Neuroccord

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I using Neuroccord?

Neuroccord contains the active ingredient Pregabalin. Neuroccord is used to treat neuropathic pain which is pain caused by an abnormality of, or damage to, nerves.

For more information, see Section 1. Why am I using Neuroccord? in the full CMI.

2. What should I know before I use Neuroccord?

Do not use if you have ever had an allergic reaction to Neuroccord or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines (including benzodiazepines and opioids), or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Neuroccord? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Neuroccord and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Neuroccord?

- Your doctor will tell you how many capsules you need to take each day.
- Take your medicine at about the same time each day and swallow the capsules whole with a full glass of water.

More instructions can be found in Section 4. How do I use Neuroccord? in the full CMI.

5. What should I know while using Neuroccord?

Things you should do	Remind any doctor, dentist or pharmacist you visit that you are using Neuroccord	
Things you should not do	 Do not stop taking this medicine suddenly It is recommended to withdraw it gradually over a minimum of one week 	
Driving or using machines	 Neuroccord may cause dizziness and drowsiness in some people If you experience any of these symptoms, do not drive, operate machinery or do not do anything else that could be dangerous 	
Drinking alcohol	• If you drink alcohol, symptoms such as dizziness and drowsiness may be worse	
Looking after your medicine	Neuroccord should be stored below 25°C	

For more information, see Section 5. What should I know while using Neuroccord? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. **Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.** Some common, less serious side effects include dizziness, feeling tired or drowsy, headache, unsteadiness when walking, reduced coordination, shaking or tremors, constipation, diarrhoea, nausea, dry mouth, blurred or double vision, abdominal pain, and increase in weight. Serious side effects include unusual changes in mood or behaviour, increased irritability, anxiety or depression, thoughts of suicide, swelling of the face, lips, tongue, hands, ankles or feet, unexplained muscle pain, tenderness and weakness, irritated red eyes that are sensitive to light, and shortness of breath, wheezing or difficulty breathing. This is not a full list of side effects. For more information, including what to do if you have any side effects, see Section <u>6</u>. Are there any side effects? in the full CMI.

WARNING:

Neuroccord as an add-on therapy for adults with partial onset seizures has not been established. Neuroccord should be gradually decreased over a minimum period of 1 week to avoid seizures.

Before taking Neuroccord, tell your doctor if you have a history of drug abuse. Neuroccord poses risks of misuse, abuse and dependence. Using Neuroccord with other medicines that can make you feel drowsy such as sleeping tablets and other pain relievers (e.g. benzodiazepines and opioids), antihistamines, antidepressants, antipsychotics, cannabis, and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. If you have any concern about taking this medicine, speak to your doctor.

Neuroccord

Active ingredient(s): pregabalin

Consumer Medicine Information (CMI)

This leaflet provides important information about using Neuroccord. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Neuroccord.

Where to find information in this leaflet:

- 1. Why am I using Neuroccord?
- 2. What should I know before I use Neuroccord?
- 3. What if I am taking other medicines?
- 4. How do I use Neuroccord?
- 5. What should I know while using Neuroccord?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Neuroccord?

Neuroccord contains the active ingredient Pregabalin.

Neuroccord belongs to a group of medicines called anticonvulsants. These medicines are thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

Neuroccord is used to treat neuropathic pain, which is pain caused by an abnormality of, or damage to, the nerves.

Neuroccord is also used to control epilepsy. Epilepsy is a condition where you have repeated seizures (fits). There are many different types of seizures, ranging from mild to severe.

Neuroccord also has pain relieving effects.

Neuroccord may be used alone, or in combination with other medicines, to treat your condition.

Your doctor may prescribe Neuroccord in addition to your current therapy when your current treatment is no longer working as well as before.

Ask your doctor if you have any questions about why Neuroccord has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I use Neuroccord?

Warnings

Do not use Neuroccord if:

- You are allergic to Pregabalin, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
 - Shortness of breath, wheezing or difficulty breathing
 - Swelling of the face, lips, tongue or other parts of the body
 - o Rach, itching or hives on the skin
 - Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of the mouth, throat, nose, genitals and eyes
- Always check the ingredients to make sure you can use this medicine.
- The expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering. If the capsules have expired or the pack is damaged, return to your pharmacist for disposal

Check with your doctor if you:

- Have allergies to:
 - Any other medicines, especially barbiturates or any other anticonvulsant medicines
 - Any other substances, such as foods, preservatives or dyes
- Have or have had any of the following medical conditions:
 - congestive heart failure
 - hereditary problems with galactose metabolism
 - kidney problems
 - o diabetes
 - o depression
- Take any medicines for any other condition
- Have a history of substance abuse.

