

**Package leaflet: Information for the patient****Lacosamide Neuraxpharm 10 mg/ml syrup**

lacosamide

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

**1. What Lacosamide Neuraxpharm is and what it is used for****What Lacosamide Neuraxpharm is**

Lacosamide Neuraxpharm contains lacosamide. This belongs to a group of medicines called “antiepileptic medicines”.

These medicines are used to treat epilepsy.

- You have been given this medicine to lower the number of fits (seizures) you have.

**What Lacosamide Neuraxpharm is used for**

- Lacosamide Neuraxpharm is used in adults, adolescents and children aged 4 years and older.
- It is used:
  - on its own and in association with other antiepileptic medicines to treat a certain type of epilepsy characterised by the occurrence of partial-onset seizure with or without secondary generalisation. In this type of epilepsy, fits first affect only one side of your brain. However, these may then spread to larger areas on both sides of your brain;
  - in association with other antiepileptic medicines to treat primary generalised tonic-clonic seizures (major fits, including loss of consciousness) in patients with idiopathic generalised epilepsy (the type of epilepsy that is thought to have a genetic cause).

**2. What you need to know before you take Lacosamide Neuraxpharm****Do not take Lacosamide Neuraxpharm**

- if you are allergic to lacosamide, or any of the other ingredients of this medicine (listed in section 6). If you are not sure whether you are allergic, please discuss with your doctor.
- if you have a certain type of heart beat problem called second- or third-degree AV block.

Do not take Lacosamide Neuraxpharm if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

## **Warnings and precautions**

Talk to your doctor before taking Lacosamide Neuraxpharm if:

- you have thoughts of harming or killing yourself. A small number of people being treated with antiepileptic medicinal products such as lacosamide have had thoughts of harming or killing themselves. If you have any of these thoughts at any time, tell your doctor straight away.
- you have a heart problem that affects the beat of your heart and you often have a particularly slow, fast or irregular heart beat (such as AV block, atrial fibrillation or atrial flutter).
- you have severe heart disease such as heart failure or have had a heart attack.
- you are often dizzy or fall over. Lacosamide Neuraxpharm may make you dizzy - this could increase the risk of accidental injury or a fall. This means that you should take care until you are used to the effects of this medicine.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Lacosamide Neuraxpharm

If you are taking Lacosamide Neuraxpharm, talk to your doctor if you are experiencing a new type of seizure or worsening of existing seizures.

If you are taking Lacosamide Neuraxpharm and you are experiencing symptoms of abnormal heartbeat (such as slow, rapid or irregular heartbeat, palpitations, shortness of breath, feeling lightheaded, fainting), seek medical advice immediately (see section 4).

## **Children under 4 years**

Lacosamide Neuraxpharm is not recommended for children aged under 4 years. This is because we do not yet know whether it will work and whether it is safe for children in this age group.

## **Other medicines and Lacosamide Neuraxpharm**

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

In particular, tell your doctor or pharmacist if you are taking any of the following medicines that affect your heart - this is because Lacosamide Neuraxpharm can also affect your heart:

- medicines to treat heart problems;
- medicines which can increase the “PR interval” on a scan of the heart (ECG or electrocardiogram) such as medicines for epilepsy or pain called carbamazepine, lamotrigine or pregabalin;
- medicines used to treat certain types of irregular heart beat or heart failure.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Lacosamide Neuraxpharm

Also tell your doctor or pharmacist if you are taking any of the following medicines - this is because they may increase or decrease the effect of Lacosamide Neuraxpharm on your body:

- medicines for fungal infections called fluconazole, itraconazole or ketoconazole;
- a medicine for HIV called ritonavir;
- medicines for bacterial infections called clarithromycin or rifampicin;
- a herbal medicine used to treat mild anxiety and depression called St. John’s wort.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Lacosamide Neuraxpharm

## **Lacosamide Neuraxpharm with alcohol**

As a safety precaution do not take Lacosamide Neuraxpharm with alcohol.

## **Pregnancy and breast-feeding**

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.

