PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Lacosamide Consilient Health 10 mg/ml Oral Solution Sugar Free

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

1. WHAT LACOSAMIDE IS AND WHAT IT IS USED FOR

What Lacosamide is

Lacosamide 10 mg/ml Oral Solution 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 is used for

Lacosamide is used:
- on its own and in association with other antiepileptic medicines in adults, adolescents and children aged 2 years and older 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 in adults, adolescents and children aged 4 years and older 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

Do not take Lacosamide
- 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 heartbeat problem called second- or third-degree AV block.

Do not take Lacosamide 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 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 particulary 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 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.

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

Lacosamide is not recommended for children aged under 2 years with epilepsy characterised by the occurrence of partial-onset seizure and not recommended for children aged under 4 years with primary generalised tonic-clonic seizures. 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

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 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.

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 on your body:
- medicines for fungal infections such as fluconazole, itraconazole or ketoconazole;
- medicines for HIV such as ritonavir;
- medicines for bacterial infections such as 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.

Lacosamide with alcohol

As a safety precaution do not take Lacosamide with alcohol.

Pregnancy and breast-feeding

Fertile women should discuss the use of contraceptives with the doctor.
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 if you are pregnant, as the effects of Lacosamide on pregnancy and the unborn baby are not known.
It is not recommended to breast-feed your baby while taking Lacosamide, as Lacosamide passes into 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 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 may make you feel dizzy or cause blurred vision.

Lacosamide 10 mg/ml Oral Solution contains sorbitol, sodium, sodium methyl parahydroxybenzoate, aspartame, propylene glycol and potassium
- Sorbitol (a type of sugar): This medicine contains 187 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.
- Sodium (salt): This medicine contains 1.42 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0.07 % of the recommended maximum daily dietary intake of sodium for an adult.
- Sodium methyl parahydroxybenzoate (E219) may cause allergic reactions (possibly delayed).
- Aspartame (E951): This medicine contains 0.032 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.
- Propylene glycol (E1520): This medicine contains 2.14 mg propylene glycol in each ml.
- Potassium: This medicine contains potassium, less than 1 mmol (39 mg) per 60 ml, i.e. essentially 'potassium-free'.

3. HOW TO TAKE LACOSAMIDE

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
- Take Lacosamide twice each day - approximately 12 hours apart.
- Try to take it at about the same time each day.
- You may take Lacosamide 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 is used as a long term treatment. You should continue to take Lacosamide until your doctor tells you to stop.

How much to take

Listed below are the normal recommended doses of Lacosamide for different age groups and weights. Your doctor may prescribe a different dose if you have problems with your kidneys or with your liver.
Use the 10 ml oral syringe (black graduation marks) or the 30 ml measuring cup provided in the carton box, as appropriate, according to the dosage required. See instructions for use below.

Adolescents and children weighing 50 kg or more and adults

When you take Lacosamide on its own
- The usual starting dose of Lacosamide is 50 mg (5 ml) twice a day.
- Your doctor may also prescribe a starting dose of 100 mg (10 ml) of Lacosamide 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 with other antiepileptic medicines
- The usual starting dose of Lacosamide 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 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
- ***In the treatment of partial-onset seizure:*** Observe that Lacosamide is not recommended for children under 2 years of age.
- ***In the treatment of primary generalised tonic-clonic seizures:*** Observe that Lacosamide is not recommended for children under 4 years of age.

When you take Lacosamide on its own
- Your doctor will decide the dose of Lacosamide 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.
- Dosing charts including the maximum recommended dose are provided below. This is for information only. Your doctor will work out the right dose for you.

To be taken twice daily for children from 2 years of age weighing from 10 kg to less than 40 kg

Weight	Week 1 Starting dose: 0.1 ml/kg	Week 2 0.2 ml/kg	Week 3 0.3 ml/kg	Week 4 0.4 ml/kg	Week 5 0.5 ml/kg	Week 6 Maximum recommended dose: 0.6 ml/kg
Use the 10 ml syringe (black graduation marks) for volume between 1 ml and 20 ml * Use the 30 ml measuring cup (engraved graduation marks)for volume more than 20 ml						
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 **weighing from 40 kg to less than 50 kg**

Weight	Week 1 Starting dose: 0.1 ml/kg	Week 2 0.2 ml/kg	Week 3 0.3 ml/kg	Week 4 0.4 ml/kg	Week 5 0.5 ml/kg
Use the 10 ml syringe (black graduation marks) for volume between 1 ml and 20 ml * Use the 30 ml measuring cup (engraved graduation marks)for volume more than 20 ml					
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 with other antiepileptic medicines
- Your doctor will decide the dose of Lacosamide 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 body weight. This will be until you reach a maintenance dose.
- Dosing charts including the maximum recommended dose are provided below. This is for information only. Your doctor will work out the right dose for you.

