

PACKAGE LEAFLET: INFORMATION FOR THE USER

Etomidate 2 mg/ml Emulsion for Injection

Etomidate

Read all of this leaflet carefully before you start using 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

1. What Etomidate is and what it is used for

Etomidate belongs to a group of medicines called general anaesthetics. It is used to induce a general anaesthesia, that is, to put patients to sleep before operations and other procedures, so they do not feel anything. It is injected into a vein.

Etomidate is used in adults, adolescents and children older than 6 months.

2. What you need to know before you use Etomidate

Do not use Etomidate:

- if you are allergic to etomidate, soya, peanut or any of the other ingredients of this medicine (listed in section 6).
- It should not be used in children who are under 6 months old, unless the case is a hospital emergency.

Warnings and precautions

Talk to your doctor or pharmacist before using Etomidate.

Only doctors trained in putting tubes down into patients' windpipes should use Etomidate. Life-saving respiration equipment should always be available during the use of this product.

Your doctor may give you painkillers first, in order to prevent pain during injection of etomidate. To minimise the risk of local pain, your doctor should use larger veins for injection.

In most cases your doctor will give you some medicines helping to prevent uncontrolled muscle spasms.

Because etomidate does not affect pain but only puts you to sleep, your doctor will give you a strong painkiller with etomidate for short operations.

Your doctor will give you lower doses of etomidate:

- if you have problems with your liver
- if you received drugs for the treatment of mental illness (neuroleptic drugs)

- if you received strong painkillers (so-called opioids) or sedatives (see also section 3).

In elderly patients, etomidate may reduce cardiac output and therefore will be administered with caution (see also section 3).

The use of etomidate may lead to a drop in blood pressure. Your doctor will take special care if you are very weak (debilitated), because low blood pressure can be dangerous in this case.

Doctors should not administer etomidate to patients with an inborn disorder of production of the red blood pigment (haem) unless there is no safer anaesthetic.

Etomidate should not be used for keeping people under anaesthesia because etomidate may cause a drop in a hormone called cortisol, especially when administered over a longer time. To prevent a drop of the cortisol level below normal values, the doctor may need to give cortisol to some patients (especially those undergoing severe stress) before etomidate.

Single induction doses of etomidate can lead to transient adrenal insufficiency and decreased serum cortisol levels.

Etomidate should be used with caution in critically ill patients, including patients with sepsis as it has been associated with an increased risk of mortality in some studies in these patient groups.

Children and adolescents

Etomidate should not be used in children younger than 6 months unless the doctor considers it necessary (see also “Do not use Etomidate”).

Children under 15 years of age may need higher doses of Etomidate to obtain the same depth and duration of sleep as in adults (see also section 3).

Other medicines and Etomidate

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

Some drugs for treatment of mental illness (neuroleptic drugs), some strong painkillers (so-called opioids) and sedatives can make the anaesthetic effect of etomidate stronger.

Your doctor will take into account, that the required dose of etomidate may change if the strong pain killers alfentanil and fentanyl are given in combination with etomidate.

Alpha-blockers and other agents used to lower the blood pressure

Etomidate may enhance the effect of alpha-blockers and other medicines that reduce your blood pressure.

Calcium channel blockers (e.g. Verapamil, Diltiazem; used to treat high blood pressure and heart diseases)

When you take Verapamil in combination with etomidate your blood pressure may decrease. Moreover your heart function could be affected.

Monoamine oxidase inhibitors (MAOI, substances used to treat mental depression or Parkinson's disease)

You should not take MAOI at least two weeks before a treatment with etomidate. Otherwise this could harm your health.

Etomidate with alcohol

You should not drink any alcoholic beverages before you are given etomidate because this may increase the effect of etomidate.

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 for advice before taking this medicine.

There are no data demonstrating that it is safe to use etomidate during pregnancy, so doctors only use it in exceptional cases if there is no safer alternative available.

Like other anaesthetics used in childbirth, etomidate may cross the placenta.

Etomidate passes into breast milk. Do not breast-feed your baby for 24 hours after you have had etomidate. Throw away any milk you express during this time.

Driving and using machines

Do not drive or use machines for at least 24 hours after you received etomidate. Your doctor will tell you when you can drive and use machinery again.

Etomidate contains soya-bean oil and sodium

Etomidate contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

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

3. How to use Etomidate

The doctor will decide on the right dose of Etomidate depending on how you respond.

Adults and adolescents

Normally the dose is 0.3 mg per kilogram (kg) of bodyweight for both adults and adolescents. This is the same as 0.15 ml per kg body weight. No more than 3 ampoules (30 ml) of Etomidate will be given to you.

