

Patient Information Leaflet

SCHEDULING STATUS

S3

EPITEC 25 / 50 / 100 / 200 TABLETS

Lamotrigine

Contains sugar: lactose monohydrate 52,50 mg per 25 mg tablet.

Contains sugar: lactose monohydrate 105,50 mg per 50 mg tablet.

Contains sugar: lactose monohydrate 211,00 mg per 100 mg tablet.

Contains sugar: lactose monohydrate 420,00 mg per 200 mg tablet.

Read all of this leaflet carefully before you start taking EPITEC.

- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor pharmacist, nurse or other health care provider.**
- **EPITEC has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

What is in this leaflet

1. What EPITEC is and what it is used for
2. What you need to know before you take EPITEC
3. How to take EPITEC

4. Possible side effects
5. How to store EPITEC
6. Contents of the pack and other information

1. What EPITEC is and what it is used for

EPITEC contains the active substance lamotrigine, and belongs to a group of medicines called anticonvulsants or antiepileptics. They are also sometimes called antiseizure medicines.

EPITEC is used to treat various types of epilepsy (seizures) in adults and children, including seizures associated with Lennox-Gastaut syndrome.

EPITEC may be used on its own to treat adults and children over 12 years.

EPITEC can also be used in combination with other antiepileptic medicines in both adults and children aged 2 years and over.

EPITEC should not be used on its own in children under 12 years.

Apart from the treatment of epilepsy (seizures) EPITEC is also indicated for the treatment of bipolar mood disorder. Bipolar disorder is a mood disorder characterised by episodes of depression that alternates with episodes of extremely elevated mood (also known as mania).

2. What you need to know before you take EPITEC

Do not take EPITEC:

- If you are hypersensitive (allergic) to lamotrigine or any of the other ingredients in EPITEC.
- If you are pregnant or breastfeeding.

EPITEC should not be administered to children younger than 2 years of age, since safety and efficacy in this age group have not been demonstrated.

Warnings and precautions

Take special care with EPITEC:

- If you have a history of heart problems or irregular heart beats or any of your family members have any heart problem, including genetic abnormalities.
- If you suffer from kidney or liver problems, because you will require adjustments of your EPITEC dosage. Please inform your doctor if you have kidney or liver function impairment.
- If you develop a rash, flu-like symptoms, fever, drowsiness or if your epilepsy gets worse (your seizures become more frequent), especially during the first 2 months of treatment. Contact your doctor immediately in these instances. If you have developed a rash due to EPITEC, you should not take it again after your doctor has stopped your treatment.
- When the weight of your child increases, as the dosage may have to be increased.
- If you develop hives, itching, fever, swollen lymph glands or swelling of your face, lips or tongue, as these symptoms may be the first signs of a serious allergic reaction, which may be life-threatening. Contact your doctor immediately.

- A life-threatening condition called haemophagocytic lymphohistiocytosis (HLH) may occur whilst on treatment with EPITEC. Signs of HLH include extreme swelling of the body, fever, rash and liver impairment (associated with pallor or yellowish skin and gut problems). HLH usually occurs within 8 to 24 days of initiating treatment with EPITEC. You must consult your doctor immediately if you suspect development of HLH.
- When taken in combination with other antiepileptic medicines, especially medicines containing valproate.
- If you are taking combined oral contraceptives (the pill).
- If you are taking antidepressants or suffer from depression.
- If you suffer from bipolar disorder (a mood disorder), EPITEC may increase your risk of developing depressive thoughts, or thoughts about suicide. If you experience such symptoms, report to your doctor immediately.
- If you suffer from Parkinson's disease as some of the symptoms may be worsened when you are taking EPITEC.

If you suffer from epilepsy, you should not suddenly stop taking EPITEC, as this may cause you to develop rebound convulsions (seizures). Your doctor will gradually reduce your EPITEC dose if you need to stop treatment with EPITEC.

You will undergo regular blood tests to monitor your liver and kidney function as well as platelet counts.

