Package Leaflet: Information for the user
Pregabalin Genus 20 mg/ml oral solution

1. What Pregabalin Genus 20 mg/ml oral solution is and what it is used for

Pregabalin Genus 20 mg/ml oral solution belongs to a group of medicines called anti-epileptics, neuropathic pain and Generalised Anxiety Disorder (GAD) in adults.

2. What you need to know before you take Pregabalin Genus 20 mg/ml oral solution

You should tell your doctor if you have ever abused alcohol or other medicines that may cause dependence, as yours.

3. How to take Pregabalin Genus 20 mg/ml oral solution

Before taking this medicine you should tell your doctor if you have ever abused alcohol or other medicines that may cause dependence, as yours.

4. Possible side effects

Some patients taking pregabalin have reported symptoms suggesting anxiety, for example, excessive sweating, dizziness, blurred vision, dysarthria, tremor, shuffling, staggering, Difficulty in sleeping, nightmares, irritability, increased sexual drive, impotence, excitement, aggressiveness, or delusions. These symptoms usually developed after increasing the dose or changing to another medicine. It is not clear whether these symptoms are related to the dose of the medicine or the underlying condition.

5. How to stop your medicine (listed in section 6).

If you experience any of the symptoms related to these side effects, stop taking the medicine and contact your doctor.

6. Pregnancy and breast-feeding

Pregabalin may be taken with or without food.

7. Driving and using machines

Pregabalin Genus 20 mg/ml oral solution may produce dizziness, drowsiness and decreased concentration. They can increase the risk of a road traffic accident or other accident, so you should not drive, operate complex machinery or engage in any other hazardous activities until you know whether this medicine affects your ability to perform these tasks.

8. Alcohol

Pregabalin Genus 20 mg/ml oral solution is used to treat long lasting pain caused by damage to the nerves. A type of medicine called topical anaesthetic solution is used to treat generalised anxiety disorder (GAD). If you have the impression that the effect of Pregabalin Genus 20 mg/ml oral solution is too strong or too weak, talk to your doctor or pharmacist. If you have the impression that the effect of Pregabalin Genus 20 mg/ml oral solution is too strong or too weak, talk to your doctor or pharmacist.

9. What is in this leaflet

Before taking this medicine you should tell your doctor if you have ever abused alcohol or other medicines that may cause dependence, as yours.

10. After using Pregabalin Genus 20 mg/ml oral solution

Before you start taking this medicine, this leaflet carefully before you start taking this medicine because it contains important information for you.

11. Preventing Pregabalin Genus 20 mg/ml oral solution

Some people may become dependent on this medicine (a need to keep taking the drugs). They may also experience withdrawal symptoms when they stop taking this medicine (see section 3). “How to take Pregabalin Genus 20 mg/ml oral solution”, you should stop taking your medicine and consult your doctor immediately. If you notice any of the following whilst taking this medicine, it could be a sign that you have become dependent:

12. What to do if you forget to take your medicine

You should not take the medicine together or less frequently than the dose recommended by your prescriber.

13. What you need to do before you take your medicine

You should tell your doctor or pharmacist before you take Pregabalin Genus 20 mg/ml oral solution, if you are taking any other medicines that may cause dependence, as yours.

14. What to do if you take too much of your medicine

If you experience any side effects, tell your doctor or pharmacist as soon as possible. You should not take any other medicines or herbal preparations that have been prescribed by your doctor (Figure 4). Remove any bubbles from the syringe by pulling the plunger down to just below the graduation mark corresponding to the quantity in millilitres (ml) you require.

15. Further information

Some medicines may interact with others that may cause dependence, as yours.

16. What should I tell my doctor before I take this medicine

Alcohol

Pregabalin Genus 20 mg/ml oral solution and alcohol

You should stop taking this medicine and consult your doctor immediately. If you experience any side effects, tell your doctor or pharmacist as soon as possible.

17. What is this medicine

Pregabalin Genus 20 mg/ml oral solution is used to treat long lasting pain caused by damage to the nerves.

18. How to use or store Pregabalin Genus 20 mg/ml oral solution

If you experience any side effects, tell your doctor or pharmacist as soon as possible.

