Patient Information Leaflet for EPROLEP CR

Read this leaflet carefully before you start taking EPROLEP CR.

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

SCHEDULING STATUS: **S3**

PROPRIETARY NAMES (AND DOSAGE FORM)

EPROLEP CR 200 (film-coated tablets)

EPROLEP CR 300 (film-coated tablets)

EPROLEP CR 500 (film-coated tablets)

WHAT EPROLEP CR CONTAINS

Active ingredients

EPROLEP CR 200: Each film-coated controlled release tablet contains 133,2 mg sodium valproate and 58,0 mg valproic acid, together equivalent to 200 mg sodium valproate.

EPROLEP CR 300: Each film-coated controlled release tablet contains 199,8 mg sodium valproate and 87,0 mg valproic acid, together equivalent to 300 mg sodium valproate.

EPROLEP CR 500: Each film-coated controlled release tablet contains 333,0 mg sodium valproate and 145,0 mg valproic acid, together equivalent to 500 mg sodium valproate.

"Controlled release" means that the active ingredient, sodium valproate, is slowly released from the tablets over a period of time.

Other ingredients

EPROLEP CR 200, 300 and 500 tablets are sugar free.

In addition, **EPROLEP CR 200, 300 and 500** contains the following inactive ingredients:

Hypromellose, acesulfame potassium (as sweetener), colloidal hydrate silica, sodium laurylsulphate, dibutyl sebacate, basic butylated methacrylate copolymer, magnesium stearate, titanium dioxide.

WHAT EPROLEP CR IS USED FOR

EPROLEP CR is used to treat epilepsy (fits) in adults.

BEFORE TAKING EPROLEP CR

Do not take EPROLEP CR if you:

- are hypersensitive (allergic) to sodium valproate or any of the ingredients of **EPROLEP CR** (signs of allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue).
- are pregnant or breastfeeding.
- have liver or pancreas problems or you or your family have a history of liver problems.
- have porphyria (hereditary disorders that may affect the skin or nervous system).
- suffer from blood coagulation (clotting) disorders.
- have “urea cycle disorder” where too much ammonia builds up in the body.
- are taking medicines called monoamine oxidase inhibitors (such as selegiline, phenelzine) – see **Taking other medicines with EPROLEP CR**.
- are an elderly person.

Do not take **EPROLEP CR** if any of the above apply to you. If you are not sure, talk to your doctor pharmacist or healthcare professional before taking **EPROLEP CR**.

Take special care with EPROLEP CR

The presence of other medical problems may affect the use of **EPROLEP CR.** Talk to your doctor, pharmacist or healthcare professional before taking **EPROLEP CR** if you:

- have a liver problem (see *Liver damage* below).
- have kidney problems, as your doctor may give you a lower dose.
- have diabetes, as this medicine may affect the results of urine tests.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking **EPROLEP CR**. You will need to take extra care in cleaning your teeth to prevent infection.
- have an illness called “systemic lupus erythematosus (SLE)” – a disease of the immune system which affects skin, bones, joints and internal organs.

You should also know the following:

Birth defects in babies and developmental delay in children

If you are a young girl or a woman who can have children, see **Do not take EPROLEP CR** and be sure to read the important information and advice under **Pregnancy and breastfeeding**.

Liver damage

EPROLEP CR may cause severe and life-threatening damage to the liver.

The risk of developing liver damage is greatest in children who are younger than 2 years of age and in people who are taking more than one medication to prevent seizures or who have any of the following conditions: brain damage (any condition that affects the ability to think, learn, and understand, mental retardation), liver disease, severe seizure disorder and certain inherited diseases that prevent the body from changing food to energy normally.

Signs that you may notice are that your seizures are becoming more severe or happen more often, or you may experience excessive tiredness, lack of energy, weakness, stomach pain, loss of appetite, nausea, vomiting, or swelling of the face. *Call your doctor immediately if you notice these symptoms*.

Pancreas damage

EPROLEP CR may cause serious or life-threatening damage to the pancreas. This may occur at any time during your treatment. If you experience any of the following symptoms, call your doctor immediately: stomach pain, nausea, vomiting, or loss of appetite.

