

Directions for Use

B. Braun Melsungen AG · 34209 Melsungen, Germany

Composition

10 ml emulsion contain

Active ingredient:

Etomidate 20 mg

Excipients:

Soya oil, medium-chain triglycerides, glycerol, egg lecithin, sodium oleate, water for injections.

Pharmaceutical form

Emulsion for intravenous injection in glass ampoules of 10 ml.

Pharmaco-therapeutic group

Hypnotic

Indications

Induction of general anaesthesia

Notice:

For short-term narcosis, Etomidate-®Lipuro must be combined with an analgesic drug.

Contraindications

Etomidate-®Lipuro must not be administered to patients with known hypersensitivity to etomidate or fat emulsions.

In animal experiments, Etomidate-®Lipuro has been shown to possess a porphyrogenic potential. Therefore it should not be administered to patients with hereditary disorder of hem biosynthesis, unless the indication for administration of etomidate has been definitely established after careful consideration of its potential risks and expected benefits.

Newborns and infants up to the age of 6 months should be excluded from treatment with Etomidate-®Lipuro except for imperative indications during in-patient treatment.

Pregnancy, see section "Use in pregnancy and lactation" below.

Precautions for use

Etomidate-®Lipuro may be used only by a doctor skilled in endotracheal intubation with equipment for mechanical ventilation available.

Etomidate-®Lipuro has no analgesic effect. If used for short-term narcosis, a strong analgesic, e. g. fentanyl, must be given prior to or simultaneously with Etomidate-®Lipuro; attention should also be paid to further information given under "Interactions".

Use in pregnancy and lactation:

Safety of the use of Etomidate-®Lipuro during pregnancy has not been established. Therefore, Etomidate-®Lipuro should be administered to pregnant women only exceptionally if there is no alternative.

Published animal studies of some anaesthetic / sedation drugs have reported adverse effects on brain development in early life and late pregnancy. These studies have demonstrated that anaesthetic / sedation drugs that block N-methyl-D-aspartate (NMDA) receptors and / or potentiate gamma-aminobutyric acid (GABA) activity during the period of rapid brain growth or synaptogenesis may result in neuronal and oligodendrocyte cell loss in the developing brain and alterations in synaptic morphology and neurogenesis when used for longer than 3 hours. The clinical significance of these non-clinical findings is yet to be determined. However, based on comparisons across species, the window of vulnerability to these changes is believed to correlate with exposures in the third trimester through the first several months of life, but may extend out to approximately 3 years of age in humans.

Etomidate is secreted into breastmilk. If Etomidate-®Lipuro must be given during the lactation period, nursing is to be interrupted and not to be resumed before 24 hours after administration; breastmilk secreted during this period must be discarded.

Etomidate-®Lipuro

Interactions

The hypnotic effect of etomidate is enhanced by neuroleptics, opioids, sedatives, and alcohol.

Etomidate-®Lipuro must not be mixed with other injection solutions without having previously been tested for compatibility.

Furthermore, Etomidate-®Lipuro must not be administered simultaneously with other injection solutions through the same line, unless compatibility has been established. Drugs to be given concurrently, e. g. an analgesic, must therefore be administered consecutively through the same line or through separate venous cannulae.

Etomidate-®Lipuro may be injected into the tubing of an infusion of isotonic sodium chloride having temporarily been stopped.

Special warnings

After prolonged continuous administration of etomidate there is a risk of transient adrenocortical failure.

Effects on the ability to drive or to use machines:

Even when Etomidate-®Lipuro is used as directed, patients having received this drug will not be able to drive or to use machines for at least 24 hours after administration.

Some published studies in children have observed cognitive deficits after repeated or prolonged exposures to anaesthetic / sedative agents early in life. These studies have substantial limitations, and it is not clear if the observed effects are due to the anaesthetic / sedation drug administration or other factors such as the surgery or underlying illness.

Dosage

The dosage is adjusted acc. to the individual response and the clinical effect.

The following dosage guidelines should be followed:

As a rule, the effective hypnotic dose is between 0.15 and 0.3 mg of etomidate per kg body weight, corresponding to 0.075 to 0.15 ml of Etomidate-®Lipuro per kg body weight.

Children up to the age of 15 and elderly patients are given a single dose of 0.15 to 0.2 mg of etomidate, corresponding to 0.075 to 0.1 ml of Etomidate-®Lipuro per kg body weight. Also in patients belonging to these age groups, the exact dosage has to be adjusted acc. to the clinical effect.

In patients with liver cirrhosis and patients having been premedicated with neuroleptics opioids or sedatives the dose has to be reduced.

