

SIZE : 190 x 420mm for Ethosuximide OS

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PHARMACODE 25 X 7 MM

50 mm

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Package leaflet: Information for the patient

Ethosuximide Noumed

250mg/5ml oral solution

Ethosuximide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ethosuximide Noumed is and what it is used for
2. What you need to know before you take Ethosuximide Noumed
3. How to take Ethosuximide Noumed
4. Possible side effects
5. How to store Ethosuximide Noumed
6. Contents of the pack and other information

1. What Ethosuximide Noumed is and what it is used for

Ethosuximide Noumed is a medicine for the treatment of epileptic fits (anti-epileptic). Ethosuximide Noumed is used to treat

- Pyknoleptic absences and complex and atypical absences.
- Myoclonic-astatic petit mal and myoclonic fits of adolescents (impulsive petit mal), if other medicines are not effective and/or are not tolerated.

2. What you need to know before you take Ethosuximide Noumed

Do not take Ethosuximide Noumed if you

- are allergic (hypersensitive) to ethosuximide, other succinimides (group of medicines to which ethosuximide belongs) or any other ingredients of this medicine (listed in section 6).
- have porphyria (a metabolism disorder which causes abdominal pain and mental disorder).

Warnings and precautions

Talk to your doctor before taking Ethosuximide Noumed, if you:

- have kidney or liver problems
- are pregnant or planning a pregnancy, or if you are breast-feeding
- have bruising, fever, looking pale or a severe sore throat. These may be the first signs of a potentially serious blood disorder, which could be fatal if not detected.

Your doctor may take regular blood and/or urine samples to test for these.

If you experience movement disorders (see section 4) do not continue taking Ethosuximide Noumed. 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 injury of the medulla such as fever, inflammation of throat or pharynx tonsils as well as haemorrhagic tendency, and 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.

If you are taking anti-epileptic drugs, your doctor will routinely assess you for depression, anxiety and suicidality. If you are taking anti-epileptic drugs and you feel depressed and anxious, the symptoms of which are feeling low, loss of interest in everyday activities, lack of energy and a general feeling of unease, please consult your doctor.

Serious skin reactions including Stevens-Johnson syndrome and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with ethosuximide treatment. **Stop using Ethosuximide** and seek medical attention immediately if you notice any of the symptoms described in section 4.

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

Note:

To prevent grand mals which are often associated with complex and atypical absences, ethosuximide can be combined with effective anti-epileptics (e.g. primidone or phenobarbital). Additional grand mal prophylaxis can be dispensed with only in the case of pyknoleptic absence epilepsies in children of school age.

Other medicines and Ethosuximide Noumed

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

In particular, tell your doctor if you are taking any of the following:

- Other medicines used to control epilepsy, especially **carbamazepine, phenytoin, primidone, phenobarbital, lamotrigine and sodium valproate.**
- **Isoniazid**, a medicine used for certain types of infection.

If ethosuximide is being used to replace another medicine for epilepsy your doctor will withdraw these gradually to stop you getting seizures.

What other medicines affect the efficacy of Ethosuximide Noumed?

In patients also taking carbamazepine (medicine for the treatment of epileptic fits), the plasma clearance (excretion rate) of ethosuximide, the active substance of Ethosuximide Noumed, may be elevated. In patients taking valproic acid (medicine for the treatment of epileptic fits), the concentration of ethosuximide in blood may rise.

It cannot be excluded that CNS depressants and Ethosuximide Noumed mutually potentiate their sedative (calming and sleep inducing) effects.

The efficacy of what other medicines is affected by Ethosuximide Noumed?

Ethosuximide, the active substance of Ethosuximide Noumed, normally does not change the concentration of other medicines for the treatment of epileptic fits (e.g. primidone, phenobarbital, phenytoin) in blood. In individual cases the phenytoin level in blood may rise, however.

Ethosuximide Noumed with alcohol

Alcohol can change and potentiate the effects of Ethosuximide Noumed in an unforeseeable manner. Do not drink alcohol or consume alcohol-containing food while you take Ethosuximide Noumed.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Before you start taking ethosuximide:

If you are of childbearing age and are planning to become pregnant, talk to your doctor for advice before you start taking ethosuximide.

If you become pregnant while taking ethosuximide:

- Tell your doctor **immediately**.
- Do not stop taking Ethosuximide without telling your doctor as your fits may start again. Your doctor may reduce your dose, but it is still important for your fits to be controlled.
- 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 professionals.
- It is recommended that pregnant women take Folic Acid and Vitamin K supplements.

Breast-feeding

Ethosuximide passes into breast milk.