It is not recommended to take Lacosamide Neuraxpharm if you are pregnant or breast-feeding, as the effects of Lacosamide Neuraxpharm on pregnancy and the unborn baby or the new-born child are not known. Also, it is not known whether Lacosamide Neuraxpharm passes into the breast milk. Seek

advice immediately from your doctor if you get pregnant or are planning to become pregnant. They will help you decide if you should take Lacosamide Neuraxpharm or not.

Do not stop treatment without talking to your doctor first as this could increase your fits (seizures). A worsening of your disease can also harm your baby.

### **Driving and using machines**

Do not drive, cycle or use any tools or machines until you know how this medicine affects you. This is because Lacosamide Neuraxpharm may make you feel dizzy or cause blurred vision.

### **Lacosamide Neuraxpharm contains sorbitol (E 420) , propylene glycol (E 1520), sodium, sodium methyl para-hydroxybenzoate (E 219) and aspartame (E 951)**

- sorbitol (E 420): This medicine contains 280 mg sorbitol in each ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- propylene glycol (E 1520): This medicine contains 40.55 mg propylene glycol in each ml.
- sodium: This medicine contains between 4.43 mg and 4.64 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0.2 % of the recommended maximum daily dietary intake of sodium for an adult.
- sodium methyl para-hydroxybenzoate (E 219): May cause allergic reactions (possibly delayed).
- aspartame (E 951): This medicine contains 0.4 mg aspartame in each ml. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

## **3. How to take Lacosamide Neuraxpharm**

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

### **Taking Lacosamide Neuraxpharm**

- Take Lacosamide Neuraxpharm twice each day - once in the morning and once in the evening.
- Try to take it at about the same time each day.
- You may take Lacosamide Neuraxpharm with or without food.

You will usually start by taking a low dose each day and your doctor will slowly increase this over a number of weeks. When you reach the dose that works for you, this is called the “maintenance dose”, you then take the same amount each day. Lacosamide Neuraxpharm is used as a long term treatment. You should continue to take Lacosamide Neuraxpharm until your doctor tells you to stop.

### **How much to take**

Listed below are the normal recommended doses of Lacosamide Neuraxpharm for different age groups and weights.

Your doctor may prescribe a different dose if you have problems with your kidneys or with your liver.

### **Adolescents and children weighing 50 kg or more and adults**

- Use the measuring cup provided in the carton box.

### When you take Lacosamide Neuraxpharm on its own

The usual starting dose of Lacosamide Neuraxpharm is 50 mg (5 ml) twice a day.

Your doctor may also prescribe a starting dose of 100 mg (10 ml) of Lacosamide Neuraxpharm twice a day.

Your doctor may increase your twice daily dose every week by 50 mg (5 ml). This will be until you reach a maintenance dose of between 100 mg (10 ml) and 300 mg (30 ml) twice a day.

When you take Lacosamide Neuraxpharm with other antiepileptic medicines

The usual starting dose of Lacosamide Neuraxpharm is 50 mg (5 ml) twice a day.

Your doctor may increase your twice daily dose every week by 50 mg (5 ml). This will be until you reach a maintenance dose of between 100 mg (10 ml) and 200 mg (20 ml) twice a day.

If you weigh 50 kg or more, your doctor may decide to start Lacosamide Neuraxpharm treatment with a single “loading” dose of 200 mg (20 ml). You would then start your ongoing maintenance dose 12 hours later.

**Children and adolescents weighing less than 50 kg**

- Use the oral syringe provided in the carton box.

When you take Lacosamide Neuraxpharm on its own

Your doctor will decide the dose of Lacosamide Neuraxpharm based on your body weight.

The usual starting dose is 1 mg (0.1 ml), for each kilogram (kg) of body weight, twice a day.

