9. SPECIAL STORAGE CONDITIONS

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

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Mylan S.A.S.
117 Allée des Parcs
69800 Saint-Priest
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/15/998/022

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

Pregabalin Mylan Pharma 100 mg hard capsules
pregabalin

2. STATEMENT OF ACTIVE SUBSTANCE

Each hard capsule contains 100 mg pregabalin.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Hard capsule.

21 hard capsules
84 hard capsules
100 hard capsules
84 x 1 hard capsules
100 x 1 hard capsules

5. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

Oral use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

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

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Mylan S.A.S.
117 Allée des Parcs
69800 Saint-Priest
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/15/998/023
EU/1/15/998/024
EU/1/15/998/025
EU/1/15/998/026
EU/1/15/998/027

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Pregabalin Mylan Pharma 100 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC
SN
NN

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Pregabalin Mylan Pharma 100 mg hard capsules
pregabalin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Mylan S.A.S

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON FOR BLISTER AND BOTTLE

1. NAME OF THE MEDICINAL PRODUCT

Pregabalin Mylan Pharma 150 mg hard capsules
pregabalin

2. STATEMENT OF ACTIVE SUBSTANCE

Each hard capsule contains 150 mg pregabalin.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Hard capsule.

14 hard capsules
56 hard capsules
100 hard capsules
200 hard capsules
14 x 1 hard capsules
56 x 1 hard capsules
100 x 1 hard capsules

5. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Blister: Store in the original package in order to protect from moisture.
Bottle: Keep the bottle tightly closed in order to protect from moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Mylan S.A.S
117 Allée des Parcs
69800 Saint-Priest
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/15/998/028
EU/1/15/998/029
EU/1/15/998/030
EU/1/15/998/034
EU/1/15/998/031
EU/1/15/998/032
EU/1/15/998/033

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Pregabalin Mylan Pharma 150 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC
SN
NN

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Pregabalin Mylan Pharma 150 mg hard capsules
pregabalin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Mylan S.A.S

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

BOTTLE LABEL

1. NAME OF THE MEDICINAL PRODUCT

Pregabalin Mylan Pharma 150 mg hard capsules
pregabalin

2. STATEMENT OF ACTIVE SUBSTANCE

Each hard capsule contains 150 mg pregabalin.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Hard capsule.

200 hard capsules

5. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

Oral use.

<For multilayer label only>
'Peel here'

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

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

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Mylan S.A.S.
117 Allée des Parcs
69800 Saint-Priest
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/15/998/034

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

Pregabalin Mylan Pharma 200 mg hard capsules
pregabalin

2. STATEMENT OF ACTIVE SUBSTANCE

Each hard capsule contains 200 mg pregabalin.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Hard capsule.

21 hard capsules
84 hard capsules
100 hard capsules
84 x 1 hard capsules
100 x 1 hard capsules

5. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

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

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Mylan S.A.S
117 Allée des Parcs
69800 Saint-Priest
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/15/998/035
EU/1/15/998/036
EU/1/15/998/037
EU/1/15/998/038
EU/1/15/998/039

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Pregabalin Mylan Pharma 200 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC
SN
NN

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Pregabalin Mylan Pharma 200 mg hard capsules
pregabalin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Mylan S.A.S

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

Pregabalin Mylan Pharma 225 mg hard capsules
pregabalin

2. STATEMENT OF ACTIVE SUBSTANCE

Each hard capsule contains 225 mg pregabalin.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Hard capsule.

14 hard capsules
56 hard capsules
100 hard capsules
56 x 1 hard capsules
100 x 1 hard capsules

5. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

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

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Mylan S.A.S
117 Allée des Parcs
69800 Saint-Priest
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/15/998/040
EU/1/15/998/041
EU/1/15/998/042
EU/1/15/998/043
EU/1/15/998/044

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Pregabalin Mylan Pharma 225 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC
SN
NN

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Pregabalin Mylan Pharma 225 mg hard capsules
pregabalin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Mylan S.A.S

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON FOR BLISTER AND BOTTLE

1. NAME OF THE MEDICINAL PRODUCT

Pregabalin Mylan Pharma 300 mg hard capsules
pregabalin

2. STATEMENT OF ACTIVE SUBSTANCE

Each hard capsule contains 300 mg pregabalin.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Hard capsule.

14 hard capsules
56 hard capsules
100 hard capsules
200 hard capsules
56 x 1 hard capsules
100 x 1 hard capsules

5. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Blister: Store in the original package in order to protect from moisture.
Bottle: Keep the bottle tightly closed in order to protect from moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Mylan S.A.S
117 Allée des Pares
69800 Saint-Priest
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/15/998/045
EU/1/15/998/046
EU/1/15/998/047
EU/1/15/998/050
EU/1/15/998/048
EU/1/15/998/049

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Pregabalin Mylan Pharma 300 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC
SN
NN

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Pregabalin Mylan Pharma 300 mg hard capsules
pregabalin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Mylan S.A.S

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

BOTTLE LABEL

1. NAME OF THE MEDICINAL PRODUCT

Pregabalin Mylan Pharma 300 mg hard capsules
pregabalin

2. STATEMENT OF ACTIVE SUBSTANCE

Each hard capsule contains 300 mg pregabalin.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Hard capsule.

