

PATIENT INFORMATION LEAFLET FOR

EPITEC 25 / 50 / 100 / 200

SCHEDULING STATUS: S3

EPITEC 25 / 50 / 100 / 200, tablets

EPITEC 25 Each tablet contains lamotrigine 25 mg.

Contains sugar: lactose monohydrate 52,500 mg per tablet.

EPITEC 50 Each tablet contains lamotrigine 50 mg.

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

EPITEC 100 Each tablet contains lamotrigine 100 mg.

Contains sugar: lactose monohydrate 211,00 mg per tablet

EPITEC 200 Each tablet contains lamotrigine 200 mg.

Contains sugar: lactose monohydrate 420,00 mg per 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.

Epilepsy

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.

Sometimes other anti-epileptic medicines may be stopped after EPITEC has been started.

Bipolar disorder

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

EPITEC should not be used to treat bipolar disorder in children under 18 years of age.

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 of EPITEC (listed in **section 6**).

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 ever developed a rash after taking EPITEC or other medicines for bipolar disorder or epilepsy
- if you have ever developed meningitis after taking EPITEC (read the description of these symptoms in **section 4** of this leaflet: Less frequent side effects)
- if you are already taking medicine that contains lamotrigine

- if you have a history of heart problems or irregular heart beats or any of your family members have any heart problem, including a condition called Brugada syndrome which is a genetic disease that affects the heart
- 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 are pregnant or want to become pregnant.

If any of these apply to you, tell your doctor, who may decide to lower the dose, or decide that EPITEC is not suitable for you.

Conditions you need to look out for:

- ***Important information about potentially serious skin reactions:***

Some people taking EPITEC get an allergic reaction or potentially serious skin reaction, which may develop into more serious problems such as organ failure if they are not treated. These can include Stevens–Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). You need to know the symptoms to look out for while you are taking EPITEC. This risk may be associated with a variant in genes in people from Asian origin (mainly Han Chinese and Thai). If you are of such origin and have been tested previously carrying this genetic variant (HLA-B* 1502), discuss this with your doctor before taking EPITEC.

- Read the descriptions on these symptoms in **section 4** of this leaflet under 'Potentially serious skin reaction'.

- ***Serious immune system condition (haemophagocytic lymphosistocytosis or HLH):***

A serious immune system condition, in which the part of the body that fights disease is overactive. Although it has been reported very rarely in people taking EPITEC, it can be life-threatening. If you have any of the associated symptoms, immediately report them to your doctor.

- Read the descriptions on these symptoms in **section 4** of this leaflet under 'Serious immune system condition'.

- ***Thoughts of harming yourself or suicide:***

There have been reports of suicidal behaviour (including suicidal thoughts and suicide attempts) in patients being treated with anti-epileptic medicines such as EPITEC. If at any time you have these thoughts, contact your doctor immediately.

If you are taking EPITEC to prevent extreme mood swings, you may not experience the full effect for several weeks. Occasionally, the symptoms of depression or bipolar disorder may include thoughts of harming yourself or committing suicide. This risk may be higher:

- when starting treatment or changing dose
- for patients who currently have (or have previously had) thoughts of harming themselves or committing suicide

- for young adults.

If you have distressing thoughts or experiences, or if you notice that you feel worse or develop new symptoms while you're taking EPITEC:

Contact a doctor immediately or go to the nearest hospital for help.

You may find it helpful to tell a family member, caregiver or close friend that you can become depressed or have significant changes in mood and ask them to read this leaflet. You might ask them to tell you if they are worried about your depression or other changes in your behaviour.

EPITEC should not be given to people aged under 18 years to treat bipolar disorder. Medicines to treat depression and other mental health problems increase the risk of suicidal thoughts and behaviour in children and adolescents aged under 18 years.

- ***If you are taking EPITEC for epilepsy:***

The seizures in some types of epilepsy may occasionally become worse or happen more often while you are taking EPITEC. Some patients may experience severe seizures, which may cause serious health problems. If your seizures happen more often or if you experience a severe seizure while you are taking EPITEC: Contact a doctor as soon as possible.

Other medicines and EPITEC

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Some medicines may affect how EPITEC works or make it more likely that people will have side effects. EPITEC can also affect how some other medicines work.

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, a mental health problem.

Tell your doctor or pharmacist if you are taking any of these, or if you start or stop taking any. Your doctor may decide to adjust your dose.

Hormonal contraceptive pills can affect the way EPITEC works:

Your doctor may recommend that you take a particular type of hormonal contraceptive pill, or use another method of contraception, such as condoms, a cap or coil. If you are taking a hormonal contraceptive pill, or if you plan to start or stop taking one:

Talk to your doctor, who will discuss suitable methods of contraception with you.

EPITEC may also affect the way hormonal contraceptives work:

If you are taking a hormonal contraceptive pill, EPITEC may affect how well this works. If you notice any changes in your menstrual pattern, such as breakthrough bleeding or spotting between periods:

Tell your doctor. These may be signs that EPITEC is affecting how well your contraceptive pill is working.

