

Pregabalin Inovamed 25 mg Pregabalin Inovamed 50 mg Pregabalin Inovamed 75 mg Pregabalin Inovamed 150 mg Pregabalin Inovamed 300 mg Capsules

Active ingredient:

Pregabalin 25, 50, 75, 150, 300 mg

For a list of inactive and allergenic ingredients in the preparation, see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others; it may harm them even if it seems to you that their medical condition is similar to yours.

This medicine is not intended for treatment of children and adolescents under 18 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

For treatment of pain of neuropathic (neural) origin in adults, for treatment of fibromyalgia and for treatment of generalized anxiety disorder in adults.

Therapeutic group:

A gamma-aminobutyric acid analogue

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (detailed in section 6).

Special warnings regarding use of the medicine

Refer to your doctor before taking the medicine:

- Some patients taking Pregabalin Inovamed have reported allergic effects. These effects include swelling of the face, lips, tongue and throat, as well as a diffuse skin rash. If you experience one or more of these effects, refer to a doctor immediately.

- Serious skin rashes, such as Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in association with Pregabalin Inovamed use. Stop using the medicine and refer to a doctor immediately if you experience one or more of the symptoms related to the serious skin reactions described in section 4.

- The medicine may cause dizziness and sleepiness, such that elderly patients taking the preparation are at increased risk of falls and injuries. Exercise caution until you become accustomed to the effect of the medicine on you.

- The medicine may cause blurring or loss of vision, or other changes in eyesight, most of which are transient – inform the doctor immediately of any change that occurred in your vision.

- In some diabetic patients, who gain weight during treatment with the preparation, the dosage of medicines for lowering the blood sugar level may have to be adjusted.

- Certain side effects, such as sleepiness, may be more common, because patients with spinal cord injury may be taking other medicines to treat pain and spasticity. These have side effects similar to those of Pregabalin Inovamed and their severity may increase when these are taken together.

- Heart failure has been reported in a number of patients who took Pregabalin Inovamed, particularly, in elderly patients with heart and blood vessel diseases.

Before starting use of the medicine, inform the doctor if you are suffering, or have suffered in the past, from a heart disease.

- There have been several reports of renal failure due to treatment with Pregabalin Inovamed. If you notice decreased urination during the course of treatment with the medicine, inform the doctor, as discontinuation of treatment with the medicine should bring an improvement.

- Some patients who were treated with antiepileptic medicines such as Pregabalin Inovamed, have been reported about thoughts of harming or killing themselves or shown suicidal behavior. In case of onset of such thoughts or behavior at any stage, refer to the doctor immediately.

- The combination of Pregabalin Inovamed with other medicines (e.g., certain types of analgesics) which might cause constipation, may cause gastrointestinal problems (e.g., constipation, blocked or paralyzed bowel). Inform the doctor if you are suffering from constipation, especially if you are prone to constipation.

- Before commencing use of the medicine, inform the doctor if you are or have previously been dependent on or addicted to alcoholic beverages, drugs or any medicines. In this case, you may have a greater risk of becoming dependent on Pregabalin Inovamed.

- Convulsions may occur during treatment with the medicine or immediately after its discontinuation – inform the doctor immediately if you are suffering from convulsions.

- Reduced brain functioning (encephalopathy) has been reported in a number of patients with other underlying ailments.

Tell your doctor if you are aware of any medical condition that has significant consequences, including liver or kidney disease.

- There have been reports of breathing difficulties. If you have nervous system disorders, respiratory disorders, renal impairment, or you are older than 65, your doctor may prescribe you a different dosing regimen. Consult your doctor if you experience trouble breathing or shallow breaths.

Dependence

Some people may become dependent on Pregabalin Inovamed (a need to keep taking the medicine). They may have withdrawal symptoms when they stop using Pregabalin Inovamed (see section 3, "How should you use the medicine?" and "If you stop taking the medicine"). If you have concerns that you may become dependent on Pregabalin Inovamed, it is important that you consult your doctor.

If you notice any of the following signs while taking Pregabalin Inovamed, it could be a sign that you have become dependent:

- You need to take the medicine for longer than prescribed for you
- You feel you need to take more than the dose prescribed for you
- You are using the medicine for reasons other than those for which it was prescribed for you
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, refer to the doctor and consult the best treatment for you, including when you should stop taking the medicine and how to do this safely.

Drug interactions

If you are taking, or if have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Pregabalin Inovamed and certain other medicines may have mutual influences on activity.

If Pregabalin Inovamed is taken with certain medicines which have sedative effects (including opioids), Pregabalin Inovamed may increase these effects and lead to respiratory failure, coma and death. The degree of dizziness, sleepiness and decreased concentration may be increased if Pregabalin Inovamed is taken together with:

Oxycodone – an analgesic

Lorazepam – a medicine for treatment of anxiety

Alcohol

Pregabalin Inovamed may be taken with oral contraceptives.

