. The lower part of the capsule is marked with a black band
75 mg capsules	White-orange hard capsules, with imprint "VTRS" on the upper part and "PGN 75" on the lower part of the capsule
100 mg capsules	Orange hard capsules, with imprint "VTRS" on the upper part and "PGN 100" on the lower part of the capsule
150 mg capsules	White hard capsules, with imprint "VTRS" on the upper part and "PGN 150" on the lower part of the capsule
200 mg capsules	Light orange hard capsules, with imprint "VTRS" on the upper part and "PGN 200" on the lower part of the capsule
225 mg capsules	White-light orange hard capsules, with imprint "VTRS" on the upper part and "PGN 225" on the lower part of the capsule
300 mg capsules	White-orange hard capsules, with imprint "VTRS" on the upper part and "PGN 300" on the lower part of the capsule

Lyrica is available in eight pack sizes manufactured from PVC with aluminum foil on the back side: a package of 14 capsules with 1 blister strip, a package of 21 capsules with 1 blister strip, a package of 56 capsules with 4 blister strips, a package of 70 capsules with 5 blister strips, a package of 84 capsules with 4 blister strips, a package of 100 capsules with 10 blister strips, a package of 112 capsules with 8 blister strips and a perforated unit dose blister pack of 100 x 1 capsules.

Lyrica is also available in an HDPE bottle with 200 capsules for de 25 mg, 75 mg, 150 mg and 300 mg strengths.

Not all mentioned package sizes are marketed . Holder.

authorization for marketing . in the market bring and manufacturer

Holder of the license for the placing on the market bring:

Upjohn EESV, Rivium Westlaan 142, 2909 LD Capelle on the IJssel, Netherlands.

Manufacturer:

Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79108 Freiburg im Breisgau, Germany.

or

Mylan Hungary Kft., Mylan street 1, Komárom 2900, Hungary.

or

MEDIS INTERNATIONAL a.s., manufacturing závod Bolatice, Průmyslová 961/16, 747 23 Bolatice, Czech Republic.

Contact for all information about this medication with the local representative of the holder of the authorization for placing on the market ::

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This leaflet is for the last approved in {MM/YYYY}.

More information about this medicine is available on the website of the European Medicines Agency: <http://www.ema.europa.eu>.

Transtoyou