Laboratory tests

EPITEC may interfere with some laboratory tests to detect medicines. If you require a laboratory test, tell your doctor or hospital that you are taking EPITEC.

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 health care provider for advice before taking EPITEC.

- There may be an increased risk of babies developing a cleft lip or cleft palate if EPITEC is taken during the first few months of pregnancy.
- Talk to your doctor if you are breastfeeding or planning to breastfeed. The active ingredient in EPITEC passes into breast milk and may affect your baby.
- **Driving and using machines** EPITEC can cause drowsiness, dizziness and double vision.
- Don't drive or operate machines unless you are sure you are not affected.
- If you have epilepsy, talk to your doctor about driving and using machines.

It is not always possible to predict to what extent [PRODUCT NAME] may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which EPITEC affects them.

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.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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), your age and weight, as well as on whether you are taking other antiepileptic or other psychiatric medicines. 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.

Your doctor will tell you how long your treatment with EPITEC will last. Do not stop treatment early.

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.

Do not increase your dose of EPITEC, or take more frequent doses than those prescribed 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 planing to take any other prescription or over-the-counter medicines.

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

How to take/use EPITEC tablets:

Swallow EPITEC tablets with a little water. Do not chew.

Your doctor may also advise you to start or stop taking other medicines, depending on what condition you are being treated for and the way you respond to treatment.

If you take more EPITEC than you should

If you take too much EPITEC you may be more likely to have serious side effects which may be fatal. Possible side effects if you take too much EPITEC include:

- rapid, uncontrollable eye movements (nystagmus)
- clumsiness and lack of co-ordination, affecting your balance (ataxia)
- impaired or loss of consciousness, fits (convulsions) or coma.

If you take too much EPITEC contact your doctor or your nearest hospital emergency department immediately. If possible, show them the EPITEC pack. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take EPITEC

Always take EPITEC as prescribed by your doctor. If you miss a dose, take it as soon as you remember. However, if you do not remember the missed dose until the next dose is due, skip the missed dose and carry on with your regular dosing schedule. Do not take two doses to make up for forgotten individual dose.

If you forget to take several doses of EPITEC, ask your doctor for advice on how to start taking it again, even if you only stop for a few days.

Contact your doctor before restarting EPITEC, even if you only stop for a few days.

If you stop taking EPITEC

- Take EPITEC for as long as your doctor recommends. Do not stop unless your doctor advises you.
- If you are taking EPITEC for epilepsy: To stop taking EPITEC, it is important that the dose is reduced gradually, over about 2 weeks. If you suddenly stop taking EPITEC,

your epilepsy may come back or get worse. Speak to your doctor before stopping EPITEC.

- If you're taking EPITEC for bipolar disorder: If you are taking EPITEC to prevent extreme mood swings, you may not experience the full effect for several weeks. If you stop taking EPITEC, your dose will not need to be reduced gradually. But you should still talk to your doctor first, if you want to stop EPITEC.

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 health care 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.

- ***Potentially serious skin reaction:*** A small number of people taking EPITEC get an allergic reaction or potentially serious skin reaction, which may develop into more serious problems if they are not treated. These symptoms are more likely to happen during the first few months of treatment with EPITEC, especially if the dose is too high or if the dose is increased too quickly, or if EPITEC is taken together

with a medicine called *valproate*. Serious skin reactions are more common in children. Isolated cases have occurred after prolonged treatment (e.g. 6 months).

Symptoms of these allergic reactions include:

- skin rashes or redness, which may develop into severe skin reactions including widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome and toxic epidermal necrolysis) or extended rashes with liver, blood and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS hypersensitivity syndrome)
- a sore mouth or eyes
- a high temperature (fever), flu-like symptoms or drowsiness
- swelling around your face, or swollen glands in your neck, armpit or groin

In many cases, these symptoms will be signs of less serious side effects. But you must be aware that they are potentially serious and can develop into more serious problems, such as organ failure (kidney and liver failure) and a serious blood clotting disorder which can cause unexpected bruising or bleeding (disseminated intravascular coagulation).

These are all potentially very serious side effects. If you have them, you may have had a serious reaction to EPITEC. Rarely, deaths have been reported. You may need urgent medical attention or hospitalisation. It is not possible to predict whether a mild rash will develop into a more serious reaction. A doctor should therefore be consulted immediately.

- ***Serious immune system condition (haemophagocytic lymphohistiocytosis or HLH):*** A serious immune system condition, in which the part of the body system that fights disease is overactive, has been reported while taking EPITEC. Although, it has been reported very rarely, it can be life-threatening, so it is important that you know the symptoms to look out for.

Symptoms include:

- a high temperature (fever)
- skin rashes
- trouble walking or seeing, and fits (seizures) for the first time or happening more often
- enlarged liver and/or spleen with pain and/or tenderness in the region towards the top of the stomach
- yellowing of the skin and/or eyes
- swollen glands in the neck, armpit and/or groin
- bleeding and/or bruising more easily; looking pale, feeling tired.

In most cases these symptoms may be signs of less serious side effects, but you must be aware that they can be signs of a condition which can be serious if not recognised early. Contact a doctor immediately if you have any of these symptoms.

