

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ETHOSUXIMIDE EQUITY 250 mg/5 mL oral solution

Ethosuximide

Contains sucralose 5 mg/5 mL (1 mg/mL) as sweetener

Contains sugar (glycerol 400 mg/5 mL (80 mg/mL))

Read all of this leaflet carefully before you start taking ETHOSUXIMIDE EQUITY

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ETHOSUXIMIDE EQUITY 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 EQUITY is and what it is used for
2. What you need to know before you take ETHOSUXIMIDE EQUITY
3. How to take ETHOSUXIMIDE EQUITY
4. Possible side effects
5. How to store ETHOSUXIMIDE EQUITY
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1. What ETHOSUXIMIDE EQUITY is and what it is used for

ETHOSUXIMIDE EQUITY contains a medicine called ethosuximide, an anticonvulsant.

ETHOSUXIMIDE EQUITY 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 EQUITY

Do not take ETHOSUXIMIDE EQUITY:

- if you are hypersensitive (allergic) to ethosuximide or any of the other ingredients of ETHOSUXIMIDE EQUITY (listed in section 6).
- if you have porphyria.
- if you also experience other types of seizures such as tonic clonic (grand mal) seizures.

Warnings and precautions

Take special care with ETHOSUXIMIDE EQUITY:

- if you have kidney or liver problems.
- if you have a history of mental illness.

If you experience movement disorders (see section 4), do not continue taking ETHOSUXIMIDE EQUITY. Please contact the nearest doctor who, in the event of significant disturbances, can administer diphenhydramine as an antidote by the intravenous route.

Pay special attention to symptoms of bone marrow depression such as fever, inflammation of the throat or pharynx tonsils as well as bleeding or bruising easily. Consult your doctor if you experience any of these symptoms.

Your blood count should be checked regularly (initially monthly, after one year every six months) to identify potential injury of the medulla. Your liver enzymes should also be checked regularly (initially monthly, after one year every six months).

Serious skin reactions including Stevens-Johnson syndrome (a serious disorder of the skin and mucous membranes characterised by fever, rash, blistering and peeling skin) and drug reaction with eosinophilia and systemic symptoms (DRESS, a serious reaction to medicine characterised by rash, fever, swelling of lymph nodes and increased white blood cells) have been reported in association with ETHOSUXIMIDE EQUITY treatment. Stop using ETHOSUXIMIDE EQUITY and seek medical attention immediately if you notice

any of the symptoms described in section 4.

If you have previously experienced a serious reaction when taking ethosuximide as contained in ETHOSUXIMIDE EQUITY it is advised to wear a medic-alert bracelet or pendant to let healthcare providers know.

Psychic side effects (anxiety, illusion) can occur in particular in patients with a history of psychiatric disorders. Special caution is required when ETHOSUXIMIDE EQUITY is administered to this group of patients. When being treated with ETHOSUXIMIDE EQUITY you should be routinely evaluated for depression and anxiety.

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

Children

Do not give ETHOSUXIMIDE EQUITY to children below the age of 3 years because its safety has not been determined.

Other medicines and ETHOSUXIMIDE EQUITY

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

- Other medicines used to control epilepsy, especially carbamazepine, phenytoin, primidone, phenobarbital and sodium valproate.
- Isoniazid for treatment of tuberculosis.

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 healthcare provider for advice before taking this medicine.

Ethosuximide crosses the placenta which may increase the risk of foetal abnormalities. Discuss the need for any diagnostic tests with your doctor or other healthcare providers.

Ethosuximide passes into breast milk. Caution should be exercised when ETHOSUXIMIDE EQUITY is administered to a nursing mother.

Driving and using machines

You may feel drowsy while you are taking ETHOSUXIMIDE EQUITY, particularly when you first start taking it. DO NOT drive or use any tools or machines until your doctor tells you it is OK to do so.

It is not always possible to predict to what extent ETHOSUXIMIDE EQUITY may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which ETHOSUXIMIDE EQUITY affects you.

ETHOSUXIMIDE EQUITY contains sodium benzoate (as preservative)

This medicine contains 2,5 mg sodium benzoate in each 5 mL dose which is equivalent to 0,5 mg/mL.

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

ETHOSUXIMIDE EQUITY contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 5 mL, that is to say essentially 'sodium-free'.

ETHOSUXIMIDE EQUITY contains propylene glycol

This medicine contains 3,7 mg propylene glycol in each 5 mL dose which is equivalent to 0,74 mg/mL.

If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them ETHOSUXIMIDE EQUITY, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

3. How to take ETHOSUXIMIDE EQUITY

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

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

For oral use only. Take this medicine by mouth.

Shake the bottle before use.

The usual dose is:

Adults, the elderly and children over 6 years

- The starting dose is 500 mg (10 mL) daily.
- Your doctor may decide to increase your dose every 4 to 7 days until your fits are under control.
- The maximum dose is 1 500 mg (30 mL) daily, in divided doses.

Children between 3 and 6 years

- The starting dose is 250 mg (5 mL) daily.
- Your doctor may decide to increase this every few days until your child's fits are under control.
- The dose will be calculated on the weight of your child to a maximum of 20 mg/kg/day.