Your doctor may then increase your twice daily dose every week by 1 mg (0.1 ml), for each kg of your body weight. This will be until you reach a maintenance dose. The maximum recommended dose is 6 mg (0.6 ml) for each kg of body weight, twice a day, for children weighing under 40 kg. The maximum recommended dose is 5 mg (0.5 ml) for each kg of body weight, twice a day, for children weighing from 40 kg to under 50 kg. Dosing charts are provided below:

Taking Lacosamide Neuraxpharm on its own - This is for information only. Your doctor will work out the right dose for you:

**To be taken twice daily** for children from 4 years of age **weighing less than 40 kg**

Weight	Starting dose: 0.1 ml/kg	0.2 ml/kg	0.3 ml/kg	0.4 ml/kg	0.5 ml/kg	Maximum recommended dose: 0.6 ml/kg
10 kg	1 ml	2 ml	3 ml	4 ml	5 ml	6 ml
15 kg	1.5 ml	3 ml	4.5 ml	6 ml	7.5 ml	9 ml
20 kg	2 ml	4 ml	6 ml	8 ml	10 ml	12 ml
25 kg	2.5 ml	5 ml	7.5 ml	10 ml	12.5 ml	15 ml
30 kg	3 ml	6 ml	9 ml	12 ml	15 ml	18 ml
35 kg	3.5 ml	7 ml	10.5 ml	14 ml	17.5 ml	21 ml

**To be taken twice daily** for children and adolescents from 4 years of age **weighing 40 kg to under 50 kg:**

Weight	Starting dose: 0.1 ml/kg	0.2 ml/kg	0.3 ml/kg	0.4 ml/kg	Maximum recommended dose: 0.5 ml/kg
40 kg	4 ml	8 ml	12 ml	16 ml	20 ml
45 kg	4.5 ml	9 ml	13.5 ml	18 ml	22.5 ml

When you take Lacosamide Neuraxpharm with other antiepileptic medicines

Your doctor will decide the dose of Lacosamide Neuraxpharm based on your body weight.

In children from 4 years of age with a body weight of under 20 kg:

- the usual starting dose is 1 mg (0.1 ml), for each kilogram (kg) of body weight, twice a day.

Your doctor may then increase your twice daily dose every week by 1 mg (0.1 ml) for each kg of body weight. This will be until you reach a maintenance dose. The maximum recommended dose is 6 mg (0.6 ml), for each kg of body weight, twice a day. A dosing chart is provided below.

Taking Lacosamide Neuraxpharm with other antiepileptic medicines - **Children above 4 years of age weighing less than 20 kg** - This is for information only. Your doctor will work out the right dose for you:

**To be taken twice daily** for children from 4 years of age **weighing less than 20 kg**

Weight	Starting dose: 0.1 ml/kg	0.2 ml/kg	0.3 ml/kg	0.4 ml/kg	0.5 ml/kg	Maximum recommended dose: 0.6 ml/kg
10 kg	1 ml	2 ml	3 ml	4 ml	5 ml	6 ml
15 kg	1.5 ml	3 ml	4.5 ml	6 ml	7.5 ml	9 ml

In children from 4 years of age with a body weight of 20 to under 30 kg:

- the usual starting dose is 1 mg (0.1 ml), for each kilogram (kg) of body weight, twice a day.

Your doctor may then increase your twice daily dose every week by 1 mg (0.1 ml) for each kg of body weight. This will be until you reach a maintenance dose. The maximum recommended dose is 5 mg (0.5 ml), for each kg of body weight, twice a day. A dosing chart is provided below.

Taking Lacosamide Neuraxpharm with other antiepileptic medicines - **Children and adolescents with a body weight of 20 kg to under 30 kg** - This is for information only. Your doctor will work out the right dose for you:

**To be taken twice daily** for children and adolescents from 4 years of age **weighing 20 kg to under 30 kg**:

Weight	Starting dose: 0.1 ml/kg	0.2 ml/kg	0.3 ml/kg	0.4 ml/kg	Maximum recommended dose: 0.5 ml/kg
20 kg	2 ml	4 ml	6 ml	8 ml	10 ml
25 kg	2.5 ml	5 ml	7.5 ml	10 ml	12.5 ml

In children from 4 years of age with a body weight of 30 to under 50 kg:

- the usual starting dose is 1 mg (0.1 ml), for each kilogram (kg) of body weight, twice a day.

Your doctor may then increase your twice daily dose every week by 1 mg (0.1 ml) for each kg of body weight. This will be until you reach a maintenance dose. The maximum recommended dose is 4 mg (0.4 ml), for each kg of body weight, twice a day. A dosing chart is provided below.

