Package leaflet: Information for the patient



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.

What is in this leaflet

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

1. What Vimpat is and what it is used for

Vimpat is used to treat a certain form of epilepsy (see below) in patients aged 16 years and older. Vimpat is used in addition to other antiepileptic medicines.

Epilepsy is a condition where the patients have repeated fits (seizures). Vimpat is used for the epilepsy form in which the fits initially affect only one side of the brain, but could thereafter extend to larger areas on both sides of the brain (partial onset seizure with or without secondary generalisation).

2. What you need to know before you take Vimpat

5 Do <u>not</u> take Vimpat

- 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 suffer from a certain type of heart rhythm disorder (second or third degree AV block)

Warning and precautions

Talk to your doctor before taking Vimpat

- if you are taking any medicine which can cause an abnormality on the ECG (electrocardiogram) called increased PR interval, for example medicines used to treat certain types of irregular heart beat or heart failure. If you are not sure if the medicines you are taking could have this effect, discuss this with your doctor.
- if you suffer from a condition that is associated with impaired electric conduction across the heart or from severe heart disease such as, heart failure or heart attack

Vimpat may cause dizziness, which could increase the risk of accidental injury or a fall. Therefore, you should be careful until you are used to the effects this medicine might have.

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

Other medicines and Vimpat

Tell your doctor or pharmacist if you are taking / have recently taken or might take any other medicines. This is especially important if you take medicines to treat heart problems (see also above "Warning and precautions").

Vimpat with food, drink and alcohol

You may take Vimpat with or without food.

It is not advisable to drink alcohol while you are under treatment with Vimpat, because Vimpat could make you feel tired or dizzy. Drinking alcohol could make these effects worse.

Pregnancy and breast-feeding

It is not recommended to take Vimpat if you are pregnant, as the effects of Vimpat on pregnancy and the unborn baby are not known. Tell your doctor immediately if you are pregnant or planning to become pregnant; he/she will decide if you should take Vimpat.

It is not recommended to breast-feed your baby while taking Vimpat, as it is not known if Vimpat passes into the breast milk. If you are breast-feeding, please inform your doctor immediately; he/she will decide if you should take Vimpat.

Research has shown an increased risk of birth defects in children of women taking anti-epileptic medicines. On the other hand effective anti-epileptic therapy must not be interrupted since the worsening of the disease is harmful to both the mother and the unborn child.

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Vimpat may cause dizziness or blurred vision. This may affect your ability to drive or operate any tools or machinery. You should not drive or use machines until you know whether this medicine affects your ability to perform these activities.

Important information about some of the ingredients of Vimpat

Vimpat syrup contains:

- sorbitol (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- sodium. One graduation mark of syrup contains 0.31 mmol (or 7.09 mg) sodium. If you take more than 3 graduation marks of syrup per day and are on a controlled sodium diet, you should take into consideration the amount of sodium in the syrup.
- one ingredient called sodium methyl parahydroxybenzoate-E219 which may cause allergic reactions (possibly delayed).
- aspartame (E951), a source of phenylalanine. This substance may be harmful for people with phenylketonuria (a metabolic disease).

3. How to take Vimpat

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Administration of a loading dose has not been studied in patients with status epilepticus.

Dosage

Vimpat must be taken twice a day, once in the morning and once in the evening, at about the same time each day. Vimpat is used as a long term treatment.

The usual starting dose of Vimpat is 100 mg per day - taken twice a day – 50 mg (5ml) in the morning and 50 mg (5ml) in the evening.

Your doctor may decide to initiate Vimpat treatment with a single loading dose, followed approximately 12 hours later by initiation of a maintenance dose regimen. A loading dose should be administered under medical supervision.

Your doctor may increase your daily dose every week by 100 mg, until you reach a so called maintenance dose between 200 mg and 400 mg per day, taken twice a day. You will use this maintenance dose for the long term treatment.

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

How to take the Vimpat syrup

Shake the bottle well before use. *Use only the measuring* cup within this pack.

Fill the measuring cup to the graduation mark(s) corresponding to your prescribed dose.

Each graduation mark (5ml) of the measuring cup corresponds to 50 mg (for example 2 graduation marks correspond to 100 mg).

Swallow the dose of syrup, then drink some water. You may take Vimpat with or without food.

Duration of the treatment with Vimpat

Vimpat is used as a long term treatment. You should continue to take Vimpat until your doctor tells you to stop.

