

PACKAGE LEAFLET: INFORMATION FOR PATIENTS
Ethosuximide neuraxpharm 250 mg soft capsules
(ethosuximide)

Your medicine is known as Ethosuximide neuraxpharm 250 mg soft capsules but will be referred to as Ethosuximide neuraxpharm throughout the following leaflet.

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

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

Ethosuximide neuraxpharm is a medicine for the treatment of epileptic fits (anti-epileptic).

Ethosuximide neuraxpharm 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 neuraxpharm

Do not take Ethosuximide neuraxpharm capsules

- if you are allergic to ethosuximide, other succinimides (group of medicines to which ethosuximide belongs) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before taking Ethosuximide neuraxpharm.

- If you experience movement disorders (see section 4) do not continue taking Ethosuximide neuraxpharm. 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 damage 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 bone marrow damage. At a leucocyte count (number of white blood cells) of less than 3500/mm³ or a granulocyte ratio of less than 25% the dose should be reduced or Ethosuximide neuraxpharm discontinued completely. Your liver enzymes should also be checked regularly.
- Psychiatric side effects (anxiety, illusion) can occur in particular in patients with a history of psychiatric disorders. Special caution is required when Ethosuximide neuraxpharm is administered to this group of patients.
- A small number of patients treated with anti-epileptics such as ethosuximide have developed thoughts about self-harm or suicidal thoughts. If at any time during the treatment you have such thoughts, tell your doctor immediately.
- 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 neuraxpharm and seek medical attention immediately if you notice any of the symptoms described in section 4.

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 neuraxpharm

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

What other medicines affect the efficacy of Ethosuximide neuraxpharm?

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

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

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

Ethosuximide, the active substance of Ethosuximide neuraxpharm, 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 neuraxpharm with alcohol

Alcohol can change and potentiate the effects of Ethosuximide neuraxpharm in an unforeseeable manner.

Do not drink alcohol or consume alcohol-containing food while you take Ethosuximide neuraxpharm!

Pregnancy and breast-feeding

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

If you are of childbearing age, you should be advised by your doctor regarding the necessity of planning and monitoring any pregnancy before starting the treatment with Ethosuximide neuraxpharm. Do not discontinue Ethosuximide neuraxpharm without first consulting your doctor as epileptic seizures might recur, which could harm you and/or your unborn child.

No specific malformations of babies are known which were caused by the treatment with ethosuximide, the active substance of Ethosuximide neuraxpharm. However, patients treated with medicines against epileptic seizures generally have a higher risk for malformations than other women. The most commonly reported malformations are cleft lip, cardiovascular malformation and neural tube defects (spina bifida). This risk is even higher in patients treated with more than one anti-epileptic, and therefore combination treatment should be avoided during pregnancy.

Prenatal diagnostic measures like high level ultrasound and the determination of α -fetoprotein are recommended for the early detection of foetal damage.

The lowest effective ethosuximide dose ensuring seizure control must not be exceeded, particularly from the 20th to the 40th day of pregnancy. Your ethosuximide serum concentration must be checked regularly. You should take extra folic acid if you are planning to have a baby or if you are pregnant.

To prevent vitamin K1 deficiency in your baby and bleeding caused by this deficiency, you should also be given vitamin K1 during the last month of your pregnancy.

Breast-feeding

Ethosuximide passes into breast milk and might lead to sedation, poor suckling and irritability in breast-fed infants. Therefore, you should stop breast-feeding during treatment with Ethosuximide neuraxpharm.

Driving and using machines

Ethosuximide can impair reactivity. Therefore, the following should be considered throughout the treatment period, in particular, however, during the adjustment phase: You are not able to respond quickly and purposefully to unexpected and sudden events. Do not drive cars or other vehicles! Do not operate dangerous electric tools or machines! Do not work without a secure hold! The decision about whether you are able to drive and use machines will be taken in each case by your doctor considering your individual response to the medicine. Be advised that alcohol further impairs your driving capacity.

Ethosuximide neuraxpharm capsules contains sorbitol (E420)

This medicine contains 3.4 to 9.9 mg sorbitol in each capsule. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

3. How to take Ethosuximide neuraxpharm

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

Dosage

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 low daily dose of 500 mg (2 soft capsules). Depending on the patient's tolerance, the dose is increased every five to seven days in increments of max. 250 mg until the fits are controlled by a daily dose of 1000-1500 mg (4-6 soft capsules). In an individual case, a daily dose of 2000 mg (8 soft capsules), divided into several single doses, may be required.