Taking Lacosamide Neuraxpharm with other antiepileptic medicines - **Children and adolescents with a body weight of 30 kg to under 50 kg** - This is for information only. Your doctor will work out the right dose for you:

**To be taken twice daily** for children and adolescents from 4 years of age **weighing 30 kg to under 50 kg**:

Weight	Starting dose: 0.1 ml/kg	0.2 ml/kg	0.3 ml/kg	Maximum recommended dose: 0.4 ml/kg
30 kg	3 ml	6 ml	9 ml	12 ml
35 kg	3.5 ml	7 ml	10.5 ml	14 ml
40 kg	4 ml	8 ml	12 ml	16 ml
45 kg	4.5 ml	9 ml	13.5 ml	18 ml

### Instructions for use: measuring cup

#### Adolescents and children weighing 50 kg or more and adults

- Use the measuring cup provided in this pack.
1. Shake the bottle well before use.
  2. Fill the measuring cup to the millilitre (ml) dose marker prescribed by your doctor.
  3. Swallow the dose of syrup.
  4. Then drink some water.

### Instructions for use: oral syringe

Your doctor will show you how to use the oral syringe, before you use it for the first time. If you have any questions, please go back to your doctor or pharmacist.

#### Children and adolescents weighing less than 50 kg

- Use the oral syringe and the adaptor provided in this pack.

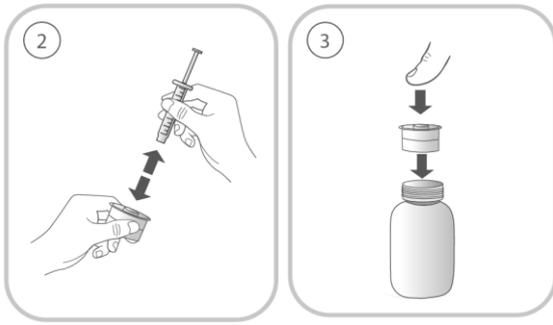
Shake the bottle well before use.

Open the bottle by pressing the cap while turning it anti-clockwise (figure 1).



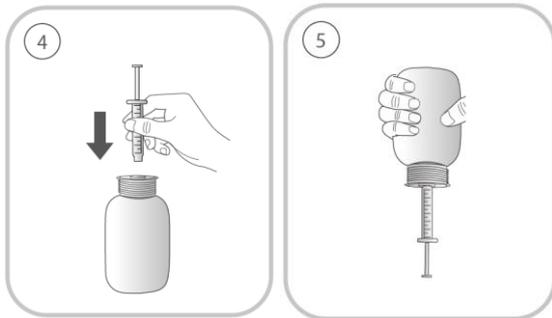
Follow these steps the first time you take Lacosamide Neuraxpharm:

- Put the adaptor into the top of the bottle (figure 3). Make sure it is fixed well in place. You do not need to remove the adaptor after use.

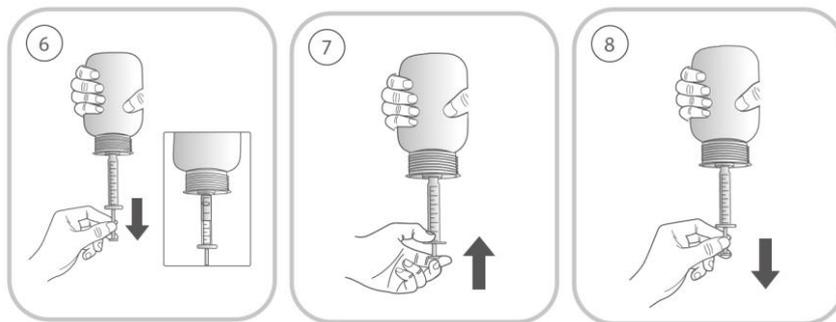


Follow these steps each time you take Lacosamide Neuraxpharm:

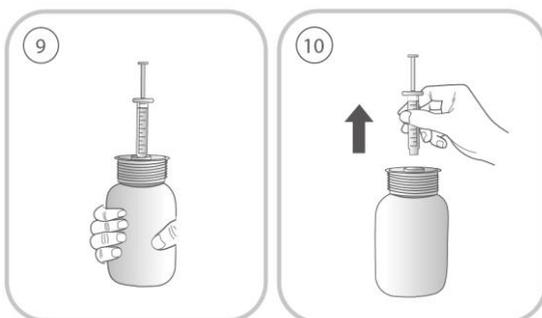
- Put the oral syringe into the adaptor opening (figure 4).
- Turn the bottle upside down (figure 5).