- ***Liver and blood problems:*** These have been reported less frequently while taking EPITEC. The following symptoms may be accompanied by a general feeling of being sick or unwell:
 - yellowing of the skin

- itching
- abdominal pain and/or tenderness
- feeling very tired
- unexpected bleeding or bruising, or the fingers turning blue
- a sore throat, or more infections (such as colds) than usual.

Contact a doctor immediately if you notice any of these symptoms. Your doctor may decide to carry out tests on your liver, kidneys or blood, and may tell you to stop taking EPITEC.

- ***Seizures in Epilepsy worsening:*** In people who already have epilepsy: seizures happening more often. Tell your doctor as soon as possible if this happens.
- ***Thoughts of harming yourself or suicide:*** Occasionally, the symptoms of depression or bipolar disorder may include thoughts of harming yourself or committing suicide. If you have distressing thoughts or experiences, or if you notice that you feel worse or develop new symptoms while you are taking EPITEC, contact a doctor immediately or go to the nearest hospital for help.

Frequent side effects include:

- headache
- skin rash
- feeling sleepy, clumsiness and lack of co-ordination (ataxia), feeling dizzy
- aggression, agitation or irritability
- feeling drowsy, difficulty sleeping (insomnia), tremors, rapid, uncontrollable eye movements (nystagmus)

- feeling sick (nausea) or being sick (vomiting), diarrhoea
- feeling tired
- pain in your back, joints or elsewhere

Less frequent side effects include:

- blurred or double vision
- a severe skin reaction (Stevens-Johnson syndrome)
- itchy eyes with discharge and crusty eyelids (conjunctivitis)
- a group of side effects together including: headache, fever, nausea, vomiting, stiff neck, rash, unusual sensitivity to light, muscle pains, chills, confusion and drowsiness. This may be caused by an inflammation of the membranes that cover the brain and spinal cord (meningitis)
- unusual hair loss or thinning (alopecia)
- a severe skin reaction including extensive peeling of the skin (toxic epidermal necrolysis) multi-organ failure or a serious blood clotting disorder which can cause unexpected bruising or bleeding (disseminated intravascular coagulation)
- a serious immune system condition (haemophagocytic lymphohistiocytosis or HLH), see also the information at the beginning of **section 4**
- swelling of the face (oedema) or swollen glands in the neck, armpits or groin (lymphadenopathy)
- a high temperature (fever)
- in people who already have epilepsy, seizures happening more often

- inflammation of the kidney (tubulointerstitial nephritis), which may occur in association with inflammation of the eye (uveitis)
- uncontrollable bodily movements (tics), uncontrollable muscle spasms affecting the eyes, head and torso (choreoathetosis), or other unusual body movements such as jerking, shaking or stiffness
- feeling wobbly or unsteady when you move around
- confusion or agitation
- seeing or hearing things that aren't really there (hallucinations)
- nightmares
- in people who already have Parkinson's disease, a worsening of the symptoms
- lupus (symptoms may include: back or joint pain which sometimes may be accompanied by fever and/or general ill health)
- changes in liver function
- reduced numbers of red blood cells (anaemia)
- reduced numbers of white blood cells (neutropenia, leucopenia, agranulocytosis)
- reduced numbers of blood platelets, the cells that help blood to clot (thrombocytopenia)
- a reduced number of all these types of cells (pancytopenia)
- a disorder of the bone marrow called aplastic anaemia
- a decrease in antibodies (immunoglobulins).

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

Very rare side effects

These may affect up to 1 in 10,000 people:

- uncontrollable repeated body movements and/or sounds or words (*tics*), uncontrollable muscle spasms affecting the eyes, head and torso (*choreoathetosis*), or other unusual body movements such as jerking, shaking or stiffness.

Other side effects

- red nodules or patches on the skin (pseudolymphoma).

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 “**Adverse drug reaction and quality problem reporting form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/> or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafety@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of EPITEC.

5. How to store EPITEC

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

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

Store all medicines out of reach of children.

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

Do not use 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.
Contains sugar: lactose monohydrate 52,50 mg per tablet.
 - EPITEC 50: Each tablet contains lamotrigine 50 mg.
Contains sugar: lactose monohydrate 105,50 mg per tablet.
 - EPITEC 100: Each tablet contains lamotrigine 100 mg.
Contains sugar: lactose monohydrate 211,00 mg per tablet.
 - EPITEC 200: Each tablet contains lamotrigine 200 mg.
Contains sugar: lactose monohydrate 420,00 mg per tablet.
- 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.

Building 9

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Mispel Street

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7530

Customer care number: 080 222 6662

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EPITEC 50: A38/2.5/0572

EPITEC 100: A38/2.5/0573

EPITEC 200: A38/2.5/0574

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EPITEC 25: 06/2.5/0092

EPITEC 50: 06/2.5/0091

EPITEC 100: 06/2.5/0090

EPITEC 200: 06/2.5/0089

Botswana: S2

EPITEC 25: BOT0700978

EPITEC 50: BOT0700977

EPITEC 100: BOT0700976

EPITEC 200: BOT0700975

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER:

The QR Code to
be generated and
included after
approval.