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

The therapeutic plasma level of ethosuximide is normally between 40 and 100 μ g/ml. However, the dose depends on the patient's clinical response. The half-life of ethosuximide in plasma is more than 24 hours and the daily dose can be divided and 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.

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.

Use in children

Not all posologies are possible with the soft capsules. Children in the age of 0 to 6 years and patients who cannot swallow soft capsules, should take ethosuximide as oral solution. Dosage of older children over 6 years is the same as mentioned for adults (see beginning of section 3).

Method of administration

Ethosuximide neuraxpharm is for oral use. The soft capsules can be taken during or after meals with half a glass of water.

How long to take Ethosuximide neuraxpharm

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 neuraxpharm are determined by a specialist with experience in the treatment of epilepsy.

If you take more Ethosuximide neuraxpharm than you should

If by mistake you have taken a double dose Ethosuximide neuraxpharm, do not change your dosage regimen, but continue taking Ethosuximide neuraxpharm as prescribed. Significantly higher doses potentiate effects such as tiredness, lethargy (lack of drive, apathy), depressive states and states of agitation, in some cases also irritability as well as any other side effects depending on the quantity taken (overdose effects may occur at concentrations over 150 µg ethosuximide per ml blood).

Overdose symptoms are potentiated by alcohol and other CNS depressants.

If any of these symptoms occur, contact the nearest doctor and, if possible, present the medicine taken and the package leaflet.

If a significant overdose was taken, the doctor will perform gastric lavage and administer medicinal charcoal. Monitoring of the cardiovascular and respiratory systems in an intensive care unit is required.

If you forget to take Ethosuximide neuraxpharm

Do not take a double dose to make up for the forgotten dose. Normally no symptoms will appear when you forgot to take a single dose. Continue taking the medicine as prescribed, i.e. do not take the forgotten dose at a later time. Be advised, however, that Ethosuximide neuraxpharm will control your state safely and appropriately only when taken regularly!

If you stop taking Ethosuximide neuraxpharm

If you wish to discontinue the treatment, talk to your doctor first. Do not stop taking the medicine without checking with your doctor, as this may jeopardise the success of the treatment. Strictly follow the treatment recommendations of your doctor, as otherwise you may have again epileptic fits! If you think that you do not tolerate Ethosuximide neuraxpharm, please contact your doctor! If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

STOP using Ethosuximide neuraxpharm 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).
- Widespread rash, high body temperature and enlarged lymph nodes (drug reaction with eosinophilia and systemic symptoms (DRESS)).

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

- 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.

Other possible side effects

Common (may affect up to 1 in 10 patients) to very common (may affect more than 1 in 10 patients):

- Nausea, vomiting, hiccup and abdominal pain

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

- Severe headache, sleep disturbances, lethargy (lack of drive, apathy), ataxia (movement disorders)
- Withdrawal, anxiety
- Loss of appetite, loss of weight
- Diarrhoea, constipation

Rare (may affect up to 1 in 1000 patients):

- Paranoid and hallucinatory phenomena developing over days and weeks (illusion, persecution complex)
- Lupus erythematoses* of varying extent (skin disease that may involve internal organs)
- Leucopenia* (shortage of white blood cells), eosinophilia* (increase of a certain type of white blood cells), thrombocytopenia* (shortage of blood platelets) or agranulocytosis* (absence of certain defensive cells)

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

- In individual cases dyskinesias (movement disorders, see section 2) may occur during the first 12 hours of the treatment.
- Allergic skin reactions* such as rash
- In individual cases aplastic anaemia* (shortage of red blood cells due to failure of body to produce new cells) and pancytopenia* (shortage of all blood cells) may occur (see section 2).

* Side effects which are independent of the dose of the medicine

If side effects occur which are independent of the dose taken, the medicine is usually discontinued and the side effects disappear. They may reappear when Ethosuximide neuraxpharm is taken again.

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

Note:

Long-term treatment may affect the patient's performance, e.g. the performance in school of children and adolescents.