- Hold the bottle upside down in one hand and use the other hand to fill the oral syringe.
- Pull the piston down to fill the oral syringe with a small amount of solution (figure 6).
- Push the piston up to get rid of any bubbles (figure 7).
- Pull the piston down to the millilitre (ml) dose marker prescribed by your doctor (figure 8).

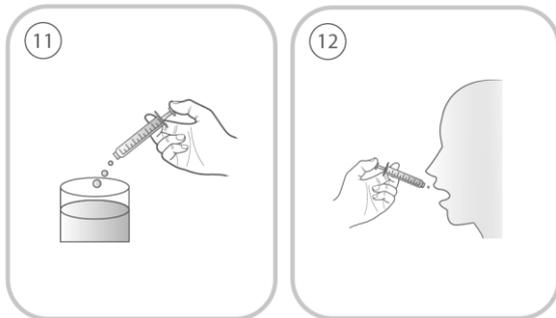


- Turn the bottle the right way up (figure 9).
- Take the oral syringe out of the adaptor (figure 10).

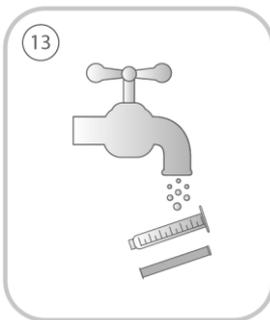


There are two ways in which you can choose to drink the medicine:

- empty the contents of the oral syringe into a little water by pushing the piston to the bottom of the oral syringe (figure 11) - you will then need to drink all of the water (add just enough to make it easy to drink) or
- drink the solution directly from the oral syringe without water (figure 12) - drink the whole contents of the oral syringe.



- Close the bottle with the plastic screw cap (you do not need to remove the adaptor).
- Wash the oral syringe with water only (figure 13).



### **If you take more Lacosamide Neuraxpharm than you should**

If you have taken more Lacosamide Neuraxpharm than you should, contact your doctor immediately. Do not try to drive. You may experience:

- dizziness;
- feeling sick (nausea) or being sick (vomiting);
- fits (seizures), heart beat problems such as a slow, fast or irregular heart beat, coma or a fall in blood pressure with rapid heartbeat and sweating.

### **If you forget to take Lacosamide Neuraxpharm**

- If you have missed a dose within the first 6 hours of the scheduled dose, take it as soon as you remember.
- If you have missed a dose beyond the first 6 hours of the scheduled dose, do not take the missed syrup anymore. Instead take Lacosamide Neuraxpharm at the next time that you would normally take it.
- Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Lacosamide Neuraxpharm**

- Do not stop taking Lacosamide Neuraxpharm without talking to your doctor, as your epilepsy may come back again or become worse.
- If your doctor decides to stop your treatment with Lacosamide Neuraxpharm, they will tell you how to decrease the dose step by step.

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.

Nervous system side effects such as dizziness may be higher after a single “loading” dose.

**Talk to your doctor or pharmacist if you get any of the following:**

**Very common:** may affect more than 1 in 10 people

- Headache;
- Feeling dizzy or sick (nausea);
- Double vision (diplopia).

**Common:** may affect up to 1 in 10 people

- Short jerks of a muscle or group of muscles (myoclonic seizures);
- Difficulties in coordinating your movements or walking
- Problems in keeping your balance, shaking (tremor), tingling (paresthesia) or muscle spasms, falling easily and getting bruises;
- Trouble with your memory, thinking or finding words, confusion;
- Rapid and uncontrollable movements of the eyes (nystagmus), blurred vision;
- A spinning sensation (vertigo), feeling drunk;
- Being sick (vomiting), dry mouth, constipation, indigestion, excessive gas in the stomach or bowel, diarrhoea;
- Decreased feeling or sensitivity, difficulty in articulating words, disturbance in attention;
- Noise in the ear such as buzzing, ringing or whistling;
- Irritability, trouble sleeping, depression;
- Sleepiness, tiredness or weakness (asthenia);
- Itching, rash.