Use of Pregabalin Inovamed and food

The medicine can be taken without regard to meals.

Use of Pregabalin Inovamed and consumption of alcohol

Do not consume alcohol during the course of treatment with the medicine.

Pregnancy, breastfeeding and fertility

Do not use Pregabalin Inovamed during pregnancy or when breastfeeding, unless the doctor has instructed you to do so after consulting with him. Pregabalin use during the first 3 months of pregnancy may cause birth defects in the unborn child that require medical treatment. In a study reviewing data from women in Nordic countries who took pregabalin in the first 3 months of pregnancy, 6 babies in every 100 had such birth defects. This compares to 4 babies in every 100 born to women not treated with pregabalin in the study. Abnormalities of the face (orofacial clefts), the eyes, the nervous system (including the brain), kidneys and genitals have been reported.

Women who may become pregnant during treatment with the medicine must use effective contraceptive measures.

Consult a doctor or pharmacist before using the medicine if you are pregnant or breastfeeding, if you suspect that you are pregnant or you are planning a pregnancy.

Driving and operating machinery

Do not drive or operate dangerous machinery until you know how the medicine affects you, since use of this medicine may cause dizziness, drowsiness or decreased concentration.

Important information about some of the ingredients of the medicine

This medicine contains less than 23 mg of sodium per capsule and is therefore considered sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and treatment regimen of the preparation, the dosage and treatment regimen will be determined by your doctor only.

Do not exceed the recommended dose!

Swallow the capsule whole. Do not open and disperse the contents of the capsule, since such forms of administration have not been tested. Swallow the medicine with water.

If you have taken an overdose or if a child has accidentally swallowed the medicine, refer to a doctor immediately or proceed to a hospital emergency room and bring the package of the medicine with you. You may feel sleepy, confused, anxious or restless as a result of taking an overdose of Pregabalin Inovamed. In addition, there have been reports of fits (convulsions) and unconsciousness (coma).

If you forget to take this medicine at the required time

It is important to take the medicine every day at a set time. If you forget to take this medicine at the designated time, do not take a double dose. Take the next dose at the usual time and consult the doctor.

Adhere to the treatment regimen as recommended by the doctor.

If you stop taking the medicine

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor. If discontinuation of treatment is decided upon, the doctor will explain you how to do it. Discontinuation of treatment with the medicine must be gradual, over a period of at least one week. After stopping treatment with the medicine (whether the treatment was short-term or long-term), you may experience certain symptoms called withdrawal symptoms. These symptoms include: insomnia, headaches, nausea, anxiety, flu-like symptoms, convulsions, nervousness, depression, pain, dizziness, sweating and diarrhea. These effects may be more common and more severe if the medicine has been taken for a longer period of time. If you experience withdrawal symptoms, refer to the doctor.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Pregabalin Inovamed may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Refer to a doctor immediately if you suffer from swelling of the face or tongue, or a severe skin reaction (the skin reddens and becomes covered with blisters or peels).

Very common side effects – effects that occur in more than 1 user in 10 are:

- Dizziness, feeling drowsy, headaches.

Common side effects – effects that occur in up to 1 user in 10:

- Increased appetite.
- Feeling of elation, confusion, disorientation, decreased libido, nervousness.
- Concentration or memory disturbance, loss of memory, clumsiness, tremor, speech disturbance, tingling feeling, numbness, sedation, lethargy, insomnia, fatigue, a strange feeling.
- Blurred vision, double vision.
- Vertigo, balance disorders, falls.
- Dry mouth, constipation, vomiting, flatulence, diarrhea, nausea, swollen abdomen.
- Erection problems.
- Swelling of the body including the extremities.
- Feeling drunk, abnormal style of walking.
- Weight gain.
- Muscle cramps, joint pain, back and limb pains.
- Sore throat.

Uncommon side effects – effects that occur in up to 1 user in 100:

- Loss of appetite, weight loss, decreased blood sugar level, increased blood sugar level.
- Change in self-perception, restlessness, depression, anxiety, mood swings, difficulty finding words, hallucinations, strange dreams, panic attacks, apathy, aggression, elevated mood, mental disorder, difficulty with thinking, increased libido, problems with sexual functioning, including inability to achieve a sexual climax, delayed ejaculation.
- Vision changes including loss of peripheral vision, nystagmus, flashes of light, jerky movements, decreased reflex responses, increased activity, dizziness when standing, skin sensitivity, loss of taste, burning sensation, tremor on movement, decreased level of consciousness, loss of consciousness, fainting, increased sensitivity to noise, feeling ill.
- Dry eyes, eye swelling or pain, weak eyes, watery eyes, eye irritation.
- Heart rhythm disturbances, increased heart rate, low or high blood pressure, changes in pulse, heart failure.
- Flushing, hot flushes.
- Difficulty breathing, dry nose, nasal congestion.
- Increased saliva production, heartburn, numbness around the mouth.
- Sweating, rash, chills, fever.
- Muscle twitching, joint swelling, muscle stiffness, pain including muscle pain, neck pain.
- Breast pain.
- Difficulty with or painful urination, incontinence.
- Weakness, thirst, chest tightness.
- Changes in blood and liver function tests (increased blood creatine phosphokinase, increased liver enzymes, decreased blood platelets, neutropenia, increased blood creatinine, decrease in blood potassium).
- Hypersensitivity, swollen face, itching, hives, runny nose, nosebleed, cough, snoring.
- Painful menstrual periods.
- Cold hands and feet.

Rare side effects – effects that occur in up to 1 user in 1,000:

- Abnormal sense of smell, swinging vision, change in depth perception, visual brightness, vision loss.
- Dilated pupils, crossed eyes.
- Cold sweat, irritation of the throat, swollen tongue.
- Inflammation of the pancreas.
- Difficulty in swallowing.
- Slower or reduced movement of the body.
- Writing difficulty.
- Edema in the abdominal area.
- Fluid in the lungs.
- Convulsions.
- Changes in ECG which correspond to heart rhythm disturbances.
- Muscle damage.
- Breast discharge, abnormal breast growth, breast growth in men.
- Menstrual period disturbances.
- Kidney failure, reduced urine volume, urinary retention.
- Decrease in white blood cell count in blood tests.
- Abnormal behavior, suicidal behavior, suicidal thoughts.
- Allergic reactions (may be manifested by: breathing difficulties, inflammation of the eyes [keratitis] and serious skin reactions characterized by reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [Stevens-Johnson syndrome, toxic epidermal necrolysis]).
- Jaundice (yellowing of the skin and whites of the eyes).
- Parkinsonism, i.e., symptoms similar to Parkinson's disease, such as: tremor, bradykinesia (impaired ability to move), and rigidity (muscle stiffness).

Very rare side effects – effects that occur in up to 1 user in 10,000:

- Liver failure.
- Hepatitis (inflammation of the liver).

Side effects of unknown frequency:

- Becoming dependent on Pregabalin Inovamed

After stopping treatment with Pregabalin Inovamed (whether the treatment was short-term or long-term), you may experience certain symptoms called withdrawal symptoms (see Section 3 "**If you stop taking the medicine**").

Certain side effects, such as sleepiness, may be more common, because patients with spinal cord injury may be taking additional medicines to treat pain and spasticity. These have side effects similar to those of Pregabalin Inovamed and their severity may increase when these are taken together.

The following side effects have been reported after marketing of the medicine: difficulty breathing and shallow breathing.

If a side effect occurs, if any of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions:

- Store below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Starch pregelatinized (maize), Talc, Gelatin, Purified water, Titanium dioxide (E 171), Sodium lauryl sulfate.

Pregabalin Inovamed 75 mg and 300 mg capsules also contain: Iron oxide red (E 172)

What does the medicine look like and what are the contents of the package:

Pregabalin Inovamed 25 mg – A white opaque capsule, 'PG' is imprinted on the cap and '25' is imprinted on the body of the capsule.

Pregabalin Inovamed 50 mg – A white opaque capsule, 'PG' is imprinted on the cap and '50' is imprinted on the body of the capsule.

Pregabalin Inovamed 75 mg – A red/white opaque capsule, 'PG' is imprinted on the cap and '75' is imprinted on the body of the capsule.

Pregabalin Inovamed 150 mg – A white opaque capsule, 'PG' is imprinted on the cap and '150' is imprinted on the body of the capsule.

Pregabalin Inovamed 300 mg – A red/white opaque capsule, 'PG' is imprinted on the cap and '300' is imprinted on the body of the capsule.

Package size: The medicine is supplied in the package as follows:

Carton packages each containing 4 trays/blisters of 14 capsules, totaling 56 capsules in a carton package. The number of capsules appears on the carton packaging.

Registration Holder and its Address: Inovamed Ltd, 55 Beer Ganim Street, P.O.B. 62, Even Yehuda 40500.

Name of Manufacturer and its Address: Intas Pharmaceuticals Ltd., Ahmedabad, Gujarat, India.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Pregabalin Inovamed 25 mg – 156-14-34772

Pregabalin Inovamed 50 mg – 156-15-34726

Pregabalin Inovamed 75 mg – 156-16-34773

Pregabalin Inovamed 150 mg – 156-17-34774

Pregabalin Inovamed 300 mg – 156-18-34738