200 hard capsules

5. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

Oral use.

<For multilayer label only>
'Peel here'

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

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

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Mylan S.A.S
117 Allée des Parcs
69800 Saint-Priest
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/15/998/050

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

B. PACKAGE LEAFLET

Package leaflet: Information for the user

Pregabalin Mylan Pharma 25 mg hard capsules
Pregabalin Mylan Pharma 50 mg hard capsules
Pregabalin Mylan Pharma 75 mg hard capsules
Pregabalin Mylan Pharma 100 mg hard capsules
Pregabalin Mylan Pharma 150 mg hard capsules
Pregabalin Mylan Pharma 200 mg hard capsules
Pregabalin Mylan Pharma 225 mg hard capsules
Pregabalin Mylan Pharma 300 mg hard capsules

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 Mylan Pharma is and what it is used for

Pregabalin Mylan Pharma contains the active substance pregabalin which belongs to a group of medicines used to treat epilepsy and Generalised Anxiety Disorder (GAD) in adults.

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

Generalised Anxiety Disorder: Pregabalin Mylan Pharma 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.

2. What you need to know before you take Pregabalin Mylan Pharma

Do not take Pregabalin Mylan Pharma
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 doctor or pharmacist before taking Pregabalin Mylan Pharma.

- Some patients taking Pregabalin Mylan Pharma 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 Mylan Pharma 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 Mylan Pharma 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 Mylan Pharma; 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 Mylan Pharma. If while taking Pregabalin Mylan Pharma you notice decreased urination, you should tell your doctor as stopping the medicine may improve this.

- A small number of people being treated with anti-epileptics such as Pregabalin Mylan Pharma have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

- When Pregabalin Mylan Pharma 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 you should tell your doctor if you have a history of alcoholism or any drug abuse or dependence. Do not take more medicine than prescribed.

- There have been reports of convulsions when taking Pregabalin Mylan Pharma or shortly after stopping Pregabalin Mylan Pharma. If you experience a convulsion, contact your doctor immediately.

- There have been reports of reduction in brain function (encephalopathy) in some patients taking Pregabalin Mylan Pharma 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.

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 Mylan Pharma
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregabalin Mylan Pharma and certain other medicines may influence each other (interaction). When taken with certain other medicines, which have sedative effects (including opioids), Pregabalin Mylan Pharma 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 Mylan Pharma is taken together with medicinal products containing:
- Oxycodone – (used as a pain-killer)
- Lorazepam – (used for treating anxiety)
- Alcohol

Pregabalin Mylan Pharma may be taken with oral contraceptives.

Pregabalin Mylan Pharma with food, drink and alcohol
Pregabalin Mylan Pharma capsules may be taken with or without food.
It is advised not to drink alcohol while taking Pregabalin Mylan Pharma.

Pregnancy and breast-feeding
Pregabalin Mylan Pharma should not be taken during pregnancy or when breast-feeding, unless you are told otherwise by your doctor. 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 Mylan Pharma 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.

Sodium content
This medicine contains less than 1 mmol sodium (23 mg) per capsule. That is to say essentially 'sodium-free'

3. How to take Pregabalin Mylan Pharma

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

Your doctor will determine what dose is appropriate for you.

Pregabalin Mylan Pharma is for oral use only.

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 Mylan Pharma either twice or three times a day. For twice a day take Pregabalin Mylan Pharma once in the morning and once in the evening, at about the same time each day. For three times a day take Pregabalin Mylan Pharma 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 Mylan Pharma is too strong or too weak, talk to your doctor or pharmacist.

If you are an older patient (over 65 years of age), you should take Pregabalin Mylan Pharma 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.
Continue taking Pregabalin Mylan Pharma until your doctor tells you to stop.

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

If you forget to take Pregabalin Mylan Pharma
It is important to take your Pregabalin Mylan Pharma 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 Mylan Pharma
Do not stop taking Pregabalin Mylan Pharma unless your doctor tells you to. If your treatment is stopped it should be done gradually over a minimum of 1 week.

After stopping long and short-term Pregabalin Mylan Pharma treatment, you need to know that you may experience certain side effects. These include, trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flulike symptoms, convulsions, nervousness, depression, pain, sweating, and dizziness. These symptoms may occur more commonly or severely if you have been taking Pregabalin Mylan Pharma for a longer period of time.

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

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
- Allergic reactions (which may include difficulty breathing, inflammation of the eyes (keratitis) and a serious skin reaction characterized by rash, blisters, peeling skin and pain)
- Jaundice (yellowing of the skin and eyes).

Very rare: may affect up to 1 in 10,000 people

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

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pregabalin Mylan Pharma

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 Pharma 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: hydroxylpropylcellulose, 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 Pharma looks like and contents of the pack

Hard capsule.

Pregabalin Mylan Pharma 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 **MYLAN** over **PB25** 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 Pharma 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 **MYLAN** over **PB50** 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 Pharma 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 **MYLAN** over **PB75** 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 Pharma 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 **MYLAN** over **PB100** 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 Pharma 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 **MYLAN** over **PB150** 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 Pharma 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 **MYLAN** over **PB200** 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 Pharma 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 **MYLAN** over **PB225** 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 Pharma 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 **MYLAN** over **PB300** 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.

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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.