Reporting of side effects

If you get any side effects, talk to your doctor, 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 at: 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 NEURAXPHARM

- **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**
- Do not use Ethosuximide neuraxpharm after the expiry date which is stated on the carton and blister strip. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ethosuximide neuraxpharm contains

- The active substance is Ethosuximide. Each soft capsule contains 250 mg Ethosuximide.
- The other ingredients are: Macrogol 300, Gelatin, Glycerol, Sorbitol liquid partially dehydrated E420, Purified Water, Titanium dioxide (E 171), Iron oxide yellow (E 172).

What Ethosuximide neuraxpharm looks like and contents of the pack

Ethosuximide neuraxpharm 250 mg soft capsules are oval, yellow and opaque soft capsules.

Ethosuximide neuraxpharm 250 mg soft capsules are available as blister packs of 50, 56 or 60 soft capsules.

Product Licence holder

Procured from within the EU and repackaged by the Product Licence holder: S&M Medical Ltd, Chemilines House, Alperton Lane, Wembley, HA0 1DX.

Manufacturer

This product is manufactured by Neuraxpharm Arzneimittel GmbH, Elisabeth-Selbert-Straße 23 40764, Langenfeld, Germany.

POM PL: 19488/1870

Leaflet revision date: 23 July 2021

Blind or partially sighted? Is this leaflet hard to see or read? Call 02087997607 to obtain the leaflet in large print, tape, CD or Braille.

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1. What Ethosuximide S&M Medical is and what it is used for

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Warnings and precautions

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Your blood count should be checked regularly (initially monthly, after one year every six months) to identify potential bone marrow damage. At a leucocyte count (number of white blood cells) of less than 3500/mm³ or a granulocyte ratio of less than 25% the dose should be reduced or Ethosuximide S&M Medical discontinued completely. Your liver enzymes should also be checked regularly.
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- 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 S&M Medical and seek medical attention immediately if you notice any of the symptoms described in section 4.

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.

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What other medicines affect the efficacy of Ethosuximide S&M Medical?

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Ethosuximide S&M Medical with alcohol

Alcohol can change and potentiate the effects of Ethosuximide S&M Medical in an unforeseeable manner.

Do not drink alcohol or consume alcohol-containing food while you take Ethosuximide S&M Medical!

Pregnancy and breast-feeding

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

If you are of childbearing age, you should be advised by your doctor regarding the necessity of planning and monitoring any pregnancy before starting the treatment with Ethosuximide S&M Medical. Do not discontinue Ethosuximide S&M Medical without first consulting your doctor as epileptic seizures might recur, which could harm you and/or your unborn child.

No specific malformations of babies are known which were caused by the treatment with ethosuximide, the active substance of Ethosuximide S&M Medical. However, patients treated with medicines against epileptic seizures generally have a higher risk for malformations than other women. The most commonly reported malformations are cleft lip, cardiovascular malformation and neural tube defects (spina bifida). This risk is even higher in patients treated with more than one anti-epileptic, and therefore combination treatment should be avoided during pregnancy.

Prenatal diagnostic measures like high level ultrasound and the determination of α -fetoprotein are recommended for the early detection of foetal damage.

The lowest effective ethosuximide dose ensuring seizure control must not be exceeded, particularly from the 20th to the 40th day of pregnancy. Your ethosuximide serum concentration must be checked regularly. You should take extra folic acid if you are planning to have a baby or if you are pregnant.

To prevent vitamin K1 deficiency in your baby and bleeding caused by this deficiency, you should also be given vitamin K1 during the last month of your pregnancy.

Breast-feeding

Ethosuximide passes into breast milk and might lead to sedation, poor suckling and irritability in breast-fed infants. Therefore, you should stop breast-feeding during treatment with Ethosuximide S&M Medical.

Driving and using machines

Ethosuximide can impair reactivity. Therefore, the following should be considered throughout the treatment period, in particular, however, during the adjustment phase: You are not able to respond quickly and purposefully to unexpected and sudden events. Do not drive cars or other vehicles! Do not operate dangerous electric tools or machines! Do not work without a secure hold! The decision about whether you are able to drive and use machines will be taken in each case by your doctor considering your individual response to the medicine. Be advised that alcohol further impairs your driving capacity.