Regular examinations

Keep all appointments with your doctor and the laboratory. Your doctor will also order certain blood tests before treating you and during your treatment, to check your response to **EPROLEP CR** therapy.

Suicidal thoughts and conduct

Your mental health may change in unexpected ways and you may become suicidal (thinking about harming or killing yourself or planning or trying to do so) while you are taking **EPROLEP CR**. There may also be a risk that you will experience changes in your mental health if your condition is not treated.

You, your family, or your caregiver should call your doctor right away if you experience anxiety, depression, talking or thinking about wanting to hurt yourself or end your life or if you have any other unusual changes in behaviour or mood.

Weight gain

Taking **EPROLEP CR** may make you put on weight. Talk to your doctor about how this will affect you and how often he/she would like to check on your health if you gain weight.

Taking EPROLEP CR with food and drink

You can take **EPROLEP CR** tablets with food to help stop the feeling of sickness that may happen after taking **EPROLEP CR.**

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking **EPROLEP CR**.

Pregnancy:

You should not take **EPROLEP CR** if you are pregnant, can become pregnant, or if you are breastfeeding your baby (see **Do not take EPROLEP CR**).

Important information:

Women taking EPROLEP CR during pregnancy have a higher risk than other women of having a child with an abnormality. These abnormalities include:

- Head and face deformities including cleft lip.
- Heart and blood vessel malformations, including heart defects.
- Defects of the lining of the spinal cord.
- Malformations of the arms and legs.
- Deformities of the tube from the bladder to the penis, where the opening is formed in a different place.
- Delay in development, autism disorders. These children may require additional educational support.
- Blood clotting problems (such as blood not clotting or not clotting very well). This may appear as bruising or bleeding which takes a long time to stop.
- Low blood sugar.
- Liver failure.
- Hypothyroidism (underactive thyroid gland, which can cause tiredness or weight gain).

Important advice:

- **You should use an effective method of contraception while taking EPROLEP CR** and talk to your doctor before planning pregnancy. If you have any questions about your treatment or contraception, speak to your doctor or pharmacist**.**
- **Tell your doctor at once if you become pregnant or think you might be pregnant. Your doctor will urgently review your treatment.**
- If you have been prescribed **EPROLEP CR,** do not stop taking it without consulting your doctor, as doing so could cause harm to you or an unborn child.

Breastfeeding:

EPROLEP CR is distributed into breast milk. You should not breastfeed your baby if you have to take **EPROLEP CR**.

Driving and using machinery

You may feel drowsy when taking **EPROLEP CR**. If this happens to you, do not drive or use any tools or machines. If you also take other medicines to treat fits or to calm your mood, it may even make you more sleepy.

Taking other medicines with EPROLEP CR

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **EPROLEP CR** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Before you begin using any new medicine (prescription or non-prescription) or if you develop any new medical problem while you are taking **EPROLEP CR**, check with your doctor, pharmacist, or healthcare professional.

EPROLEP CR may increase the effect of the following medicines:

- Monoamine oxidase inhibitors (MAOI) such as selegiline, phenelzine [which may be prescribed for Parkinson's disease or for depression (mood elevation)].
- Medicines used to calm emotional and mental conditions such as diazepam and olanzapine.
- Zidovudine used to treat HIV infection.
- Medicines used for thinning the blood (such as warfarin).

The following medicines can increase the chance of you getting side effects, when taken with EPROLEP CR:

- Some other medicines used to treat fits (epilepsy), such as phenytoin, phenobarbital, carbamazepine.
- Some medicines used for pain and inflammation (salicylates), such as aspirin.

The following medicines can affect the way EPROLEP CR works:

- Some medicines used for the prevention and treatment of malaria such as mefloquine and chloroquine.
- Cimetidine used for stomach ulcers.
- Certain antibiotics used to treat bacterial infections, such as imipenem, meropenem, ertapenem, erythromycin. The combination with **EPROLEP CR** may decrease the effect of **EPROLEP CR**.
- Cholestyramine used to lower blood fat (cholesterol) levels.
- Rifampicin used for tuberculosis (TB).

HOW TO TAKE EPROLEP CR

Always take **EPROLEP CR** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **EPROLEP CR** is too strong or too weak, you should talk to your doctor or pharmacist.