**Uncommon:** may affect up to 1 in 100 people

- Slow heart rate, palpitations, irregular pulse or other changes in the electrical activity of your heart (conduction disorder);
- Exaggerated feeling of wellbeing, seeing and/or hearing things which are not there;
- Allergic reaction to medicine intake, hives;
- Blood tests may show abnormal liver function, liver injury;
- Thoughts of harming or killing yourself or attempting suicide: tell your doctor straight away;
- Feeling angry or agitated;
- Abnormal thinking or losing of touch with reality;
- Serious allergic reaction which causes swelling of the face, throat, hands, feet, ankles, or lower legs;
- Fainting;
- Abnormal involuntary movements (dyskinesia).

**Not known:** frequency cannot be estimated from available data

- Abnormal rapid heartbeat (ventricular tachyarrhythmia);
- A sore throat, high temperature and getting more infections than usual. Blood tests may show a severe decrease in a specific class of white blood cells (agranulocytosis);
- A serious skin reaction which may include a high temperature and other flu-like symptoms, a rash on the face, extended rash, swollen glands (enlarged lymph nodes). Blood tests may show increased levels of liver enzymes and a type of white blood cell (eosinophilia);
- A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens–Johnson syndrome), and a more severe form causing skin peeling in more than 30 % of the body surface (toxic epidermal necrolysis);
- Convulsion.

**Additional side effects in children**

**Common:** may affect up to 1 in 10 children

- Runny nose (nasopharyngitis);

- Fever (pyrexia);
- Sore throat (pharyngitis);
- Eating less than usual.

**Uncommon:** may affect up to 1 in 100 children

- Feeling sleepy or lacking in energy (lethargy).

**Not known:** frequency cannot be estimated from available data

- Changes in behaviour, not acting like themselves.

### **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 HPRA Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Lacosamide Neuraxpharm**

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 bottle after EXP. The expiry date refers to the last day of that month.

Do not refrigerate.

Once you have opened the syrup bottle, do not use beyond 2 months.

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 Lacosamide Neuraxpharm contains**

- The active substance is lacosamide. 1 ml syrup contains 10 mg lacosamide.
- The other ingredients are sorbitol liquid 70 % (not crystallising) (E 420), glycerol, propylene glycol (E 1520), macrogol 4000, sodium chloride, carmellose sodium, acesulfame potassium (E 950), citric acid, sodium methyl para-hydroxybenzoate (E 219), strawberry flavour (contains propylene glycol (E 1520)), aspartame (E 951), purified water.

### **What Lacosamide Neuraxpharm looks like and contents of the pack**

- Lacosamide Neuraxpharm 10 mg/ml syrup is a slightly viscous clear, colourless liquid.
- Lacosamide Neuraxpharm is available in a bottle of 200 ml.

The carton boxes of Lacosamide Neuraxpharm syrup contain a 25 ml measuring cup with graduation marks and a 10 ml oral syringe with an adaptor.

- The measuring cup is suitable for adults, adolescents and children weighing 50 kg and above. The measuring cup shows three different, non-linear scales on three different sides to allow a fine graduation of different doses. Each graduation mark is accompanied by the respective volume statement in ml. The minimum extractable volume is 2 ml, which is 20 mg of lacosamide. The maximum extractable volume is 25 ml, which is 250 mg of lacosamide.
- The oral syringe is suitable for children and adolescents below 50 kg. One full 10 ml oral syringe corresponds to 100 mg of lacosamide. The minimum extractable volume is 1 ml, which is 10 mg of lacosamide. After this, each graduation mark (0.25 ml) corresponds to 2.5 mg of lacosamide. The maximum extractable volume is 10 ml, which is 100 mg of lacosamide.

**Marketing Authorisation Holder**

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