Once you have <u>opened the syrup bottle</u>, you must <u>not use</u> <u>it longer than 4 weeks.</u>

If you take more Vimpat than you should

If you have taken more Vimpat than you should, contact your doctor.

If you forget to take Vimpat

If you miss a dose by a few hours, take it as soon as you remember. If it is close to your next dose, don't take the missed syrup anymore. Just take Vimpat 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 Vimpat

Do not stop taking Vimpat without talking to your doctor, as your symptoms may come back again or become worse.

If your doctor decides to stop your treatment with Vimpat, he/she will instruct you about how you should 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 loading dose.

Very common: may affect more than 1 user in 10

- Dizziness, headache
- Nausea (feeling sick)
- Double vision (diplopia)

Common: may affect 1 to 10 users in 100

- Problems in keeping your balance, difficulties in coordinating your movements, troubles with your memory, sleepiness, shaking (tremor), trouble thinking or finding words, rapid and uncontrollable movements of the eyes (nystagmus)
- Blurred vision
- A feeling of "spinning" (vertigo)
- Vomiting, constipation, excessive gas in the stomach or bowel
- Itchina
- Fall
- Tiredness, difficulties in walking, unusual tiredness and weakness (asthenia)
- Depression
- Confusion
- Decreased feeling or sensitivity, difficulty in articulating words, disturbance in attention
- Noise in the ear such as buzzing, ringing or whistling
- Indigestion, dry mouth
- Irritability
- Muscle spasms
- Pash
- Trouble sleeping

Uncommon: may affect 1 to 10 users in 1000

- Slow heart rate
- Heart conduction disorder
- Exaggerated feeling of wellbeing
- Allergic reaction to drug intake
- Liver function test abnormal
- Attempt to commit suicideThoughts about suicide or hurting yourself
- Palpitations and/or rapid or irregular pulse
- Aggression
- Agitation
- Abnormal thinking and/or loss of touch with reality
- Serious allergic reaction which causes swelling of the face, throat, hand, feet, ankles, or lower legs
- Hives
- Hallucinations (Seeing and/or hearing things that are not real)

Not known: frequency cannot be estimated from available

 Severe decrease in a specific class of white blood cells (agranulocytosis)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet

5. How to store Vimpat

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 store above 30°C. Do not refrigerate.

Once you have <u>opened the syrup bottle</u> you must <u>not use</u> it longer than 4 weeks.

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 Vimpat contains

<u>The active substance</u> is lacosamide.

1 ml Vimpat syrup contains 10 mg lacosamide.

The other ingredients are: glycerol (E422), carmellose sodium, sorbitol liquid (crystallizing) (E420), Polyethylene glycol 4000, sodium chloride, citiric acid, anhydrous, acesulfame potassium (E950), sodium methyl parahydroxybenzoate (E219), strawberry flavour (contains propylene glycol, maltol), masking flavour (contains propylene glycol, aspartame (E951), acesulfame potassium (E950), maltol deionised water), purified water.

What Vimpat looks like and contents of the pack

Vimpat 10 mg/ml syrup is a slightly viscous clear, colourless to yellow-brown liquid.

Vimpat is available in bottles of 200 ml and 465 ml.

Not all pack sizes may be marketed.

A measuring cup with graduation marks (corresponding to 50 mg lacosamide) is provided with the syrup.

Marketing Authorisation Holder and Manufacturer Marketing Authorisation Holder: UCB Pharma SA, Allée de la Recherche 60, B1070 Bruxelles, Belgium.

Manufactured by: UCB Manufacturing Inc. , 331 Clay Road (755 Jefferson Road), Rochester, NY 14623, USA

Batch released by:

Aesica Pharmaceuticals GmbH

Alfred Nobel Strasse 10, 40789 Monheim Am Rhein, Germany

This leaflet was last revised in {11/2012}.

To report any side effect(s):

Saudi Arabia:

National Pharmacovigilance Center (NPC)

- Fax: +966-1-210-7398
- E-mail: npc.drug@sfda.gov.sa
- Website: www.sfda.gov.sa/npc

• Other GCC States:

Please contact the relevant competent authority.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The Doctor and the Pharmacist are experts in medicine, its benefits and risks.
- prescribed for you.Do not repeat the same prescription without consult-

Keep medicaments out of reach of children

- Do not by yourself interrupt the period of treatment

Council of Arab Health Ministers
Union of Arab Pharmacists

ing your Doctor.



