



#### 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 aminotransferase increased, aspartate aminotransferase increased, platelet count decreased, neutropenia, 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 serious skin reaction characterised 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**

- Becoming dependent on Pregabalin Mylan ('drug dependence').

After stopping a short or long-term treatment with Pregabalin Mylan, you need to know that you may experience certain side effects, so-called withdrawal effects (see "If you stop taking Pregabalin Mylan").

**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 side effects were reported in the postmarketing experience: trouble breathing, shallow breaths.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://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 Mylan

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 carton and blister after EXP. The expiry date refers to the last day of that month.

Blister: Store in the original package in order to protect from moisture.

Bottle: Keep the bottle tightly closed in order to protect from moisture.

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 protect the environment.

#### 6. Contents of the pack and other information

##### What Pregabalin Mylan contains

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

The other ingredients are: hydroxypropylcellulose, maize starch, talc, gelatin, titanium dioxide (E171), sodium laurilsulfate, purified water, shellac, black iron oxide (E172), propylene glycol, potassium hydroxide and concentrated ammonia solution, yellow iron oxide (E172) and erythrosine (E127).

##### What Pregabalin Mylan looks like and contents of the pack

Pregabalin Mylan 25 mg hard capsule	Light peach opaque cap and white opaque body, hard-shell gelatin capsule filled with white to off-white powder. The capsule is axially printed with <b>MYLAN</b> over <b>PB25</b> in black ink on cap and body.  Available in blister packs containing 14, 21, 56, 84, 100 capsules and in perforated unit dose blister packs containing 56 x 1, 84 x 1, 100 x 1 capsules.
Pregabalin Mylan 50 mg hard capsule	Dark peach opaque cap and white opaque body, hard-shell gelatin capsule filled with white to off-white powder. The capsule is axially printed with <b>MYLAN</b> over <b>PB50</b> in black ink on cap and body.  Available in blister packs containing 14, 21, 56, 84, 100 capsules and in perforated unit dose blister packs containing 84 x 1, 100 x 1 capsules.
Pregabalin Mylan 75 mg hard capsule	Light peach opaque cap and light peach opaque body, hard-shell gelatin capsule filled with white to off-white powder. The capsule is axially printed with <b>MYLAN</b> over <b>PB75</b> in black ink on cap and body.  Available in blister packs containing 14, 56, 100 capsules, in perforated unit dose blister packs containing 14 x 1, 56 x 1, 100 x 1 capsules and in bottles containing 200 capsules.
Pregabalin Mylan 100 mg hard capsule	Dark peach opaque cap and dark peach opaque body, hard-shell gelatin capsule filled with white to off-white powder. The capsule is axially printed with <b>MYLAN</b> over <b>PB100</b> in black ink on cap and body.  Available in blister packs containing 21, 84, 100 capsules and in perforated unit dose blister packs containing 84 x 1, 100 x 1 capsules.
Pregabalin Mylan 150 mg hard capsule	Light peach opaque cap and white opaque body, hard-shell gelatin capsule filled with white to off-white powder. The capsule is axially printed with <b>MYLAN</b> over <b>PB150</b> in black ink on cap and body.  Available in blister packs containing 14, 56, 100 capsules, in perforated unit dose blister packs containing 14 x 1, 56 x 1, 100 x 1 capsules and in bottles containing 200 capsules.
Pregabalin Mylan 200 mg hard capsule	Light peach opaque cap and light peach opaque body, hard-shell gelatin capsule filled with white to off-white powder. The capsule is axially printed with <b>MYLAN</b> over <b>PB200</b> in black ink on cap and body.  Available in blister packs containing 21, 84, 100 capsules and in perforated unit dose blister packs containing 84 x 1, 100 x 1 capsules.
Pregabalin Mylan 225 mg hard capsule	Dark peach opaque cap and dark peach opaque body, hard-shell gelatin capsule filled with white to off-white powder. The capsule is axially printed with <b>MYLAN</b> over <b>PB225</b> in black ink on cap and body.  Available in blister packs containing 14, 56, 100 capsules and in perforated unit dose blister packs containing 56 x 1, 100 x 1 capsules.
Pregabalin Mylan 300 mg hard capsule	Light peach opaque cap and white opaque body, hard-shell gelatin capsule filled with white to off-white powder. The capsule is axially printed with <b>MYLAN</b> over <b>PB300</b> in black ink on cap and body.  Available in blister packs containing 14, 56, 100 capsules, in perforated unit dose blister packs containing 56 x 1, 100 x 1 capsules and in bottles containing 200 capsules.

Not all pack sizes may be marketed.

##### Marketing Authorisation Holder

Mylan, Station Close, Potters Bar, Herts, EN6 1TL.

##### Manufacturer

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[ Back Page #2 ]

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