Package Leaflet: Information for the user

Pregabalin Milpharm 25 mg capsules, hard
Pregabalin Milpharm 50 mg capsules, hard
Pregabalin Milpharm 75 mg capsules, hard
Pregabalin Milpharm 100 mg capsules, hard
Pregabalin Milpharm 150 mg capsules, hard
Pregabalin Milpharm 200 mg capsules, hard
Pregabalin Milpharm 225 mg capsules, hard
Pregabalin Milpharm 300 mg capsules, hard

pregabalin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them,even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Pregabalin Milpharm is and what it is used for
2. What you need to know before you take Pregabalin Milpharm
3. How to take Pregabalin Milpharm
4. Possible side effects
5. How to store Pregabalin Milpharm
6. Contents of the pack and other information

1. What Pregabalin Milpharm is and what it is used for

This medicine has been prescribed for you to treat epilepsy, neuropathic pain and Generalised Anxiety Disorder (GAD) in adults.

Peripheral and central neuropathic pain: Pregabalin Milpharm is used to treat long lasting pain caused by damage to the nerves. A variety of diseases can cause peripheral neuropathic pain, such as diabetes or shingles. Pain sensations may be described as hot, burning, throbbing, shooting, stabbing, sharp, cramping, aching, tingling, numbness, pins and needles. Peripheral and central neuropathic pain may also be associated with mood changes, sleep disturbance, fatigue (tiredness), and can have an impact on physical and social functioning and overall quality of life.

Epilepsy: Pregabalin Milpharm is used to treat a certain form of epilepsy (partial seizures with or without secondary generalisation) in adults. Your doctor will prescribe Pregabalin Milpharm for you to help treat your epilepsy when your current treatment is not controlling your condition. You should take Pregabalin Milpharm in addition to your current treatment. Pregabalin Milpharm is not intended to be used alone, but should always be used in combination with other anti-epileptic treatment.

Generalised Anxiety Disorder: Pregabalin Milpharm is used to treat Generalised Anxiety Disorder(GAD). The symptoms of GAD are prolonged excessive anxiety and worry that are difficult to control.GAD can also cause restlessness or feeling keyed up or on edge, being easily fatigued (tired), having difficulty concentrating or mind going blank, feeling irritable, having muscle tension or sleep disturbance.This is different to the stresses and strains of everyday life.

It contains the pregabalin which belongs to a class of medicines called Gabapentinoids.

This medicine has been prescribed to you and should not be given to anyone else.

Gabapentinoids can cause dependence, tolerance and addiction, and you may get withdrawal symptoms if you stop taking it or reduce the dose suddenly. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months. If this medicine is being used for the treatment of epilepsy you must continue to take it as prescribed by your doctor.

2. What you need to know before you take Pregabalin Milpharm

Do not take Pregabalin Milpharm
If you are allergic to pregabalin or any of the other ingredients of this medicine (listed in section 6).

Warnings and Precautions
Talk to your prescriber before taking this medicine if:
- Some patients taking Pregabalin Milpharm have reported symptoms suggesting an allergic reaction. These symptoms include swelling of the face, lips, tongue, and throat, as well as diffuse skin rash. Should you experience any of these reactions, you should contact your physician immediately.
- Pregabalin Milpharm has been associated with dizziness and somnolence, which could increase the occurrence of accidental injury (fall) in elderly patients. Therefore, you should be careful until you are used to any effect the medicine might have.
- Pregabalin Milpharm may cause blurring or loss of vision, or other changes in eyesight, many of which are temporary. You should immediately tell your doctor if you experience any changes in your vision.
- Some patients with diabetes who gain weight while taking pregabalin may need an alteration in their diabetic medicines.
- Certain side effects may be more common, such as sleepiness, because patients with spinal cord injury may be taking other medicines to treat, for example, pain or spasticity, that have similar side effects to Pregabalin and the severity of these effects may be increased when taken together.
- There have been reports of heart failure in some patients when taking Pregabalin Milpharm; these patients were mostly elderly with cardiovascular conditions. **Before taking this medicine you should tell your doctor if you have a history of heart disease**.
- There have been reports of kidney failure in some patients when taking Pregabalin Milpharm. If while taking Pregabalin Milpharm you notice decreased urination, you should tell your doctor as stopping the medicine may improve this.
- Some patients being treated with anti-epileptics such as Pregabalin Milpharm have had thoughts of harming or killing themselves or shown suicidal behaviour. If at any time you have these thoughts or shown such behaviour, immediately contact your doctor.
- When Pregabalin Milpharm is taken with other medicines that may cause constipation (such as some types of pain medicines) it is possible that gastrointestinal problems may occur (e.g., constipation, blocked or paralysed bowel). Tell your doctor if you experience constipation, especially if you are prone to this problem.
- Before taking this medicine, tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or illegal drugs; it may mean you have a greater risk of becoming dependent on Pregabalin Milpharm.
- There have been reports of convulsions when taking Pregabalin Milpharm or shortly after stopping Pregabalin Milpharm. If you experience a convulsion, contact your doctor immediately.
- There have been reports of reduction in brain function (encephalopathy) in some patients taking Pregabalin Milpharm when they have other conditions. Tell your doctor if you have a history of any serious medical conditions, 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. Contact your doctor if you experience trouble breathing or shallow breaths.
- Serious skin rashes including Stevens-Johnson syndrome, toxic epidermal necrolysis have been reported in association with pregabalin. Stop using pregabalin and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.
- you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs, or if you have ever had a history of struggling to control your alcohol or drug intake.
- you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- you feel you need to take more of pregabalin to get the same level of symptom control, this may mean you are developing tolerance to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative medication.