To be taken twice daily for children from 2 years of age **weighing from 10 kg to less than 20 kg**

Weight	Week 1 Starting dose: 0.1 ml/kg	Week 2 0.2 ml/kg	Week 3 0.3 ml/kg	Week 4 0.4 ml/kg	Week 5 0.5 ml/kg	Week 6 Maximum recommended dose: 0.6 ml/kg
Use the 10 ml syringe for volume between 1 ml and 20 ml						
10 kg	1 ml	2 ml	3 ml	4 ml	5 ml	6 ml
12 kg	1.2 ml	2.4 ml	3.6 ml	4.8 ml	6 ml	7.2 ml
14 kg	1.4 ml	2.8 ml	4.2 ml	5.6 ml	7 ml	8.4 ml
15 kg	1.5 ml	3 ml	4.5 ml	6 ml	7.5 ml	9 ml
16 kg	1.6 ml	3.2 ml	4.8 ml	6.4 ml	8 ml	9.6 ml
18 kg	1.8 ml	3.6 ml	5.4 ml	7.2 ml	9 ml	10.8 ml

To be taken twice daily for children and adolescents **weighing from 20 kg to less than 30 kg**

Weight	Week 1 Starting dose: 0.1 ml/kg	Week 2 0.2 ml/kg	Week 3 0.3 ml/kg	Week 4 0.4 ml/kg	Week 5 Maximum recommended dose: 0.5 ml/kg
Use the 10 ml syringe for volume between 1 ml and 20 ml					
20 kg	2 ml	4 ml	6 ml	8 ml	10 ml
22 kg	2.2 ml	4.4 ml	6.6 ml	8.8 ml	11 ml
24 kg	2.4 ml	4.8 ml	7.2 ml	9.6 ml	12 ml
25 kg	2.5 ml	5 ml	7.5 ml	10 ml	12.5 ml
26 kg	2.6 ml	5.2 ml	7.8 ml	10.4 ml	13 ml
28 kg	2.8 ml	5.6 ml	8.4 ml	11.2 ml	14 ml

To be taken twice daily for children and adolescents **weighing from 30 kg to less than 50 kg**

Weight	Week 1 Starting dose: 0.1 ml/kg	Week 2 0.2 ml/kg	Week 3 0.3 ml/kg	Week 4 Maximum recommended dose: 0.4 ml/kg
Use the 10 ml syringe for volume between 1 ml and 20 ml				
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
It is important that you use the correct device to measure your dose. Your doctor or pharmacist will let you know which device to use depending on the dose that has been prescribed.

10 ml oral dosing syringe	30 ml measuring cup
The 10 ml oral syringe has black graduations in steps of 0.25 ml. If the required dose is between 1 ml and 10 ml, you should use the 10 ml oral syringe and the adaptor provided in this pack. If the required dose is between 10 ml and 20 ml, you will need to use the 10 ml syringe two times.	The 30 ml measuring cup has engraved graduations in steps of 2.5 ml. From the 10 ml graduation mark, each increment corresponds to 5 ml. If the required dose is above 20 ml, you should use the 30 ml measuring cup provided in this pack.

Instructions for use: measuring cup
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.

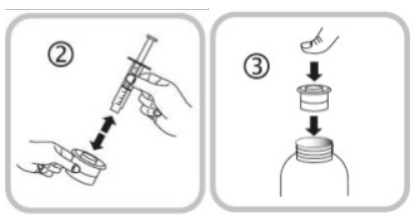
Instructions for use: oral syringe

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.

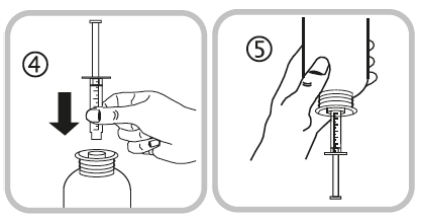
Shake the bottle well before use.
Open the bottle by pressing the cap while turning it anti-clockwise (figure 1).



