**Package leaflet: Information for patients**

**Apictro 250 mg soft capsules**

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


## 1. What Apictro is and what it is used for

Apictro contains the active substance ethosuximide. Ethosuximide is one of a group of medicines called anti-epileptic drugs; these medicines are used to treat epilepsy.

Ethosuximide is used to control brief, sudden loss of consciousness (absence seizures, also called petit mal), and uncontrolled jerking movements (myoclonic seizures).

## 2. What you need to know before you take Apictro

**Do not take Apictro**
- 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 Apictro

**If you experience movement disorders** (see section 4) do not continue taking Apictro. Please, contact the nearest doctor, in the event of significant disturbances.

Special attention should be given to clinical symptoms of bone marrow damage such as fever, sore throat as well as any unexplained bruising or bleeding, consult your doctor, if you experience any of these symptoms.

Your blood count should be checked regularly (initially monthly, then after one year of treatment 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 Apictro 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 Apictro 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, contact 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 APICTRO and seek medical attention immediately if you notice any of the symptoms described in section 4.

**Other medicines and Apictro**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

What other medicines affect the efficacy of Apictro?
In patients also taking carbamazepine (medicine for the treatment of epileptic seizures), the plasma clearance (excretion rate) of ethosuximide, the active substance of Apictro, may be elevated. In patients taking sodium valproate (medicine for the treatment of epileptic seizures), the concentration of ethosuximide in blood may rise.
It cannot be excluded that CNS depressants and Apictro mutually potentiate their sedative (calming and sleep inducing) effects.

The efficacy of what other medicines is affected by Apictro?
Ethosuximide, the active substance of Apictro , normally does not change the concentration of other medicines for the treatment of epileptic seizures (e.g. primidone, phenobarbital, phenytoin) in blood.
In individual cases the phenytoin level in blood may rise, however.

**Apictro with alcohol**
Alcohol can change and potentiate the effects of Apictro in an unpredictable manner.
Do not drink alcohol or consume alcohol-containing food while you take Apictro

**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
Ethosuximide may affect the unborn baby. However, it is very important to control your seizures while you are pregnant. If you need to take Apictro your doctor can help you decide whether or not to take it during pregnancy

Breast-feeding
Ethosuximide passes into breast milk and might lead to sedation, poor suckling and irritability in breast-fed infants. You should not take Apictro if you are breast-feeding .

**Driving and using machines**
Apictro may cause dizziness or drowsiness and thus impair reactivity. If you experience these symptoms, do not drive or operate machinery or use any tools.

**Apictro contains sorbitol (E420)**
This medicine contains x up to 9.9mg sorbitol in each soft 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 Apictro

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 siezures 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), taken in 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 Apictro and increasing them gradually to optimum amounts 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.

Use in children
Not all posologies are possible with the soft capsules.
Children in the age of 0 to 6 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**
Apictro is for oral use.
The soft capsules can be taken during or after meals with half a glass of water.

How long to take Apictro
The treatment of epileptic seizures is principally a long-term treatment. The dose, the distribution of the daily dose, the duration of treatment and discontinuation of Apictro are determined by a specialist with experience in the treatment of epilepsy.

**If you take more Apictro than you should**
If you accidentally take too much Apictro , you may feel very drowsy or confused. Contact your doctor or pharmacist immediately or go to the nearest hospital casualty department. Remember to take the labelled medicine package with you if possible, regardless if there is any Apictro left or not.

Overdose symptoms are potentiated by alcohol and other CNS depressants.

**If you forget to take Apictro**
If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Apictro**
Do not stop taking Apictro, unless advised to do so by your doctor. If you stop taking this medicine suddenly you may have a seizure. Should you need to stop taking Apictro , your doctor will decide which method is best for you. 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, although not everybody gets them.

Serious side effects
Stop using Apictro 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.
- If you experience an increase in the number of generalized fits (tonic-clonic seizures)

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):
- Feelings of paranoia and experiencing hallucinations which can develop over days and weeks (illusion, persecution complex)
- Lupus erythematosus of varying extent (skin disease that may involve internal organs)
- Leucopenia* (decrease in the number of white blood cells), eosinophilia* (increase of a certain type of white blood cells), thrombocytopenia* (Low blood platelet count) 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, Stevens-Johnson syndrome (very severe allergic skin reaction)
- 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

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

Reporting of side effects
If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Apictro

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 "Expiry:"/"EXP.". The expiry date refers to the last day of that month.

Do not store above 30 °C.

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 Apictro contains**
The active substance is Ethosuximide.
Each soft capsule contains 250 mg ethosuximide
The other ingredients are: macrogol 300, gelatin, glycerol, sorbitol liquid (E 420), partially dehydrated, water, purified, titanium dioxide (E 171), Iron oxide yellow (E 172).

**What Apictro looks like and contents of the pack**
Apictro 250 mg soft capsules are oval, yellow and opaque soft capsules.
Apictro 250 mg soft capsules are packed in PVC/PVdC//Al blister

Pack sizes: 50, 56, 100, 200 soft capsules

Not all pack sizes may be marketed.

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