Taking this medicine regularly, particularly for a long time, can lead to physical dependence and addiction. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

Physical dependence and addiction can cause withdrawal symptoms when you stop taking this medicine.

Withdrawal symptoms can include: trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flu-like symptoms, convulsions, nervousness, depression, thoughts of harming or killing yourself, pain, sweating, and dizziness.

Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Gabapentinoids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of gabapentinoids may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

If you notice any of these, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to do this safely.

Children and adolescents
The safety and efficacy in children and adolescents (under 18 years of age) has not been established and therefore, pregabalin should not be used in this age group.

Other medicines and Pregabalin Milpharm
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregabalin Milpharm and certain other medicines may influence each other (interaction). When taken with certain other medicines which have sedative effects (including opioids), Pregabalin Milpharm may potentiate these effects, and could lead to respiratory failure, coma and death. The degree of dizziness, sleepiness and decreased concentration may be increased if Pregabalin Milpharm is taken together with medicines containing:
Oxycodone – (used as a pain-killer)
Lorazepam – (used for treating anxiety)
Alcohol
Pregabalin Milpharm may be taken with oral contraceptives.

Pregabalin Milpharm with food, drink and alcohol
Pregabalin Milpharm capsules may be taken with or without food.

It is advised not to drink alcohol while taking Pregabalin Milpharm.

Pregnancy, breast-feeding and fertility
Pregabalin Milpharm should not be taken during pregnancy or when breast-feeding, unless you are told other wise by your doctor. 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.

Effective contraception must be used by women of child-bearing potential. If you are pregnant or breast-feeding,think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Pregabalin Milpharm may produce dizziness, sleepiness and decreased concentration. You should not drive, operate complex machinery or engage in other potentially hazardous activities until you know whether this medicine affects your ability to perform these activities.

Pregabalin Milpharm contains Sodium:
This medicine contains less than 1 mmol sodium (23 mg) per each capsule, that is to say essentially ‘sodium-free’.

3. How to take Pregabalin Milpharm

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Do not take more medicine than prescribed.

Your doctor will determine what dose is appropriate for you.

Pregabalin Milpharm is for oral use only.

Your prescriber should have discussed with you how long the course of capsules will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Peripheral and central neuropathic pain, epilepsy or Generalised Anxiety Disorder:
- Take the number of capsules as instructed by your doctor.
- The dose, which has been adjusted for you and your condition, will generally be between 150 mg and 600 mg each day.
- Your doctor will tell you to take Pregabalin Milpharm either twice or three times a day. For twice a day take Pregabalin Milpharm once in the morning and once in the evening, at about the same time each day. For three times a day take Pregabalin Milpharm once in the morning, once in the afternoon and once in the evening, at about the same time each day.

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

If you are an elderly patient (over 65 years of age), you should take Pregabalin Milpharm normally except if you have problems with your kidneys.
Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

Swallow the capsule whole with water.

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Continue taking Pregabalin Milpharm until your doctor tells you to stop.

