NYRA 75 mg capsule

For oral use

Sold by prescription only.	**Pharmacological Class: Antiepileptic**	**Active Ingredient: Pregabalin**	**Not for use under 18 years of age.**

INGREDIENTS

Active ingredient: Each NYRA capsule contains 75 mg pregabalin.

Excipients: Lactose monohydrate (derived from cow's milk), corn starch, talc, titanium dioxide (E171), patent blue V (E131), carmoisine (E122), FD&C yellow #6 (E110), gelatin (bovine source).

Packaging: Presented in packages containing 14 capsules in PVC/PE/PVDC/aluminum foil blisters.

Before you start using this medicine, please read this PACKAGE LEAFLET carefully, as it contains important information for you.

Keep this package leaflet. You may need to read it again later.

If you have further questions, please ask your doctor or pharmacist.

This medicine has been prescribed for you personally, do not pass it on to others.

During the use of this medicine, if you go to a doctor or hospital, tell your doctor that you are using this medicine.

Follow the instructions in this leaflet exactly. Do not use **high or low** doses other than the dose recommended to you for this medicine.

IN THIS PACKAGE LEAFLET:

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What is NYRA and what is it used for?

NYRA 75 mg Capsule is an opaque white/opaque red, size 4 hard gelatin capsule containing white to off-white powder. Each capsule contains 75 mg pregabalin and is presented in packages containing 14 capsules in PVC/PE/PVDC/aluminum foil blisters.

The excipients in NYRA capsule include lactose, which is derived from cow's milk. The excipients in NYRA capsule include gelatin, which is bovine gelatin.

NYRA is an oral medication used as adjunctive therapy with other seizure medications in the treatment of partial epilepsy seizures; in the treatment of pain caused by damage to peripheral nerves (neuropathic pain), in the treatment of

generalized anxiety disorder, and in the treatment of fibromyalgia (a type of soft tissue pain that primarily affects muscles and the areas where muscles attach to bone, causing widespread pain).

NYRA is used in adults aged 18 years and older; its use is not recommended in individuals under 18 years of age due to insufficient safety and efficacy data.

INDICATION 1

Neuropathic Pain

NYRA is used in adults for long-term pain caused by damage to peripheral nerves. Many diseases such as diabetes and shingles can damage your nerves, causing nerve-related pain. This pain sensation can be described as hot, burning, stabbing, throbbing, aching, numbing, tingling, or as an electric shock, needle prick, sharp, cutting, or cramping pain. Neuropathic pain can lead to changes in your mood, sleep problems, and fatigue, affecting your physical and social life and overall quality of life.

INDICATION 2

Epilepsy

NYRA is used in adults to treat a type of epileptic seizure (partial convulsions with or without secondary generalized convulsions). Your doctor may add NYRA to your treatment when the medications you are currently taking cannot control your condition. NYRA is not intended for use alone in the treatment of epileptic seizures and is always used in conjunction with other medications used to control epileptic seizures.

INDICATION 3

Generalized Anxiety Disorder

NYRA is used in adults to treat generalized anxiety disorder. Symptoms of generalized anxiety disorder include persistent excessive anxiety and worry that is difficult to control. Generalized anxiety disorder can also lead to restlessness, sudden and intense excitement, feeling cornered, easily exhausted, difficulty concentrating, sudden forgetfulness, feeling irritable, muscle stiffness, or sleep problems. This is different from daily life stresses and worries.

INDICATION 4

Fibromyalgia

NYRA is used in adults for the treatment of fibromyalgia. Fibromyalgia is a type of soft tissue pain that primarily affects muscles and the areas where muscles attach to bone, causing widespread pain, and is more common in adults.

Things to consider before using NYRA

Do NOT use NYRA in the following situations

Do not use NYRA if you are allergic (hypersensitive) to pregabalin, the active ingredient of NYRA, or any of the other ingredients of the medicine. Do not use products with an open or damaged safety seal.

Use NYRA CAREFULLY in the following situations

Some patients using NYRA have reported symptoms suggestive of allergic reactions such as swelling of the face, lips, tongue and throat, as well as widespread skin rash. If you experience any of these reactions, contact your doctor immediately. NYRA should be discontinued immediately if symptoms such as swelling of the face, inside the mouth or upper respiratory tract occur.

Treatment with NYRA may increase the rate of accidental injuries (falls) in elderly patients due to drowsiness and dizziness. Therefore, if you are over 65, you should be careful until you have sufficient experience with all side effects of the drug.

NYRA may cause blurred vision or loss of vision, or other changes in vision, most of which are temporary. You should

consult your doctor immediately if you experience any changes in your vision.

If you have diabetes and have gained weight during pregabalin use, you may need a change in your diabetes medications.