Neuroccord poses risks of misuse, abuse and dependence. Your body may become used to you taking Neuroccord and this may result in physical dependence. It means that you may experience withdrawal symptoms if you stop taking Neuroccord suddenly. So it is important to strictly follow the directions given by your doctor

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Neuroccord is not recommended for use during pregnancy.

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 childbearing potential.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

The active ingredient in Neuroccord passes into breast milk and its safety in infants is unknown. It is recommended that you do not breast-feed while taking Neuroccord.

Use in children

There is not enough information to recommend the use of this medicine in children under the age of 18 years.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by Neuroccord or may affect how well it works.

You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Neuroccord and certain other medicines may influence each other (interaction). Using Neuroccord with other medicines that can make you feel drowsy, such as sleeping tablets and other pain relievers (e.g. benzodiazepines and opioids), antihistamines, antidepressants, antipsychotics, cannabis, and alcohol may result in severe drowsiness, decreased awareness,

breathing problems, coma and death. Your doctor will minimize the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Neuroccord.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Neuroccord.

4. How do I use Neuroccord?

How much to take / use

- Your doctor will tell you how many capsules you need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines
- Your doctor may recommend that you start with a low dose of Neuroccord and slowly increase the dose to the lowest amount needed to control your epilepsy/convulsions or neuropathic pain
- The usual dose range is 150 mg per day to 600 mg per day given in two divided doses
- Swallow the capsules whole with a full glass of water
- Follow the instructions provided and use Neuroccord until your doctor tells you to stop
- Take Neuroccord once a day, after an evening meal.
 Your medicine may not be as effective if taken on an empty stomach
- If you do not understand the instructions on the box, ask your doctor or pharmacist for help

When to take / use Neuroccord

 Neuroccord must be taken once daily after an evening meal. The tablet should be swallowed whole and should not be split, ushed or chewed. Always take your medicine as directed by your doctor

If you forget to use Neuroccord

Neuroccord must be taken once daily after an evening meal.

If you miss your dose at the usual time, take it prior to bedtime following a snack.

If you miss the dose prior to bedtime, then take it following your morning meal.

If you do not take the dose the following morning, then take the next dose at your regular time after your evening meal.

Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting an unwanted side effect.

- If you are not sure what to do, ask your doctor or pharmacist
- If you have trouble remembering to take your medicine, ask your pharmacist for some hints

If you use too much Neuroccord

If you think that you or anyone else may have used too much Neuroccord, you may need urgent medical attention.

Symptoms of an overdose with Neuroccord may include mood changes, feeling tired, confusion, depression, agitation, restlessness or seizures.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Neuroccord?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using Neuroccord.

If you have nervous system or respiratory disorders, kidney problems, or you are older than 65, your doctor may adjust your dose.

If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist that you are taking Neuroccord.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Tell your doctor if, for any reason, you have not taken Neuroccord exactly as prescribed.

Otherwise, your doctor may change your treatment unnecessarily.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Call your doctor straight away if you:

- Experience any hypersensitivity reactions (such as skin redness, hives, rash, 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): Discontinue Neuroccord and immediately seek medical care
- Experience any changes in your vision. Neuroccord may cause blurring or other changes in eyesight. Your doctor may ask you to stop taking Neuroccord to improve these symptoms
- Or someone you know is having any thoughts of suicide or self- harm, any unusual changes in mood or

behaviour, or showing signs of depression. Some people taking medicines to treat convulsions, such as Neuroccord have had thoughts of harming themselves or taking their life. Patients and caregivers should be alert and monitor for these effects. Mention of suicide or violence must be taken seriously. Signs and symptoms of suicidal risk include:

- Thoughts or talk of death or suicide
- Thoughts or talk of self-harm or harm to others
- Any recent attempts of self-harm
- New or an increase in aggressive behaviour, irritability or agitation
- New or worsening depression
- Experience trouble breathing or shallow breaths
- Become pregnant while taking Neuroccord
- Feel that Neuroccord is not helping your condition. Your doctor may need to change your medicine

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine, even if you feel well.

Things you should not do

- Do not stop taking your medicine or lower your dosage without checking with your doctor
- Do not let yourself run out of medicine over the weekend or on holidays. Stopping Neuroccord suddenly may worsen your condition or increase your chance of experiencing withdrawal symptoms such as sleeplessness, headache, nausea (feeling sick), anxiety, excessive sweating or diarrhoea (runny stools). If appropriate, your doctor will slowly reduce your dose before you can stop taking it completely
- Do not take Neuroccord to treat any other complaints unless your doctor tells you to
- Do not give your medicine to anyone else, even if their symptoms seem similar to yours or they have the same condition as you

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Neuroccord affects you.

As with other anticonvulsant medicines, Neuroccord may cause dizziness and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol way interfere with Neuroccord and increase side effects such as sleepiness and dizziness.