If you take more Pregabalin Milpharm than you should Call your doctor or go to the nearest hospital emergency unit immediately. Take your box or bottle of Pregabalin Milpharm capsules with you. You may feel sleepy, confused, agitated, or restless as a result of taking more Pregabalin Milpharm than you should. Fits and unconsciousness (coma) have also been reported.

If you forget to take Pregabalin Milpharm
It is important to take your Pregabalin Milpharm capsules regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. In that case, just carry on with the next dose as normal. Do not take a double dose to make up for a forgotten dose.

If you stop taking Pregabalin Milpharm
Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. This may occur over a period of weeks to months. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Withdrawal symptoms such as: trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flu-like symptoms, convulsions, nervousness, depression, thoughts of harming or killing yourself, pain, sweating, and dizziness.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common (may affect more than 1 in 10 people):
Dizziness, drowsiness, headache

Common (may affect up to 1 in 10 people):
- Increased appetite
- Feeling of elation, confusion, disorientation, decrease in sexual interest, irritability
- Disturbance in attention, clumsiness, memory impairment, loss of memory, tremor, difficulty with speaking, tingling feeling, numbness, sedation, lethargy, insomnia, fatigue, feeling abnormal
- Blurred vision, double vision
- Vertigo, problems with balance, fall
- Dry mouth, constipation, vomiting, flatulence, diarrhoea, nausea, swollen abdomen
- Difficulties with erection
- Swelling of the body including extremities
- Feeling drunk, abnormal style of walking
- Weight gain
- Muscle cramp, joint pain, back pain, pain in limb
- Sore throat

Uncommon (may affect up to 1 in 100 people)**:**
- Loss of appetite, weight loss, low blood sugar, high blood sugar.
- Change in perception of self, restlessness, depression, agitation, mood swings, difficulty finding words, hallucinations, abnormal dreams, panic attacks, apathy, aggression, elevated mood, mental impairment, difficulty with thinking, increase in sexual interest, problems with sexual functioning including inability to achieve a sexual climax, delayed ejaculation.
- Changes in eyesight, unusual eye movement, changes in vision including tunnel vision, flashes of light, jerky movements, reduced reflexes, increased activity, dizziness on standing, sensitive skin, loss of taste, burning sensation, tremor on movement, decreased consciousness, loss of consciousness, fainting, increased sensitivity to noise, feeling unwell.
- Dry eyes, eye swelling, eye pain, weak eyes, watery eyes, eye irritation.
- Heart rhythm disturbances, increased heart rate, low blood pressure, high blood pressure, changes in heart beat, heart failure.
- Flushing, hot flushes.
- Difficulty breathing, dry nose, nasal congestion.
- Increased saliva production, heartburn, numb around 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 test results (blood creatinine phosphokinase increased, alanine amino transferase increased, aspartate amino transferase increased, platelet count decreased, neutropaenia, increase in blood creatinine, decrease in blood potassium).
- Hypersensitivity, swollen face, itchiness, hives, runny nose, nose bleed, cough, snoring.
- Painful menstrual periods.
- Coldness of hands and feet.

Rare (may affect up to 1 in 1,000 people):
- Abnormal sense of smell, swinging vision, altered perception of depth, visual brightness, vision loss.
- Dilated pupils, cross eyes.
- Cold sweat, tightness of the throat, swollen tongue.
- Inflammation of the pancreas.
- Difficulty in swallowing.
- Slow or reduced movement of the body.
- Difficulty with writing properly.
- Increased fluid in the abdomen.
- Fluid in the lungs
- Convulsions
- Changes in the recording of electrical changes (ECG) in the heart which correspond to heart rhythm disturbances
- Muscle damage.
- Breast discharge, abnormal breast growth, breast growth in males.
- Interrupted menstrual periods.
- Kidney failure, reduced urine volume, urinary retention.
- Decrease in white blood cell count.
- Inappropriate behaviour, suicidal behaviour, suicidal thoughts.
- Allergic reactions which may include difficulty breathing, inflammation of the eyes (keratitis) and a serious skin reaction 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 eyes).
- Parkinsonism, that is symptoms resembling Parkinson's disease; such as tremor, bradykinesia (decreased ability to move), and rigidity (muscle stiffness).

Very rare (may affect up to 1 in 10,000 people)
- Liver failure.
- Hepatitis (inflammation of the liver).