In patients with spinal cord injury, some side effects such as drowsiness may be more common and their intensity may increase when these drugs are taken together, as they may also be taking other drugs with similar side effects to pregabalin, for example, to treat pain and spasticity.

Heart failure has been reported in some patients taking pregabalin; these patients are mostly elderly patients with cardiovascular diseases. You should tell your doctor if you have a history of heart disease before taking this medicine.

Kidney failure has been reported in some patients using pregabalin. If you notice a decrease in your urination, tell your doctor. Your doctor may discontinue the medication to correct this condition.

Thoughts of self-harm or suicide have been observed in some patients treated with antiepileptic drugs (effective in treating epilepsy) like NYRA. If you are having such thoughts or exhibiting such behaviors, you should seek help from your doctor.

When NYRA is taken with other medications that can cause constipation (such as some painkillers), gastrointestinal problems (e.g., constipation, cessation of bowel function) may occur. If you experience constipation, especially if you are prone to this problem, tell your doctor.

Tell your doctor if you have a history of alcohol or drug addiction or abuse. Do not use more medication than prescribed.

Seizures have been reported while taking pregabalin or immediately after stopping pregabalin. If you have a seizure, contact your doctor immediately.

In some patients using pregabalin, a decrease in brain function (encephalopathy) has been reported, also influenced by other conditions. If you have a history of severe liver or kidney disease, inform your doctor.

If these warnings apply to you, even at any time in the past, please consult your doctor.

Children and Adolescents

Safety and efficacy have not been established in children and adolescents (under 18 years of age). Therefore, pregabalin should not be used in this age group.

Use of NYRA with food and drink

NYRA can be taken with or without food.

Do not consume alcohol while using NYRA. Taking alcohol with NYRA will increase the frequency of side effects such as drowsiness and dizziness. This can be dangerous.

Pregnancy

Consult your doctor or pharmacist before using the medicine.

NYRA should not be used during pregnancy unless recommended by your doctor. Women of childbearing potential should use effective contraception to prevent pregnancy. If you become pregnant during treatment, think you are pregnant, or are planning to become pregnant, consult your doctor immediately.

If you discover that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breastfeeding

Consult your doctor or pharmacist before using the medicine.

It is recommended not to breastfeed your baby while using NYRA as it passes into breast milk. NYRA should not be used during breastfeeding unless recommended by your doctor.

Driving and using machines

> NYRA can cause dizziness and drowsiness and may reduce your attention. Do not drive or use machines and do not engage in potentially dangerous activities until you understand how NYRA affects you.

Important information about some excipients in NYRA

This product contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Carmoisine (E122) and FD&C yellow #6 (E110) contained in NYRA may cause allergic reactions.

Use with other medicines

NYRA and some other medicines may interact with each other. Concomitant use of NYRA with certain medications that have sedative effects (including opioids) may result in an increase in these effects and may lead to respiratory failure, coma, and death. If NYRA is taken with medications including the following, the severity of dizziness, drowsiness, and decreased attention may increase:

- Oxycodone (narcotic pain relievers)
- Lorazepam (medications used to treat anxiety)
- Alcohol

NYRA can be used with oral contraceptives.

If you are currently using or have recently used any prescription or non-prescription medicine, please inform your doctor or pharmacist.

How to use NYRA?

Instructions for proper use and dose / frequency of administration:

Always use NYRA exactly as your doctor has told you. If you are not sure, ask your doctor or pharmacist.

Your doctor will tell you when and how much NYRA to take.

Neuropathic Pain

- Take the dose of capsules prescribed by your doctor.
- The dose determined for you and your condition will generally be between 150 mg and 600 mg.
- Your doctor will tell you to take it 2 or 3 separate times a day. If taking NYRA twice a day, take it at the same time every day, morning and evening. If taking NYRA three times a day, take it at the same time every day, morning, noon, and evening.
- Your doctor may change the dose you are taking during treatment. Do not change the dose yourself without consulting your doctor.

Epilepsy

- Take the dose of capsules prescribed by your doctor.
- The dose determined for you and your condition will generally be between 150 mg and 600 mg.

Your doctor will tell you to take it 2 or 3 separate times a day. If taking NYRA twice a day, take it at the same time every day, morning and evening. If taking NYRA three times a day, take it at the same time every day, morning, noon, and evening.

Your doctor may change the dose you are taking during treatment. Do not change the dose yourself without consulting your doctor.

Generalized Anxiety Disorder

Take the dose of capsules prescribed by your doctor.

The dose determined for you and your condition will generally be between 150 mg and 600 mg in total.

Your doctor will tell you to take it 2 or 3 separate times a day. If taking NYRA twice a day, take it at the same time every day, morning and evening. If taking NYRA three times a day, take it at the same time every day, morning, noon, and evening.

Your doctor may change the dose you are taking during treatment. Do not change the dose yourself without consulting your doctor.