19. How to use this leaflet

If you experience any side effects, tell your doctor or pharmacist as soon as possible.

20. How to stop your medicine

Some people may become dependent on this medicine (a need to keep taking the drugs). They may also experience withdrawal symptoms when they stop taking this medicine (see section 3). “How to take Pregabalin Genus 20 mg/ml oral solution”, you should stop taking your medicine and consult your doctor immediately.

21. What is the purpose of this leaflet

Some people may become dependent on this medicine (a need to keep taking the drugs). They may also experience withdrawal symptoms when they stop taking this medicine (see section 3). “How to take Pregabalin Genus 20 mg/ml oral solution”, you should stop taking your medicine and consult your doctor immediately.

22. What are the ingredients of this medicine

Some patients taking pregabalin have reported symptoms suggesting anxiety, for example, excessive sweating, dizziness, blurred vision, dysarthria, tremor, shuffling, staggering, Difficulty in sleeping, nightmares, irritability, increased sexual drive, impotence, excitement, aggressiveness, or delusions. These symptoms usually developed after increasing the dose or changing to another medicine. It is not clear whether these symptoms are related to the dose of the medicine or the underlying condition.

23. How to use or store Pregabalin Genus 20 mg/ml oral solution

If you experience any side effects, tell your doctor or pharmacist as soon as possible.

24. How to use or store Pregabalin Genus 20 mg/ml oral solution

Some patients taking pregabalin have reported symptoms suggesting anxiety, for example, excessive sweating, dizziness, blurred vision, dysarthria, tremor, shuffling, staggering, Difficulty in sleeping, nightmares, irritability, increased sexual drive, impotence, excitement, aggressiveness, or delusions. These symptoms usually developed after increasing the dose or changing to another medicine. It is not clear whether these symptoms are related to the dose of the medicine or the underlying condition.

25. How to use or store Pregabalin Genus 20 mg/ml oral solution

If you experience any side effects, tell your doctor or pharmacist as soon as possible.

26. How to use or store Pregabalin Genus 20 mg/ml oral solution

If you experience any side effects, tell your doctor or pharmacist as soon as possible.

27. How to use or store Pregabalin Genus 20 mg/ml oral solution

If you experience any side effects, tell your doctor or pharmacist as soon as possible.
5. Return the bottle to an upright position with the syringe still in the bottle neck (Figure 9).

6. Remove the syringe from the bottle/PBA (Figure 6).

7. Empty the contents of the syringe directly into mouth by pushing the syringe plunger to the bottom of the syringe barrel (Figure 7).

Steps 4-7 may need to be repeated up to three times to obtain the total dose (Table 1).

8. Rinse the syringe by drawing water into the syringe and pushing the syringe plunger to the bottom of the syringe barrel, at least three times (Figure 8).

9. Replace the cap on the bottle (clearing the PBA in place in the bottle neck) (Figure 9).

If you take more Pregabalin Genus 20 mg/ml oral solution than you should

Call your doctor or go to the nearest hospital/emergency unit immediately. Take your box or bottle of Pregabalin Genus 20 mg/ml oral solution with you. You may feel sleepy, confused, irrational, or without a sense of taking as much Pregabalin Genus 20 mg/ml oral solution than you should. Feel uncoordinated or uncomfortable have also been reported.

If you forget to take Pregabalin Genus 20 mg/ml oral solution

It is important to take your Pregabalin 20 mg/ml oral solution regularly at the time of taking each dose. 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, carry on with the next dose as usual. Do not take a double dose to make up for the missed dose.

If you stop taking Pregabalin Genus 20 mg/ml oral solution

Do not suddenly stop taking Pregabalin Genus 20 mg/ml oral solution. If you stop taking the medicine, consult with your doctor first. They will tell you how to do this. If your treatment is stopped it may take several days for the withdrawal effects to subside.