DO NOT breast-feed while taking Ethosuximide as it will make your baby sleepy, not able to suckle properly or become irritable or unsettled.

Driving and using machines

You may feel drowsy while you are taking this medicine, 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.

Ethosuximide Noumed contains sodium benzoate, propylene glycol and sodium

Sodium Benzoate (E211): This medicine contains 5 mg sodium benzoate in each 5 ml. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Propylene glycol (E1520): This medicine contains 14 mg propylene glycol in each 5 ml. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

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

3. How to take Ethosuximide Noumed

Always take this medicine exactly as your doctor 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.
- Use the syringe provided and read the dosing instructions below.

How much to take

Your doctor will decide the dose appropriate for you or your child. Unless otherwise prescribed by your doctor, the recommended dose is:

Adults, elderly patients and children over 6 years of age:

- The treatment is started at a daily dose of 500 mg (10 ml).
- Depending on the patient's tolerance, the dose is increased every five to seven days in increments of max. 250 mg (5 ml) until the fits are controlled by a daily dose of 1000-1500 mg (20- 30 ml).
- The maximum dose is 2000mg (40ml) in divided doses.

The therapeutic plasma level of ethosuximide is normally between 40 and 100 µg/ml. However, the dose depends on the patient's clinical response. The half-life of ethosuximide in plasma is more than 24 hours so that the daily dose can be taken as a single dose provided the medicine is well tolerated. Higher daily doses should be taken in 2 or 3 single doses, however.

The decision about changes to the dosage regimen can be taken by your doctor only.

The risk of side effects which depend on the dose taken can be reduced by taking small initial doses of Ethosuximide Noumed and increasing them gradually to optimum amounts (increasing the amounts slowly from day to day) and by taking them during or after meals.

Haemodialysis patients

Ethosuximide is dialysable. Haemodialysis patients therefore require a supplementary dose or a modified dosage regimen. During a dialysis period of four hours, 39% to 52% of the dose taken is removed.

Children and adolescents

Children under 2 years:

- The starting dose is one of 125 mg (2.5 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 1000mg (20ml) each day.

Children between 2 and 6 years of age:

- The starting dose is of 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 1000mg (20ml) each day.

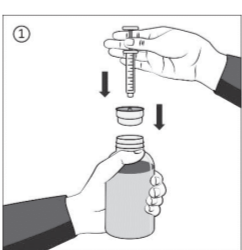
Method of administration

Ethosuximide Noumed is for oral use.

The solution can be taken during or after meals.

Instructions for use

- The pack contains a graduated oral syringe (0.5 ml steps) and an adapter for the oral syringe.
- Opening of the bottle: Turn the screw cap anti-clockwise.



- When you use the medicine for the first time, insert the adapter in the bottle neck (Fig. 1). Make sure that the adapter is tightly fitted.
- Insert the oral syringe firmly in the opening of the adapter in the neck of the bottle (Fig. 1).

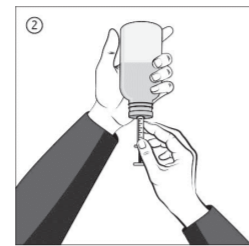
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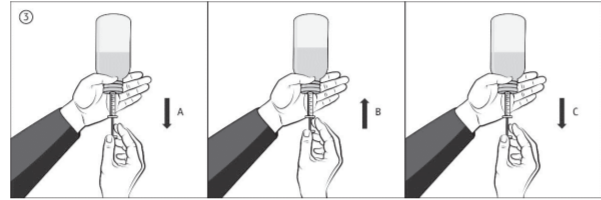
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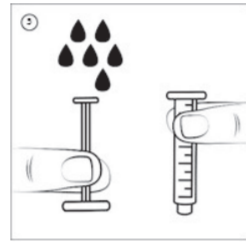
- To fill the syringe, turn the bottle upside down. Whilst holding the syringe in place, gently pull the plunger down drawing the medicine to the correct mark on the syringe. Your doctor will tell you the right dose for you or your child.



- Place the bottle in upright position. Remove the syringe from the adapter by gently twisting the syringe.



- Place the end of the syringe into the mouth and gently press the plunger down to slowly and gently release the medicine



- After use, replace the bottle cap. Rinse the syringe in warm water and allow to dry only. Store out of reach of children.

How long to take Ethosuximide Noumed

The treatment of epileptic fits is principally a long-term treatment. The dose, the distribution of the daily dose, the duration of treatment and discontinuation of Ethosuximide Noumed are determined by a specialist with experience in the treatment of epilepsy.

