Patient Information Leaflet

SCHEDULING STATUS: [S3]

ETHOSUXIMIDE MC PHARMA 250 mg/mL Syrup

Ethosuximide

Contains sugar and sweetener

Read this leaflet carefully before you start taking ETHOSUXIMIDE MC PHARMA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- ETHOSUXIMIDE MC PHARMA 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 ETHOSUXIMIDE MC PHARMA is and what it is used for

2. What you need to know before you use ETHOSUXIMIDE MC PHARMA

3. How to use ETHOSUXIMIDE MC PHARMA

4. Possible side effects

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6. Contents of the pack and other information

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1. What ETHOSUXIMIDE MC PHARMA is and what it is used for

ETHOSUXIMIDE MC PHARMA contains ethosuximide, an anticonvulsant that is used to treat a type of seizure that involves brief, sudden lapses in attention (petit mal).

2. What you need to know before you take ETHOSUXIMIDE MC PHARMA

- ETHOSUXIMIDE MC PHARMA is contraindicated in patients with hypersensitivity to succinimides, ethosuximide or any of the ingredients of this medicine. (See section 6).
- Porphyrias

  Ethosuximide as contained in ETHOSUXIMIDE MC PHARMA, is contraindicated in mixed types of epilepsy, may increase the frequency of generalised tonic clonic (grand mal) seizures in some patients.

Warnings and special precautions

Tell your doctor or health care provider before taking ETHOSUXIMIDE MC PHARMA, if you are taking any other anti-epileptic medicine.

Tell your doctor or pharmacist, before taking ETHOSUXIMIDE MC PHARMA, if you suffer from or have suffered in the past from any of the following conditions:

- Liver disease,
- Kidney disease,
- Bruising, fever, looking pale or a severe sore throat.

If you are taking ETHOSUXIMIDE MC PHARMA and you feel depressed and anxious, such as feeling low, loss of interest in everyday activities, lack of energy and a general feeling of unease, please consult your doctor, pharmacist or healthcare provider. Your doctor will routinely assess you for depression, anxiety and suicidality.

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A small number of people being treated with ETHOSUXIMIDE MC PHARMA have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor, pharmacist or healthcare provider.

Serious skin reactions have been reported with ETHOSUXIMIDE MC PHARMA treatment. Stop using ETHOSUXIMIDE MC PHARMA and seek medical attention immediately if you notice any of the following symptoms:

- Reddish patches on the trunk. The patches are target-like a flat, distinct, discoloured area of skin or circular, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms. These symptoms often occur within 28 days of starting this medicine but can happen later.
- Widespread rash, high body temperature and enlarged lymph nodes in different body areas, such as the neck and underarms may also occur.
- Pay special attention to symptoms such as fever, inflammation of throat or tonsils as well as a tendency to bleed.

Seek medical attention if you notice any of the following symptoms:

- Changes in your blood (bruising or bleeding more easily, fever, you are looking pale or you have a severe sore throat, mouth ulcers, fatigue, repeated infections or infections that will not go away.
- If you experience an increase in the number of your generalized fits (tonic-clonic seizures)

Your doctor may perform regular blood tests, due to your epileptic seizures or due to the properties of ETHOSUXIMIDE MC PHARMA, being an anti-epileptic medicine.

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Children and adolescents:

Do not give ETHOSUXIMIDE MC PHARMA to children below the age of 3 as safety and effectiveness have not been established.

Other medicine and ETHOSUXIMIDE MC PHARMA:

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

Since ETHOSUXIMIDE MC PHARMA may interact with concurrently administered anti-epileptic medicines, periodic serum level determinations of these medicines may be necessary (e.g. ethosuximide may elevate phenytoin serum levels whereas valproic acid has been reported to increase or decrease ethosuximide levels due to changes in metabolism).
The plasma concentrations of ethosuximide may be reduced by carbamazepine, primidone, phenobarbitone and lamotrigine and increased by isoniazid.

ETHOSUXIMIDE MC PHARMA with food and, drink and alcohol

No information available

Pregnancy and 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 this medicine.

Woman of childbearing potential / Contraception in males and females

Your prescribing doctor should advise you on the potential risks of taking ETHOSUXIMIDE MC PHARMA if you are epileptic women of childbearing potential.

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Pregnancy

Safe usage of ETHOSUXIMIDE MC PHARMA in human pregnancy is not documented. Ethosuximide crosses the placenta. Cases of birth defects have been reported with use of ethosuximide in pregnancy.