In the special case of narcosis to terminate a *status epilepticus* or serial epileptic seizures a sufficient dose of etomidate (0.3 mg/kg body weight, corresponding to 0.15 ml/kg body weight of Etomidate-®Lipuro) should be injected quickly, i. e. within 10 sec. This dose may be repeated several times, if required.



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Etomidate-®Lipuro

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34209 Melsungen
Germany



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Dokument = 210 x 298 mm
2 Seiten

Lätus 1383



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GIF (GA)
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Method and route of administration

Etomidate-®Lipuro must be injected strictly intravenously and, as a rule, slowly (a single dose in approx. 30 sec), and fractionated, if required.

Intra-arterial injection must be avoided as there is a danger of Etomidate-®Lipuro to cause necrosis if injected intra-arterially. Paravenous injection will cause strong pain.

Prior to administration of Etomidate-®Lipuro appropriate premedication should be given in order to avoid the occurrence of myocloni. The use of benzodiazepines is recommended, e. g. diazepam which may be injected intramuscularly about 1 hour or intravenously 10 min. prior to administration of Etomidate-®Lipuro.

In patients with manifest epilepsy or with an increased tendency to convulsions, Etomidate-®Lipuro should be injected quickly, i. e. within a few seconds, in order to avoid too slow diffusion of etomidate into the brain. The good bioavailability of etomidate and its rapid distribution within the brain prevent activation of convulsions.

Notice:

Etomidate-®Lipuro does not contain antimicrobial preservatives. Immediately after opening of the ampoule, the emulsion has to be drawn up in a syringe under aseptic conditions and injected, because fat emulsions promote microbial growth. Unused portions must be discarded.

Ampoules should be shaken prior to use to ensure homogenous distribution.

Overdosage

In cases of overdosage, especially if etomidate is combined with inhalation narcotics, the sleeping period may be extended and short periods of apnoea may occur.

When using Etomidate-®Lipuro, all equipment and medicaments usually required in general anaesthetic procedures should be available.

Undesirable effects

Etomidate inhibits the adrenocortical biosynthesis of steroids. After a single dose of etomidate the adrenocortical response to stressors is markedly reduced for approx. 4–6 hours.

After a single dose of etomidate, in unpremedicated patients, involuntary muscle movements (myocloni) are frequently observable. They correspond to the disinhibition of diencephalic excitations, similar to hypnogenic myocloni during physiological sleep. They can be prevented by premedication with opioids or benzodiazepines prior to the administration of etomidate.

Occasionally, after administration of etomidate, nausea and vomiting are observable, which are, however, caused predominantly by opioids given simultaneously or as premedication, further coughing, singultus, and shivering.

Rarely, after administration of etomidate, release of histamine has been noted. Serious effects have been reported so far in 3 cases only. Yet, etomidate is the firstchoice drug for patients with a history of allergy.

There are isolated reports about the occurrence of laryngospasm after etomidate.

Notice:

Especially after administration of higher doses of etomidate and if combined with central depressant drugs, transient apnoea may occasionally occur.

Expiry date

The product must not be used beyond the expiry date stated on the labelling.

Storage

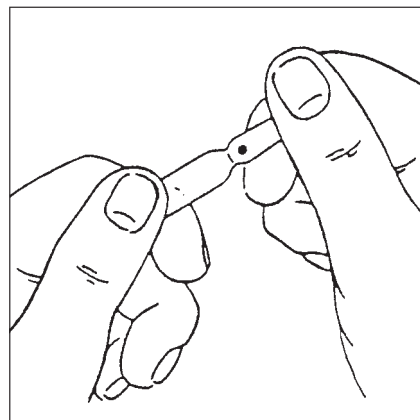
Protect from light!

Do not store above 25 °C.

Date of last revision: 04.19

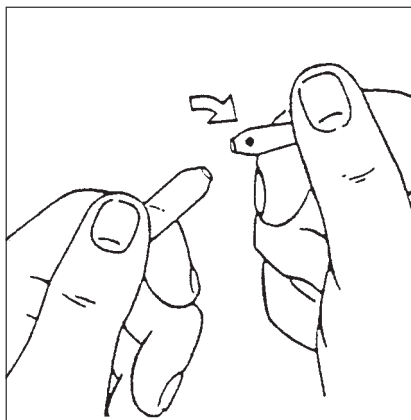
How to open OPC (One Point Cut) ampoules

(filing unnecessary)



Coloured dot upwards

Allow any solution in top of ampoule to flow down by tapping or shaking.



Coloured dot upwards

Break off top of ampoule in a downward direction.