Children and adolescents

EPITEC should not be administered to children younger than 2 years of age, since safety and efficacy in this age group have not been demonstrated (see **section 2.0**).

Other medicines and EPITEC

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary and traditional medicines.)

Tell your doctor if you are taking any of the following medicines as they can alter the effect of EPITEC in your body:

- Other medicines for treating epilepsy (fits) such as sodium valproate, phenytoin, carbamazepine, phenobarbitone and primidone.
- Oral contraceptives such as ethinyloestradiol/levonorgestrel.
- Rifampicin, used for treating tuberculosis (TB).
- Medicines for treating HIV infection: lopinavir/ritonavir and atazanavir/ritonavir.
- Aripiprazole, used for treating mood disorders.
- Risperidone, used in the treatment of psychosis.

Laboratory tests

EPITEC may cause false positive results for some urine drug tests, particularly for phencyclidine (PCP).

EPITEC with food, drink and alcohol

EPITEC may be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking EPITEC.

Do not take EPITEC if you are pregnant or breastfeeding, as the effects of EPITEC during pregnancy or breastfeeding are not known at this time.

Please see "**other medicines and EPITEC**" regarding the use of oral contraceptives (the pill) with EPITEC.

Driving and using machines

Since EPITEC may make you feel dizzy or experience double vision, you should use caution before driving a car or operating machinery, until you know if EPITEC affects your ability to perform these tasks.

EPITEC contains Lactose

EPITEC contains the sugar, lactose. You should not take EPITEC if you have rare hereditary conditions of lactose intolerance or galactose intolerance.

EPITEC may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take EPITEC

Do not share medicines prescribed for you with any other person.

Always take EPITEC exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

The dose your doctor will prescribe for you depends on the indication (epilepsy or bipolar disorder) as well as on whether you are taking other antiepileptic or other psychiatric medicines and if so, which ones. This is especially important if you are taking any medicine containing valproate. The dosage will also depend on whether you have normal kidney and liver function.

The dose of EPITEC must be increased slowly. It may take several weeks or months before your final dosage can be determined by your doctor, based on your response.

For adults and children older than 12 years, the usual dose to control epilepsy is between 100 mg and 400 mg once daily or in two divided doses. However, your doctor will start treatment on a much lower dose and will gradually increase your dose over several weeks.

For children aged between 2 and 12 years the usual dose is between 1 mg and 15 mg per kilogram of the child's weight, taken once daily or in two divided doses. Children are also started on a lower dose, which is then slowly increased over several weeks.

EPITEC is not recommended for use in children under 2 years of age.

For adults older than 18 years of age with bipolar mood disorder, the usual dose is also between 100 mg and 400 mg, depending on what other medicines you are using and on your clinical response. Once again, treatment is initiated with much smaller dosages that are gradually increased over several weeks.

EPITEC is not indicated for the treatment of bipolar disorder in individuals younger than 18 years of age.

Do not increase your dose of EPITEC, or take more frequent doses than those indicated by your doctor

Do NOT stop taking EPITEC or any of your antiepileptic medicines unless instructed by your doctor.

Tell your doctor if your epilepsy or seizures get worse or if you have any new types of seizures.

Always tell your doctor and pharmacist if you are taking or plan to take any other prescription or over-the-counter medicines.

EPITEC tablets should be swallowed whole with water.

If you have the impression that the effect of EPITEC is too strong or too weak, tell your doctor or pharmacist.

If you take more EPITEC than you should

In the event of overdosage (if you take too many tablets), or if someone else takes your medicine by mistake, you, or this other person, may experience any of the side effects listed below, including sleepiness, lack of coordination, double vision, nausea or vomiting, and seizures (fits) that involve loss of consciousness and violent muscle contractions. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take EPITEC

Always take EPITEC as prescribed. If you miss a dose, take it as soon as possible. However, if you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

If you stop taking EPITEC

- Do not stop taking your medicine suddenly, as this may lead to seizures. Always ask your doctor first.
- Should your EPITEC be stopped or withdrawn for some reason, the dose should be decreased gradually over weeks if you suffer from epilepsy.
- Contact your doctor if you stop taking EPITEC for any reason. Do not restart without consulting your doctor.