Looking after your medicine

- Store below 25°C
- Keep your capsules in the pack until it is time to take them. If you take the capsules out of the pack they may not keep well

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

Neuroccord helps most people with neuropathic pain or epilepsy, but it may have unwanted side effects in a few people. All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

It can be difficult to tell whether side effects are the result of taking Neuroccord, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the list of side effects.

You may not experience any of them.

If you get any side effects, do not stop taking Neuroccord without first talking to your doctor or pharmacist.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 Nervous system related: Dizziness Feeling tired or drowsy Headache Unsteadiness when walking, reduced co-ordination, shaking or tremors 	Speak to your doctor if you have any of these less serious side effects and they worry you.
 Gastrointestinal related: Abdominal pain Constipation Diarrhoea Nausea Dry mouth 	
Eye related:Blurred or double visionBody related:Increase in weight	

Serious side effects

Ser	ious side effects	What to do	
	Unusual changes in mood or behaviour Extreme increase in activity and talking (mania) Acting aggressive, being angry, or violent Panic attacks Signs of new or increased irritability, agitation or restlessness Signs of new or worse anxiety Signs of new or worse depression Thoughts about suicide or dying Attempts to commit suicide Acting on dangerous impulses Trouble sleeping (insomnia) Confusion More frequent or more severe	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.	
	seizures (fits)		
Ge	neral effect:		
•	Rash Itching or hives Swelling of the face, lips, tongue, hands, ankles or feet Enlargement of breasts Passing little to no urine		
Mu	sculoskeletel related:		
•	Unexplained muscle pain, tenderness and weakness Weight increase due to fluid build-up Swelling of the feet and legs		
Eye	Eye related:		
•	Irritated red eyes that are sensitive to light		
Res	Respiratory related:		
•	Shortness of breath, wheezing or difficulty breathing		

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. Some of these side effects (for example, changes in blood pressure) can only be found when your doctor does tests from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at

<u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Neuroccord contains

Active ingredient	25 mg capsules - 25 mg	
(main ingredient)	pregabalin	
	75 mg capsules - 75 mg pregabalin	
	150 mg capsules - 150 mg pregabalin	
	300 mg capsules - 300 mg pregabalin	
Other ingredients	Pregelatinised maize starch	
(inactive ingredients)	Purified talc	
	Gelatin	
	Purified water	
	Sodium lauryl sulfate	
	Titanium dioxide	
	Iron oxide red (75 mg and 300 mg capsules only)	
	The capsules have a trace of TekPrint SW-9008 black ink	
Potential allergens	n/a	

Do not take this medicine if you are allergic to any of these ingredients.

What Neuroccord looks like

25 mg - White opaque/White opaque, size "4" hard gelatin capsules imprinted with 'PG' on cap and '25' on body containing white to off white powder. Packaged in Alu- Alu blister and PVC-Alu blister packs containing 14, 21, 56, 60 or 84 hard capsules and HDPE bottle packs containing 14, 20, 30, 56, 60, 200 or 500 hard capsules.

75 mg - Red opaque/White opaque, size "4" hard gelatin capsules imprinted with 'PG' on cap and '75' on body containing white to off white powder. Packaged in Alu-Alu blister and PVC-Alu blister packs containing 14, 21, 56, 60 or 84 hard capsules and HDPE bottle packs containing 14, 20, 30, 56, 60, 200 or 500 hard capsules.

150 mg - White opaque/White opaque, size "2" hard gelatin capsules imprinted with 'PG' on cap and '150' on body containing white to off white powder. Packaged in Alu-Alu blister and PVC-Alu blister packs containing 14, 21, 56, 60 or 84 hard capsules and HDPE bottle packs containing 14, 20, 30, 56, 60, 200 or 500 hard capsules.

300 mg - Red opaque/White opaque, size "0" hard gelatin capsules imprinted with 'PG' on cap and '300' on body containing white to off white powder. Packaged in Alu-Alu blister and PVC-Alu blister packs containing 14, 21, 56, 60 or 84 hard capsules and HDPE bottle packs containing 14, 20, 30, 56, 60, 200 or 500 hard capsules.

Who distributes Neuroccord

Pharmacor Pty Ltd.

Suite 803, Tower A, The Zenith 821 Pacific Highway,

Chatswood NSW 2067

Web: www.pharmacor.com.au

Phone: 1300 138 805

Neuroccord 25 mg blister pack:

AUST R 235847

Neuroccord 25 mg bottle pack:

AUST R 235872

Neuroccord 75 mg blister pack:

AUST R 235849

Neuroccord 75 mg bottle pack:

AUST R 235854

Neuroccord 150 mg blister pack:

AUST R 235837

Neuroccord 150 mg bottle pack:

AUST R 235841

Neuroccord 300 mg blister pack:

AUST R 235864

Neuroccord 300 mg bottle pack:

AUST R 235861

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