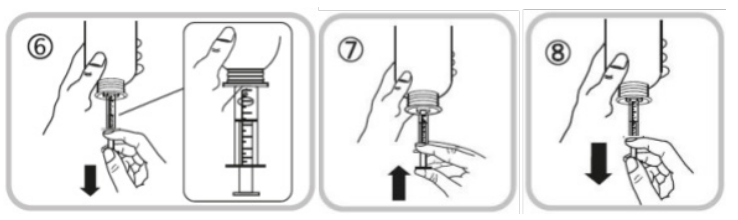
Follow these steps the first time you take Lacosamide:
- Take off the adaptor from the oral syringe (figure 2).
- Put the adaptor into the top of the bottle (figure 3). Make sure it is fixed well in place. You do not need to remove the adaptor after use.



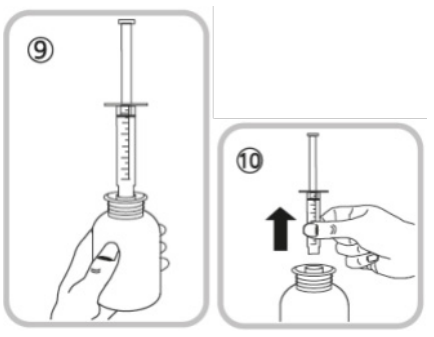
Follow these steps each time you take Lacosamide:
- Put the oral syringe into the adaptor opening (figure 4).
- Turn the bottle upside down (figure 5).



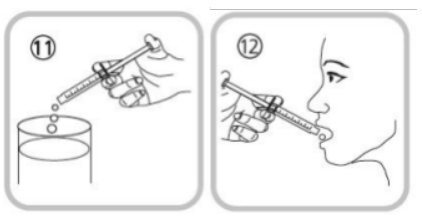
- Hold the bottle upside down in one hand and use the other hand to fill the oral syringe.
- Pull the piston down to fill the oral syringe with a small amount of solution (figure 6).
- Push the piston up to get rid of any bubbles (figure 7).
- Pull the piston down to the millilitre (ml) dose marker prescribed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



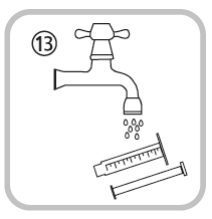
- Turn the bottle the right way up (figure 9).
- Take the oral syringe out of the adaptor (figure 10).



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 than you should
If you have taken more Lacosamide 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
- 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 dose anymore. Instead take Lacosamide 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
- Do not stop taking Lacosamide 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, 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
The additional side effects in children were fever (pyrexia), runny nose (nasopharyngitis), sore throat (pharyngitis), eating less than usual (decreased appetite), changes in behaviour, not acting like themselves (abnormal behavior) and lacking in energy (lethargy). Feeling sleepy (somnolence) is a very common side effect in children and may affect more than 1 in 10 children.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the MHRA Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE LACOSAMIDE

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 bottle, do not use beyond 6 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 10 mg/ml Oral Solution contains
- The active substance is lacosamide. 1 ml Lacosamide syrup contains 10 mg lacosamide.
- The other ingredients are glycerol (E422), carmellose sodium, sorbitol (as Sorbitol liquid (crystallizing)) (E420), macrogol 4000, sodium chloride, citric acid, acesulfame potassium (E950), sodium methyl parahydroxybenzoate (E219), strawberry flavour (contains propylene glycol), masking flavour (contains propylene glycol and aspartame), purified water.

What Lacosamide looks like and contents of the pack
- Lacosamide 10 mg/ml Oral Solution is a slightly viscous clear, colourless to yellow-brown liquid.
- Lacosamide is available in a bottle of 200 ml, with white polypropylene child resistant and tamper-evident screw cap with low density polyethylene liner.

The carton boxes of Lacosamide oral solution contain a 30 ml measuring cup (engraved graduation marks) and a 10 ml oral syringe (black graduation marks) with its adaptor.
- The measuring cup is suitable for doses above 20 ml. One full 30 ml measuring cup corresponds to 300 mg of Lacosamide. The minimum volume is 2.5 ml which corresponds to 25 mg of Lacosamide. As from the 2.5 ml graduation mark, each graduation mark corresponds to 2.5 ml which is 25 mg of Lacosamide (for example 2 graduation marks correspond to 50 mg). From the 10 ml graduation mark, each increment corresponds to 5 ml which is 50 mg of Lacosamide.
- The 10 ml oral syringe is suitable for doses between 1 ml and 20 ml. One full 10 ml oral syringe corresponds to 100 mg of Lacosamide. The minimum extractable volume is 0.5 ml, which is 5 mg of Lacosamide. After this, each graduation mark (0.25 ml) corresponds to 2.5 mg of Lacosamide (for example 4 graduation marks corresponds to 10 mg).

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