Ethosuximide S&M Medical capsules contains sorbitol (E420)

This medicine contains 3.4 to 9.9 mg sorbitol in each capsule. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

3. How to take Ethosuximide S&M Medical

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

Dosage

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 low daily dose of 500 mg (2 soft capsules). Depending on the patient's tolerance, the dose is increased every five to seven days in increments of max. 250 mg until the fits are controlled by a daily dose of 1000-1500 mg (4-6 soft capsules). In an individual case, a daily dose of 2000 mg (8 soft capsules), divided into several single doses, may be required.

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

The therapeutic plasma level of ethosuximide is normally between 40 and 100 μ g/ml. However, the dose depends on the patient's clinical response. The half-life of ethosuximide in plasma is more than 24 hours and the daily dose can be divided and 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.

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.

Use in children

Not all posologies are possible with the soft capsules. Children in the age of 0 to 6 years and patients who cannot swallow soft capsules, should take ethosuximide as oral solution. Dosage of older children over 6 years is the same as mentioned for adults (see beginning of section 3).

Method of administration

Ethosuximide S&M Medical is for oral use. The soft capsules can be taken during or after meals with half a glass of water.

How long to take Ethosuximide S&M Medical

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 S&M Medical are determined by a specialist with experience in the treatment of epilepsy.

If you take more Ethosuximide S&M Medical than you should

If by mistake you have taken a double dose Ethosuximide S&M Medical, do not change your dosage regimen, but continue taking Ethosuximide S&M Medical as prescribed. Significantly higher doses potentiate effects such as tiredness, lethargy (lack of drive, apathy), depressive states and states of agitation, in some cases also irritability as well as any other side effects depending on the quantity taken (overdose effects may occur at concentrations over 150 µg ethosuximide per ml blood).

Overdose symptoms are potentiated by alcohol and other CNS depressants.

If any of these symptoms occur, contact the nearest doctor and, if possible, present the medicine taken and the package leaflet.

If a significant overdose was taken, the doctor will perform gastric lavage and administer medicinal charcoal. Monitoring of the cardiovascular and respiratory systems in an intensive care unit is required.

If you forget to take Ethosuximide S&M Medical

Do not take a double dose to make up for the forgotten dose. Normally no symptoms will appear when you forgot to take a single dose. Continue taking the medicine as prescribed, i.e. do not take the forgotten dose at a later time. Be advised, however, that Ethosuximide S&M Medical will control your state safely and appropriately only when taken regularly!

If you stop taking Ethosuximide S&M Medical

If you wish to discontinue the treatment, talk to your doctor first. Do not stop taking the medicine without checking with your doctor, as this may jeopardise the success of the treatment. Strictly follow the treatment recommendations of your doctor, as otherwise you may have again epileptic fits! If you think that you do not tolerate Ethosuximide S&M Medical, please contact your doctor! If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

STOP using Ethosuximide S&M Medical 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).
- Widespread rash, high body temperature and enlarged lymph nodes (drug reaction with eosinophilia and systemic symptoms (DRESS)).

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

- 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.

Other possible side effects

Common (may affect up to 1 in 10 patients) to very common (may affect more than 1 in 10 patients):

- Nausea, vomiting, hiccup and abdominal pain

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

- Severe headache, sleep disturbances, lethargy (lack of drive, apathy), ataxia (movement disorders)
- Withdrawal, anxiety
- Loss of appetite, loss of weight
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Rare (may affect up to 1 in 1000 patients):

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- Leucopenia* (shortage of white blood cells), eosinophilia* (increase of a certain type of white blood cells), thrombocytopenia* (shortage of blood platelets) or agranulocytosis* (absence of certain defensive cells)

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

- In individual cases dyskinesias (movement disorders, see section 2) may occur during the first 12 hours of the treatment.
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Note:

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Reporting of side effects

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5. HOW TO STORE ETHOSUXIMIDE S&M MEDICAL

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Ethosuximide S&M Medical 250 mg soft capsules are oval, yellow and opaque soft capsules.

Ethosuximide S&M Medical 250 mg soft capsules are available as blister packs of 50, 56 or 60 soft capsules.

Product Licence holder

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Manufacturer

This product is manufactured by Neuraxpharm Arzneimittel GmbH, Elisabeth-Selbert-Straße 23 40764, Langenfeld, Germany.

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