Fibromyalgia

Take the dose of capsules prescribed by your doctor.

The dose determined for you and your condition will generally be between 300 mg and 450 mg in total.

Your doctor will tell you to take it 2 or 3 separate times a day. If taking NYRA twice a day, take it at the same time every day, morning and evening. If taking NYRA three times a day, take it at the same time every day, morning, noon, and evening.

Your doctor may change the dose you are taking during treatment. Do not change the dose yourself without consulting your doctor.

If you think the effect of NYRA is too strong or too weak for you, tell your doctor or pharmacist.

Do not stop NYRA suddenly without consulting your doctor.

Method of administration:

NYRA is taken orally.

Swallow NYRA whole with a glass of water.

Different age groups:

Use in children:

There is insufficient safety and efficacy information regarding the use of NYRA in children and adolescents (under 18 years of age), therefore it should not be used in patients in this age group.

Use in the elderly:

NYRA can be used at normal doses in elderly patients (over 65 years of age) with normal kidney function. Doses of pregabalin may need to be reduced in elderly patients with reduced kidney function.

Special use cases:

Kidney failure:

If you have a kidney problem, your doctor may plan a different dosage and/or prescribe a different dose for you.

Liver failure:

No dose adjustment is required in patients with liver failure.

If you have the impression that the effect of NYRA is too strong or too weak, talk to your doctor or pharmacist.

If you have used more NYRA than you should:

If you have used more NYRA than you should, talk to a doctor or pharmacist.

If you have taken more NYRA than you should, call your doctor or go to the nearest health center immediately, taking the NYRA box you are using with you. You may feel sleepy, confused, aggressive or restless due to this condition. Seizures have also been reported.

If you forget to use NYRA:

It is important to use NYRA regularly at the same time each day.

If you forget to take your dose:

If it is not time for your next dose when you remember, take it as soon as you remember.

If it is time for your next dose or close to it when you remember, do not take the forgotten dose. Continue your normal dosing schedule by taking the next dose at the time specified in your prescription.

Do not take a double dose to make up for forgotten doses.

Effects that may occur when NYRA treatment is discontinued

Do not stop NYRA suddenly without consulting your doctor. Your treatment will be gradually reduced over at least 1 week. After long-term or short-term treatment, some side effects (withdrawal symptoms) may occur when your treatment is discontinued. These side effects include difficulty sleeping, headache, nausea, anxiety, diarrhea, flu-like symptoms, seizures, nervousness, depression, pain, sweating, drowsiness, and significant physical dependence. If you use NYRA for a longer period, the frequency and severity of these side effects may increase depending on the dose you use.

If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

What are the possible side effects?

Like all medicines, side effects may occur in people who are hypersensitive to the ingredients contained in NYRA.

If any of the following occur, stop using NYRA and IMMEDIATELY notify your doctor or go to the emergency department of the nearest hospital:

Swelling in the face

Swelling of the tongue

These are all very serious side effects.

If you have any of these, it means you have a severe allergy to NYRA. You may need urgent medical attention or hospitalization.

The side effects listed below may also be caused by an underlying disease or concomitant medications.

Side effects are classified as follows:
Very common :May be seen in at least 1 out of 10 patients.
Common :May be seen in less than 1 out of 10 patients but more than 1 out of 100 patients.

Uncommon :May be seen in less than 1 out of 100 patients but more than 1 out of 1,000 patients.
Rare :May be seen in less than 1 out of 1,000 patients but more than 1 out of 10,000 patients.

Very rare :May be seen in less than 1 out of 10,000 patients.
Unknown :Frequency cannot be estimated from the available data.

Very common:

Dizziness, drowsiness, headache

Common:

Increased appetite

Common cold (nasopharyngitis)

Exaggerated feeling of well-being, confusion, decreased sexual desire, hypersensitivity to environmental stimuli (irritability), disorientation (loss of sense of place and time)

Attention disorder, clumsiness, memory impairment, memory loss, tremor, speech disorder (dysarthria), burning, stinging, tingling sensation, numbness, calmness, lethargy, insomnia, extreme fatigue, feeling of abnormality

Blurred vision, double vision

Dizziness (vertigo), balance disorder, falls

Dry mouth, constipation, vomiting, gas, diarrhea, nausea, abdominal distension

Erectile dysfunction

Feeling of intoxication, abnormal gait

Swelling including arms and legs (peripheral edema), edema

Weight gain

Muscle cramps, joint pain, back pain, arm or leg pain, neck cramp (cervical spasm)

Dry throat

Irregularity in voluntary muscle movements (ataxia)

Chest pain

Inflammation of the air spaces within the facial bones (sinusitis)

Fluid retention

Muscle spasms

Anxiety

Pain in the pharynx and larynx

Sore throat

Flu-like symptoms

Difficulty breathing

Myasthenia

Abnormal gait

Uncommon:

Loss of appetite, weight loss, low blood sugar, high blood sugar

Depersonalization, feeling of loss of personal identity, restlessness, depression, agitation, mood swings, difficulty finding words, hallucination, abnormal dreams, irritability, extreme happiness, impairment in cognitive mental activities, difficulty thinking, increased sexual desire, sexual dysfunction including inability to orgasm, delayed ejaculation, short-term extreme restlessness (panic attack), apathy (indifference to environmental stimuli)

Visual field disturbances, abnormal eye movements, changes in vision in the form of tunnel vision, changes in vision such as light flashes, irregular movements, weakened reflexes, increased activity, dizziness upon standing, sensitive skin, loss of taste, burning sensation, tremor in purposeful movements, decreased consciousness, loss of consciousness, fainting, sensitivity to sound/noise, feeling unwell, impaired voluntary movements (dyskinesia)

Dry eyes, swollen eyes, decreased visual acuity, eye pain, increased tearing, eye irritation, eye fatigue (asthenopia)

Arrhythmias, increased heart rate, low blood pressure, high blood pressure, heart failure, slower than normal heart rate

Facial flushing, hot flashes, coldness in hands and feet

Shortness of breath, dry nose, nasal congestion

Increased saliva secretion, heartburn, numbness around the mouth

Sweating, red papular rashes, fever, hives (urticaria), itching

Muscle twitching, joint swelling, pain including muscle pain, muscle stiffness, neck pain

Breast pain

Painful and difficult urination, involuntary urine leakage

Weakness, thirst, chest tightness, generalized edema, pain, chills, fever, higher than normal body temperature

Changes in some blood and liver test results (increase in alanine aminotransferase, creatine phosphokinase and aspartate aminotransferase), decrease in platelet count, decrease in red blood cell count, neutropenia, increase in blood creatinine, decrease in blood potassium

Hypersensitivity, facial swelling, itching, hives, runny nose, nosebleeds, cough, snoring, inflammation of the nasal cavity (rhinitis)

Painful menstruation (dysmenorrhea)

Loss of sensitivity to stimuli in oral senses (oral hypoesthesia), speech disorder, flight of ideas (psychomotor hyperactivity), drowsiness/lethargy, forgetfulness, aggression

Decubitus ulcer

Rare:

Perceiving a non-existent smell (parosmia), objects viewed appearing to vibrate (oscillopsia), altered visual depth perception, visual brightness, vision loss

Pupil dilation, strabismus, light and color perception in the visual field in the form of sparks (photopsia)

Cold sweats, throat tightness, swollen tongue, dry throat

Pancreatitis

Difficulty swallowing

Slowed or reduced movements

Impaired writing ability (dysgraphia)

Fluid accumulation in the abdominal cavity

Fluid accumulation in the lungs

Seizure

Changes in electrical activity recordings of the heart (ECG) indicating cardiac arrhythmia

Increased heart rate (sinus tachycardia), irregular heart rhythm (sinus arrhythmia)

Muscle damage, severe muscle weakness and pain (rhabdomyolysis)

Breast discharge, abnormal breast enlargement, male breast enlargement

Absence of menstruation; amenorrhea

Kidney failure, decreased urine volume, less than normal urination, urine retention in the bladder

Decreased white blood cell count (decrease in white blood cells in the blood)

Inappropriate behavior, elevated mood

Allergic reactions (may include difficulty breathing, inflammation of the eyes (keratitis) and a severe skin infection characterized by rash, bumps, peeling skin, and skin pain (Stevens-Johnson syndrome))

Jaundice (yellowing of the skin and eyes)

Very rare:

Liver failure

Hepatitis (inflammation of the liver)

These are all serious side effects. Urgent medical intervention may be required.

If you encounter any side effects not mentioned in this package leaflet, inform your doctor or pharmacist.

Reporting of side effects

> If you experience any side effects, whether or not listed in this package leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects to the Turkish Pharmacovigilance Center (TÜFAM) by clicking on the "Drug Side Effect Notification" icon on the website www.titck.gov.tr or by calling the side effect notification line 0 800 314 00 08. By reporting side effects, you will contribute to obtaining more information about the safety of the medicine you are using.

How to store NYRA?

Keep NYRA out of the sight and reach of children and in its original packaging.

Store NYRA at room temperature below 25°C.

> **Use in accordance with the expiry date.**
>
> *Do not use NYRA after the expiry date on the packaging.*

Do not throw away expired or unused medicines! Give them to the collection system determined by the Ministry of Environment and Urbanization.

Do not use NYRA if you notice any defects in the product and/or its packaging.

Do not dispose of unused NYRA in city water or trash to protect the environment. Consult your pharmacist about this.

Marketing Authorisation Holder:

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