If you take more Ethosuximide Noumed than you should

- If you take more Ethosuximide than you should, or if you think a child has accidentally swallowed any, tell a doctor or go to a hospital casualty department straight away. Take this leaflet with you. This is so the doctor knows what you have taken.

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

If you forget to take Ethosuximide Noumed

- If you forget a dose, take the next dose as soon as you remember. However, if it is nearly time for the next dose skip the missed dose.
- **Do not** take a double dose to make up for the forgotten dose.

If you stop taking Ethosuximide Noumed

- Keep taking Ethosuximide until your doctor tells you to stop.
- **Do not** stop taking the medicine 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

Like all medicines, this medicine can cause side effects too, although not everybody gets them.

Children are at higher risk of the effects.

Serious side effects

Stop using Ethosuximide and seek medical attention immediately if you notice any of the following symptoms:

- 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) (Uncommon (may affect up to 1 in 100 people)).
- Widespread rash, high body temperature and enlarged lymph nodes (drug reaction with eosinophilia and systemic symptoms (DRESS)) (Frequency not known). 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 (Uncommon (may affect up to 1 in 100 people)).

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). These may be the first signs of an abnormality of the blood, including decreases in the number of red cells, white cells or platelets and bone marrow suppression, please consult your doctor. Your doctor may take regular blood samples to test for these effects (Uncommon (may affect up to 1 in 100 people)).
- If you experience an increase in the number of your generalized fits (tonic-clonic seizures) (Frequency not known).

Other side effects are:

Common (may affect up to 1 in 10 people)

- decreased appetite,
- headaches,
- unsteadiness,
- difficulty in controlling movements,
- dizziness,
- drowsiness,
- stomach ache and cramps,
- feeling sick or being sick (vomiting),
- skin rash including measles-like reactions which are mild,
- hives.

Uncommon (may affect up to 1 in 100 people):

- aggressive behaviour,
- nightmares,
- depression,
- thinking about suicide,
- psychotic disorder,
- disturbance to sleep patterns,
- shaking,
- abnormal or uncoordinated movements,
- sluggishness,
- inability to concentrate,
- short sightedness,
- hiccups,
- diarrhoea,
- enlarged gums,
- swollen tongue,
- blood in the urine,
- vaginal bleeding,
- fatigue,
- irritability,
- weight loss,
- feelings of persecution,
- hyperactivity,
- changes to your blood counts, particularly white blood cells called eosinophils.

Not known (frequency cannot be estimated from the available data):

- sense of great well-being,
- an increased sex drive,
- extreme restlessness,
- loss of interest in activities,
- violent muscle contractions,
- swelling of the lymph glands.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse.

This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ethosuximide Noumed

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and the carton after "EXP.". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

After first opening, use within 30 days.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ethosuximide Noumed contains

The active substance is Ethosuximide.

Each 5ml of oral solution contains 250mg of the active ingredient ethosuximide.

The other ingredients are: sodium citrate, sodium benzoate (E 211), sucralose, glycerol (E 422), artificial raspberry flavour (contains propylene glycol (E 1520), citric acid monohydrate and purified water).

What Ethosuximide Noumed looks like and contents of the pack
Ethosuximide Noumed is a clear, colourless solution with raspberry odour.

Available in amber colour glass bottles containing 125ml, 200ml and 250ml oral solution closed with child resistant white cap.

Each pack is supplied with 10 ml graduated oral syringe and an adapter.

Not all pack sizes may be marketed.

This leaflet was last revised in March 2025.

Marketing Authorisation Holder and Manufacturer:

NOUMED LIFE SCIENCES LIMITED
Noumed House, Shoppenhangers Road
Maidenhead, Berkshire, SL6 2RB. UK

Other sources of information:

To listen to or request a copy of this leaflet in braille, large print or audio please call,
020 33998960 (UK only)

Please be ready to give the following information:

Product name:

Ethosuximide Noumed 250 mg/5 ml Oral Solution

Reference number: PL 44041/0176

LETH0101

190 mm

Signature of Author:	
Signature of RA:	

Font Type & Size	Heading
	Arial - Bold - 12 pts
	Body
	Arial - Regular - 7 pts
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Noumed Life Sciences

Title: Art Work Approval Form

Product	Ethosuxomide Oral Solution			Specification:	NA		
Customer	NOUMED LIFE SCIENCES LIMITED, UK						
Reason for Issue	Content update			Colours:	Single - Black		
Related FG Codes		Pharmacode No.	NA	Dimensions:	190 x 420 mm (Open size)		
Item Code	LETH01/01	Layout No.:	NA	No. OfFolds (Only for PIL)		Artwork made to	100%