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

Common 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

• Dry mouth, thirst, nausea, bloating, feeling sick

• Dizziness, drowsiness, headache

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

• Sweating, rash, chills, fever

• Increased saliva production, heartburn, numb around mouth

• Flushing, hot flushes

Uncommon: may affect up to 1 in 100 people

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

• Changes in perception of self, confusion, depression, agitation, mood swings, difficulty finding words, hallucinations, abnormal dreams, panic attack, apathy, aggression, altered mood, mental impairment, difficulty with hearing, increase in sexual interest, problems with sexual function including inability to achieve a sexual climax, dribbling ejaculation

• Changes in appetite, unusual eye movement, change in vision including visual flashes, flickers, eye twitching, reduced reflexes, increased activity, dizziness on standing, sensitive skin, loss of taste, burning sensation, tremor on movement, decreased

• Dry eyes, eye swelling, eye pain, weak eyes, watery eyes, eye irritation

• Heart rhythm disturbances, increased heart rate, low blood pressure, high blood pressure, chest pain

• Flushing, hot flashes

• Difficulty breathing, dry nose, nasal congestion

• Increased salvia production, hoarse, mouth around mouth

• Sweating, rash, shivers, fever

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

• Breast pain

• Difficulty with or painful urination, incontinence

• Weakness, chest tightness

• Changes in blood and liver test results (blood creatinine phosphokinase increased, alanine transferase increased, aspartate aminotransferase increased, plasma creatinine decreased, creatinine kinase decreased, creatinine clearance decreased, white blood cell count)

• Inappropriate behaviour, sexual behaviour, sexual thoughts

Rare: may affect up to 1 in 10,000 people

• Abnormal sense of smell, swallowing problems, abnormal perception of depth, visual brightness, vision loss

• Dilated pupils, cross eyes

• Cold sweat, tightness of 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

• Convulsions

• Changes in the recording of electrical changes (ECG) in the heart which correspond to heart rhythm disturbances

• Muscle damage

• Breast discharge, abdominal abnormal growth, growth in males

• Kidney failure, reduced urine volume, urinary retention

• Decrease in white blood cell count

• Improper排泄, sexual behaviour, sexual thoughts

• Abnormal sense of smell, swallowing problems, abnormal perception of depth, visual brightness, vision loss

• Dilated pupils, cross eyes

• Cold sweat, tightness of 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

• Convulsions

• Changes in the recording of electrical changes (ECG) in the heart which correspond to heart rhythm disturbances

• Muscle damage

• Breast discharge, abdominal abnormal growth, growth in males

• Kidney failure, reduced urine volume, urinary retention

• Decrease in white blood cell count

• Improper排泄, sexual behaviour, sexual thoughts

• Abnormal sense of smell, swallowing problems, abnormal perception of depth, visual brightness, vision loss

• Dilated pupils, cross eyes

• Cold sweat, tightness of 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

• Convulsions

• Changes in the recording of electrical changes (ECG) in the heart which correspond to heart rhythm disturbances

• Muscle damage

• Breast discharge, abdominal abnormal growth, growth in males

• Kidney failure, reduced urine volume, urinary retention

• Decrease in white blood cell count

• Abnormal sense of smell, swallowing problems, abnormal perception of depth, visual brightness, vision loss

• Dilated pupils, cross eyes

• Cold sweat, tightness of 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

• Convulsions

• Changes in the recording of electrical changes (ECG) in the heart which correspond to heart rhythm disturbances

• Muscle damage

• Breast discharge, abdominal abnormal growth, growth in males

• Kidney failure, reduced urine volume, urinary retention

• Decrease in white blood cell count

• Abnormal sense of smell, swallowing problems, abnormal perception of depth, visual brightness, vision loss

• Dilated pupils, cross eyes

• Cold sweat, tightness of 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

• Convulsions

• Changes in the recording of electrical changes (ECG) in the heart which correspond to heart rhythm disturbances

• Muscle damage

• Breast discharge, abdominal abnormal growth, growth in males

• Kidney failure, reduced urine volume, urinary retention

• Decrease in white blood cell count

• Abnormal sense of smell, swallowing problems, abnormal perception of depth, visual brightness, vision loss

• Dilated pupils, cross eyes

• Cold sweat, tightness of 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

• Convulsions

• Changes in the recording of electrical changes (ECG) in the heart which correspond to heart rhythm disturbances

• Muscle damage

• Breast discharge, abdominal abnormal growth, growth in males

• Kidney failure, reduced urine volume, urinary retention

• Decrease in white blood cell count