Breastfeeding

Ethosuximide is excreted in human breast milk. As the effects of ETHOSUXIMIDE MC PHARMA on nursing infants are unknown, caution should be exercised if you are breastfeeding.

Fertility

There is no data available of the effects of ETHOSUXIMIDE MC PHARMA on fertility.

Driving and use of machinery:

It is not always possible to predict to what extent ETHOSUXIMIDE MC PHARMA 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 ETHOSUXIMIDE MC PHARMA affects them.

Take caution when performing potentially hazardous tasks, such as driving a motor vehicle or other such activity requiring alertness as ETHOSUXIMIDE MC PHARMA may impair the mental and/or physical abilities.

ETHOSUXIMIDE MC PHARMA contains sucrose and sodium benzoate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ETHOSUXIMIDE MC PHARMA.

ETHOSUXIMIDE MC PHARMA may be harmful to the teeth.

Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take ETHOSUXIMIDE MC PHARMA

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

Always take ETHOSUXIMIDE MC PHARMA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

ETHOSUXIMIDE MC PHARMA is taken or administered orally.

The usual dose is individualised according to the patient. Initial doses for paediatric patients are usually:

Ages 3 to 6 years: 250 mg (5 ml) per day

Ages 6 years and older: 500 mg (10 ml) per day

The safety and effectiveness of ETHOSUXIMIDE MC PHARMA have not been established in children below the age of 3 years.

Maintenance therapy is prescribed by your doctor according to your individual clinical needs.

Your doctor will tell you how long your treatment with ETHOSUXIMIDE MC PHARMA will last. Do not stop treatment early if you have the impression that the effect of ETHOSUXIMIDE MC PHARMA is too strong or too weak, tell your doctor or pharmacist first.

If you take more ETHOSUXIMIDE MC PHARMA than you should

Acute overdose may produce nausea, vomiting and CNS depression including coma with respiratory depression.

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 ETHOSUXIMIDE MC PHARMA

Do not take / receive a double dose to make up for forgotten individual doses.

If you stop taking ETHOSUXIMIDE MC PHARMA

Abrupt withdrawal of anticonvulsant medication may precipitate absence (petit mal) status.

4. Possible side effects

ETHOSUXIMIDE MC PHARMA can have side effects.

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

If any of the following happens, stop taking / using ETHOSUXIMIDE MC PHARMA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- ‘swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing’,
- ‘rash or itching’,
- ‘fainting’

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

Tell your doctor if you notice any of the following:

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Frequent side effects:

Anorexia

Aggressiveness, euphoria, irritability

Dizziness, drowsiness, headache, hyperactivity

Hiccups

Abdominal pain, cramps, epigastric pain, vague gastric upset, nausea, vomiting

Pruritic erythematous rashes, urticaria

Less frequent side effects:

Leukopenia

Agranulocytosis, aplastic anaemia eosinophilia, pancytopenia with or without bone marrow suppression

Allergic reaction

Depression with overt suicidal intentions, disturbances of sleep, increased libido, increased state of paranoid psychosis, night terrors

Ataxia, inability to concentrate

Myopia

Diarrhoea, gum hypertrophy, tongue swelling

Stevens-Johnson syndrome, rash, petechiae

Systemic lupus erythematosus

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Haematuria, proteinuria

Vaginal bleeding

Fatigue, lethargy

Weight loss

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of ETHOSUXIMIDE MC PHARMA.

5. How to store ETHOSUXIMIDE MC PHARMA

- Store all medicines out of reach of children.
- Store in a cool, dry place below 25 °C.
- Protect from freezing and light.
- Do not use after the expiry date stated on the bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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6. Contents of this pack and other information

The active substances are:

Each 5 ml of ETHOSUXIMIDE MC PHARMA contains 250 mg Ethosuximide.

Contains sugar and sweetener:

Sucrose 3 g/5 ml

Saccharin sodium 8.325 mg/5 ml

This medicine contains 11,9 mg Sodium benzoate in each 5 ml which is equivalent to 2,38 mg/ml.

Other ingredients:

Citric acid monohydrate, saccharin sodium, sucrose, glycerol, sodium citrate, sodium benzoate, purified water, raspberry flavour.

What ETHOSUXIMIDE MC PHARMA looks like and contents of the pack

ETHOSUXIMIDE MC PHARMA is a clear slightly yellowish liquid with a characteristic odour.

ETHOSUXIMIDE MC PHARMA is packaged in a 200 ml round amber glass bottle and white polypropylene screw on cap and outer carton.

Holder of Certificate of Registration

MC Pharma (PTY) Ltd

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This leaflet was last revised in

21 January 2025

Registration number

57/2.5/0848