4. Possible side effects

EPITEC can have side effects.

Not all side effects reported for EPITEC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EPITEC, please consult your healthcare provider for advice.

If any of the following happens, stop taking EPITEC and tell your doctor immediately or go to the casualty department at your nearest hospital (some of these reactions are known to be more common in children, so parents should be especially aware of this):

- An unexpected skin reaction, e.g. a rash, especially if there is blister formation, itching or hives.
- Swelling around the face or of the lips or tongue.
- If you get a high temperature, “flu-like” symptoms, swollen glands, unexpected bruising or bleeding, drowsiness, or if your epilepsy gets worse, particularly during the first two months’ treatment with EPITEC.

These are all potentially very serious side effects. If you have them, you may have had a serious allergic reaction to EPITEC. You may need urgent medical attention or hospitalisation.

Although the above-mentioned rash is mild to moderate in most cases, it may be serious and life-threatening, which would require hospitalisation. Rarely, deaths have been reported. These serious skin reactions are most likely to happen within the first 8 weeks of treatment with EPITEC and occur more often in children than in adults. Isolated cases have occurred after prolonged treatment (e.g. 6 months). It is not possible to predict

whether a mild rash will develop into a more serious reaction. A doctor should therefore be consulted immediately.

Rashes may be more likely to occur if you:

- Take EPITEC in combination with valproate.
- Take a higher starting dose of EPITEC than your doctor prescribed.
- Increase your dose of EPITEC faster than prescribed.

Tell your doctor immediately if you develop any of the following:

- Easy bruising, bleeding from the gums or pinpoint red spots on your skin, as this may indicate low platelet counts.
- Fever, chills, cough, generally feeling unwell, and slow to heal infections as this may indicate low white cell counts.

Tell your doctor as soon as possible if you notice any of the following effects:

- Double or blurred vision, dizziness, sleepiness, headache, feeling more irritable or aggressive, depression, shaking of the arms, legs or hands, feeling of pins and needles, difficulty sleeping (insomnia), feeling of room spinning, feeling agitated or confused.
- Unsteadiness or loss of co-ordination when you walk.
- Feeling tired or experience hypersensitivity to sunlight.
- Nausea, vomiting or redness of the eye(s).
- Swelling of the lymph nodes.

Treatment with EPITEC may also cause back pain or joint pain.

Your doctor will regularly perform blood tests to monitor your kidney and liver function, as well as blood cell counts.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of suspected adverse reactions

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> or drugsafetysa@cipla.com. By reporting side effects, you can help provide more information on the safety of EITEC.

5. How to store EPITEC

Keep EPITEC in a dry place at or below 25 °C.

Keep the blister strips in the outer carton until required for use.

Keep all medicines out of the reach of children.

In order to protect from moisture, do not store in bathrooms.

Do not use EPITEC after the expiry date stated on the carton and blister strips.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What EPITEC contains

- The active substance is lamotrigine
 - EPITEC 25: Each tablet contains lamotrigine 25 mg.
 - EPITEC 50: Each tablet contains lamotrigine 50 mg.
 - EPITEC 100: Each tablet contains lamotrigine 100 mg.
 - EPITEC 200: Each tablet contains lamotrigine 200 mg.
- The other ingredients are: Lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, sodium starch glycolate and yellow oxide of iron

What EPITEC looks like and contents of the pack

EPITEC 25: Yellow, round, circular tablets with 25 debossed on one side and breakline on the other side.

EPITEC 50: White, round, circular tablets with 50 debossed on one side and breakline on the other side.

EPITEC 100: White, round, circular tablets with 100 debossed on one side and breakline on the other side.

EPITEC 200: Yellow, capsule-shaped, biconvex tablets with 200 debossed on one side and plain on the other side.

EPITEC tablets are supplied in blister strips of 10 tablets, packed in cartons of 60's (6 strips). This applies to all 4 strengths of EPITEC.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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