Use in children

Usually children receive the same dose as adults. There may be cases, however, where children do not sleep sufficiently deeply with this dose. Then more etomidate will have to be given, up to 0.4 mg per kg of body weight, after the doctor is sure that this will not put the patient at a higher risk.

Elderly patients

Elderly patients usually respond to 0.15 to 0.2 mg per kg bodyweight.

The dose is less in patients with a liver disease called cirrhosis and in patients who have had special drugs for treatment of mental illness (neuroleptics), strong painkillers (so-called opioids) or sedatives just before etomidate.

Your doctor will usually give the injection slowly over about 30 seconds, or as a number of very small injections, into the vein. Your doctor will avoid to inject this medicine into an artery.

Before giving etomidate, the doctor will usually give the patient a drug such as diazepam, which depresses the central nervous system and reduces uncontrolled muscle spasms.

If you have received more Etomidate than you should

In such a case the sleeping period may be extended and breathing may stop for a short time. Your blood pressure may also be lowered.

The treatment of such events depends on the severity of symptoms. In general, to manage such occurrences, all equipment and medicines usually required in general anaesthetic procedures (especially breathing support) will be available.

Overdosage may also affect the function of your adrenal glands. In such cases your doctor may give you a medicine called hydrocortisone.

4. Possible side effects

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

Most likely, etomidate may affect breathing and circulation. Uncontrolled muscle movements may occur. Besides this, etomidate may also affect the function of the adrenal glands.

The following side effects may be serious and, therefore, require immediate treatment:

Common (may affect up to 1 in 10 people):

- Breathing may slow down or stop for a short time. This can be easily managed by your anaesthetist.

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

- Slow or irregular heartbeat

Rare (may affect up to 1 in 1,000 people):

- Spasm of the voice box

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

- Allergic reactions have been observed. A special type of hypersensitivity reaction, the so-called anaphylactoid reaction, has been observed, too.
- Shock
- Difficulty in breathing that may be fatal

Other side effects include

Very common (may affect more than 1 in 10 people):

- Jerky movements
- Cortisol decreased

Common (may affect up to 1 in 10 people):

- Muscle twitching
- Low blood pressure
- Wheezing
- Hyperventilation
- Feeling sick, vomiting
- Rash

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

- Unusual muscle stiffness and involuntary muscle contractions
- Involuntary eye movements (nystagmus)
- Shivering
- High blood pressure
- Hypoventilation
- Coughing
- Hiccups
- Too much saliva
- Redness of the skin
- Pain around the injection site
- Complications associated with general anaesthesia (delayed wake-up, sensation of pain due to insufficient painkilling effect, feeling sick)

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

- Problems with your adrenal glands (glands attached to the kidneys)

- Convulsions
- Heart attack
- Severe problems with your heart
- Hives
- Severe allergic reaction of the skin and mucous membranes accompanied by blistering and reddening of the skin (Erythema), which might in very severe cases affect inner organs and might be life threatening (Stevens-Johnson syndrome)
- Lockjaw

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 Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Etomidate

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 ampoule label and the carton. The expiry date refers to the last day of that month.

Ampoules should be shaken before use. This medicine must only be used if it is homogenous and milky-white after shaking. The product must not be used if two separate layers can be seen after shaking the ampoule. The doctor or nurse will check that the ampoule is not damaged.

Keep ampoules in the outer carton in order to protect from light. Do not freeze.

Do not throw away any medicines via wastewater or household waste. 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 Etomidate contains

- The active substance is Etomidate
Each millilitre of the emulsion contains 2 mg of Etomidate.
Each ampoule (10 millilitres) contains 20 mg of Etomidate.
- The other ingredients are:
Soya-bean oil
Medium-chain triglycerides
Glycerol
Egg phospholipids for injection
Sodium oleate
Water for injections
- pH: 6.0 – 8.5

What Etomidate looks like and contents of the pack

Etomidate is a milky-white emulsion of oil in water.

It comes in colourless glass ampoules containing 10 ml of sterile emulsion.

It is available in packs of 10 ampoules.

Marketing Authorisation Holder and Manufacturer

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This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (GB and NI) under the following names:

The Netherlands: Etomidaat-Lipuro 2 mg/ml, emulsie voor injectie
Portugal: Etomidato-Lipuro 2 mg/ml, emulsão injectável
Spain: Etomidato-Lipuro 2 mg/ml, emulsión inyectable
United Kingdom (GB and NI): Etomidate 2 mg/ml, emulsion for injection

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