Not known: frequency cannot be estimated from the available data
- Dependence and addiction (see section "How do I know if I am tolerant or addicted?").

Drug Withdrawal
When you stop taking pregabalin, you may experience drug withdrawal symptoms, which include: trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flu-like symptoms, convulsions, nervousness, depression, thoughts of harming or killing yourself, pain, sweating, and dizziness.

How do I know if I am tolerant or addicted?
If you notice any of the following signs whilst taking <product name>, it could be a sign that you have become addicted.
- You may feel the need to keep taking the medication for longer than your doctor recommended
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- 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, it is important you talk to your prescriber.

If you experience swollen face or tongue or if your skin turns red and starts to blister or peel you should seek immediate medical advice.
Certain side effects may be more common, such as sleepiness, because patients with spinal cord injury may be taking other medicines to treat, for example, pain or spasticity, that have similar side effects to Pregabalin and the severity of these effects may be increased when taken together.

The following adverse reaction has been reported in the postmarketing experience: Trouble breathing, shallow breaths.

Reporting of side effects
If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pregabalin Milpharm

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label,carton or bottle after EXP.The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Pregabalin Milpharm contains
The active substance is pregabalin.
Each capsule, hard contains 25 mg of pregabalin.
Each capsule, hard contains 50 mg of pregabalin.
Each capsule, hard contains 75 mg of pregabalin.
Each capsule, hard contains 100 mg of pregabalin.
Each capsule, hard contains 150 mg of pregabalin.
Each capsule, hard contains 200 mg of pregabalin.
Each capsule, hard contains 225 mg of pregabalin.
Each capsule, hard contains 300 mg of pregabalin.
The other ingredients are:
Capsules content: Maize starch, talc

Capsules shell: Titanium dioxide (E171), gelatin, sodium lauryl sulfate, iron oxide red (E 172) (For 75 mg, 100 mg, 200 mg, 225 mg and 300 mg)

Printing Ink: Shellac, propylene glycol, black iron oxide (E172), potassium hydroxide.

What Pregabalin Milpharm looks like and contents of the pack
Capsule, hard.

Pregabalin Milpharm 25 mg capsules, hard
White cap/white body, size "5" hard gelatin capsule shells, imprinted with 'Z' on cap and '10' on body with black ink contains white to off-white granular powder.

Pregabalin Milpharm 50 mg capsules, hard
White cap/white body, size "4" hard gelatin capsule shells, imprinted with 'Z' on cap and '11' on body with black ink contains white to off-white granular powder.

Pregabalin Milpharm 75 mg capsules, hard
Orange cap/white body, size "4" hard gelatin capsule shells, imprinted with 'Z' on cap and '12' on body with black ink contains white to off-white granular powder.

Pregabalin Milpharm 100 mg capsules, hard
Orange cap/Orange body, size "3" hard gelatin capsule shells, imprinted with 'Z' on cap and '13' on body with black ink contains white to off-white granular powder.

Pregabalin Milpharm 150 mg capsules, hard
White cap/white body, size "2" hard gelatin capsule shells, imprinted with 'Z' on cap and '14' on body with black ink contains white to off-white granular powder.

Pregabalin Milpharm 200 mg capsules, hard
Light orange cap/ Light orange body, size "1" hard gelatin capsule shells, imprinted with 'Z' on cap and '15' on body with black ink contains white to off-white granular powder.

Pregabalin Milpharm 225 mg capsules, hard
Light orange cap/ White body, size "1" hard gelatin capsule shells, imprinted with 'Z' on cap and '16' on body with black ink contains white to off-white granular powder.

Pregabalin Milpharm 300 mg capsules, hard
Orange cap/ White body, size "0" hard gelatin capsule shells, imprinted with 'Z' on cap and '17' on body with black ink contains white to off-white granular powder.

Pregabalin Milpharm hard capsules are available in clear PVC/ Aluminium blisters pack and white opaque HDPE bottles with polypropylene closure.

Pack sizes:
Blister packs: 14, 21, 30, 56, 60, 84, 90, 100, 112 and 200 capsules, hard

HDPE Bottle packs:
50 mg, 75 mg, 150 mg, 200 mg, 225 mg: 30, 200, 250 and 500 capsules, hard
25 mg, 100 mg, 300 mg: 30, 200, 250 and 500 capsules, hard

Not all pack sizes may be marketed.

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