Children under 3 years

- Safe use of ETHOSUXIMIDE EQUITY in children below the age of 3 years have not been established.

Your doctor will tell you how long your treatment with ETHOSUXIMIDE EQUITY will last. Do not stop treatment early because you feel better. If you have the impression that the effect of ETHOSUXIMIDE EQUITY is too strong or too weak, tell your doctor or pharmacist.

Using the dosing syringe

- When you use ETHOSUXIMIDE EQUITY for the first time, place the adaptor in the neck of the bottle.
- Push the syringe firmly into the adaptor in the neck of the bottle.
- To fill the syringe, turn the bottle upside down. Whilst holding the syringe in place, gently pull the plunger down drawing the medicine to the correct mark on the syringe. Your doctor will tell you the

right dose for you or your child.

- Turn the bottle the right way up, remove the syringe from the adaptor by gently twisting the syringe.
- Place the end of the syringe into the mouth and gently press the plunger down to release the medicine slowly and gently.
- After use replace the bottle cap. Wash the syringe in warm water and allow to dry. Store out of reach of children.



If you take more ETHOSUXIMIDE EQUITY than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Taking too much ETHOSUXIMIDE EQUITY can be very dangerous. You may feel or be sick, feel drowsy or confused or struggle to breathe.

If you forget to take ETHOSUXIMIDE EQUITY

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

If you stop taking ETHOSUXIMIDE EQUITY

Keep taking ETHOSUXIMIDE EQUITY until your doctor tells you to stop.

Do not stop taking ETHOSUXIMIDE EQUITY just because you feel better. Your fits will not be controlled if you stop taking your medicine.

If required, your doctor will tell you how to stop taking your medicine in a gradual way.

4. Possible side effects

ETHOSUXIMIDE EQUITY can have side effects.

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

If any of the following happens, stop taking ETHOSUXIMIDE EQUITY 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 EQUITY. You may need urgent medical attention or hospitalisation.

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

- reddish patches on the trunk, the patches are target-like macules 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 (Stevens-Johnson syndrome)
- widespread rash, high body temperature and enlarged lymph nodes (drug reaction with eosinophilia and systemic: symptoms (DRESS))

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- decreased appetite
- feeling easily irritated or annoyed
- headache, movement disorders

- dizziness, sleepiness
- hiccups
- abdominal pain, cramps, upset stomach, feeling and being sick
- hives

Less frequent side effects:

- changes in your blood (bruising or bleeding more easily, fever, sore throat, mouth ulcers, fatigue, repeated infections or infections that will not go away); your doctor may take regular blood samples to test for these effects
- aggression
- screaming episodes, intense fear and flailing while still asleep, often paired with sleepwalking
- suicidal thoughts or feeling depressed
- sleep disorder
- severe mental disorders that cause abnormal thinking and perceptions
- feeling tired or a lack of energy
- near-sightedness
- diarrhoea, swollen tongue
- an overgrowth of gum tissue around the teeth
- skin rash and fever with swollen glands, as these may be signs of a hypersensitivity reaction; if these are severe and you also experience pain and inflammation of the joints this could be related to a condition called systemic lupus erythematosus (SLE)
- blood in the urine
- protein in urine
- vaginal bleeding
- weight loss

Side effects with unknown frequency:

- a low number of platelets in the blood
- feelings of strong happiness, excitement and well-being
- lack of interest, increased sexual drive
- uncontrolled, involuntary movements when you first start treatment
- increased seizures (fits); blood tests may be carried out and your doctor may adjust the dose

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 “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ETHOSUXIMIDE EQUITY.

5. How to store ETHOSUXIMIDE EQUITY

Store all medicines out of reach of children.

Store at or below 25 °C. Do not refrigerate or freeze.

After first opening use within two months.

Keep the container tightly closed.

Do not use after the expiry date stated on the label / carton / bottle.

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 ETHOSUXIMIDE EQUITY contains

- The active substance is ethosuximide. Each 5 mL of oral solution contains 250 mg ethosuximide.
- The other ingredients are citric acid anhydrous, glycerol (E422), hydrochloric acid (for pH adjustment), sodium benzoate (as preservative, E211), sodium citrate, strawberry flavour (including propylene

glycol, E1520), sucralose (as sweetener, E955) and purified water.

What ETHOSUXIMIDE EQUITY looks like and contents of the pack

ETHOSUXIMIDE EQUITY is a clear, colourless solution with characteristic strawberry odour.

ETHOSUXIMIDE EQUITY is filled into amber, Type III glass bottles of 200 mL nominal capacity, suitable for pharmaceutical use, safely sealed with a HDPE child-resistant and tampered evident screw cap with LDPE seal, placed in an outer carton. Each bottle contains 200 mL solution.

It comes with a 10 mL oral syringe, with 0,5 mL graduations, and a bottle neck adaptor.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

An electronic copy of the Translated Patient Information Leaflet (PIL) is available on the Equity website

<http://www.equitypharmaceuticals.co.za>