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

It is important to take **EPROLEP CR** every day. Do not discontinue treatment without discussing it with your doctor.

The tablets should be swallowed whole with a little water and must not be crushed.

Take **EPROLEP CR** twice daily with food.

Adults: The starting dose is 600 mg daily. Your doctor will gradually increase this dose by 200 mg every 3 days, depending on your condition and how you respond to treatment.

If you take more EPROLEP CR than you should

You may experience an increase in side effects and their frequency. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take EPROLEP CR

If you miss a dose of **EPROLEP CR**, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not double doses to make up for a forgotten dose.

POSSIBLE SIDE EFFECTS

EPROLEP CR can have side effects.

Not all side effects reported for **EPROLEP CR** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If you get any of the following very serious side effects, stop taking EPROLEP CR and tell your doctor immediately, or go to the casualty department at your nearest hospital:

- Allergic reactions (including swelling of the face, eyelids, lips, tongue, throat; difficulty in breathing and swallowing).

You may need urgent medical attention. Very serious side effects occur less frequently.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- changes in the amount of ammonia in the blood (symptoms are vomiting, problems with balance, feeling less alert);
- liver problems (being nauseous and vomiting many times, being very tired, sleepy and weak, stomach pain, yellowing of the skin or whites of the eye);
- inflammation of the pancreas (acute abdominal pain); chest pain; shortness of breath; see also **Take special care with EPROLEP CR** above.

These are all serious side effects. You may need urgent medical attention. Serious side effects occur less frequently.

Tell your doctor if you notice any of the following:

The following side effects occur frequently:

Headache; sleep disorders; clumsiness or unsteadiness; trembling of hands and arms; nervousness; changing moods; blurred vision; ringing in ears; deafness, dizziness; flu; abdominal or stomach pain; heartburn; nausea and vomiting; diarrhoea; skin rash; hair loss or thinning of hair; back pain; change in menstrual periods; lack or loss of strength; mental confusion; aggression; convulsion; memory problems; becoming unreactive; bedwetting.

The following side effects occur less frequently:

Unusual bleeding or bruising; abnormal dreams; anxiety; feeling sad; irritability; pain in joints; cough; constipation; rolling of the eyes; dry eyes; spots before the eyes; ear infection; ear pain; runny nose; dental pain; bloated full feeling; muscle pains or stiffness; fatigue; weight gain or loss; learning disorder; coma, loss of muscle control; brittle bones and fractures; shortness of breath and chest pain; blood clotting problems.

Side effects occurring at unknown frequency:

EPROLEP CR can change levels of liver enzymes, salts or sugars shown up on blood and urine tests. Various birth defects and developmental delays have been reported in babies born of women taking **EPROLEP CR** during pregnancy (see **Pregnancy and breastfeeding** for details and advice).

Not all side effects reported for **EPROLEP CR** are included in this leaflet.

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

STORAGE AND DISPOSAL INFORMATION

Store in the original packaging (keep blisters in the carton in order to protect from light and moisture) at or below 25 °C.

Do not store your medicine in the bathroom.

Do not take **EPROLEP CR** after the expiry date printed on the label, container or blister.

Return any expired or unused medicine to your pharmacist for safe disposal. Do not dispose

of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION

EPROLEP CR tablets are packed in packs of 56 or 100 tablets in blisters made of silver oPA/Al/PVC foil and Aluminium push-through foil, in a cardboard carton. Not all pack sizes are necessarily marketed.

IDENTIFICATION OF EPROLEP CR

EPROLEP CR 200: White oval film-coated tablets with dimensions of approximately 13,8 mm x 7,2 mm.

EPROLEP CR 300: White oblong film-coated tablets with dimensions of approximately 16,7 mm x 6,7 mm and with a break mark on both sides.

EPROLEP CR 500: White oblong film-coated tablets with dimensions of approximately 17,7 mm x 9,2 mm and with a break mark on both sides.

REGISTRATION NUMBERS

EPROLEP CR 200: 45/2.5/0412

EPROLEP CR 300: 45/2.5/0093

EPROLEP CR 500: 45/2.5/0094

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

Registration date: 19 April 2013

Review date: 30 March 2022

ZA_EPROTAB_2203_00