Directions for Use
B. Braun Melsungen AG · 34209 Melsungen · Germany

Etomidate-®Lipuro

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

Warnings
Etomidate should not be administered to patients with evidence, or suggestion of, reduced adrenocortical function.
Reduced serum cortisol levels, unresponsive to ACTH injections, have been reported in some patients during induction of anaesthesia but particularly during maintenance of anaesthesia with etomidate; for this reason etomidate should not be used for maintenance. However when etomidate is used for induction, the post-operative rise in serum cortisol which has been observed after thiopentone induction is delayed for approximately 3-6 hours.
In cases of adrenocortical gland dysfunction and during very long surgical procedures, a prophylactic cortisol supplement may be required (for example 50 to 100 mg hydrocortisone). After prolonged continuous administration of etomidate there is a risk of transient adrenocortical failure. Convulsions may occur in unpremedicated patients. In patients with liver cirrhosis, or in those who have already received neuroleptic, opiate or sedative agents, the dose of etomidate should be reduced.
When Etomidate is used, resuscitation equipment should be readily available to manage apnoea.

Precautions
Etomidate should only be given by slow intravenous injection.
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.
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.

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.

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.

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 children up to the age of 15 the dosage may be increased by up to 30 % of the adult dose because it is sometimes necessary in order to obtain the same depth and duration of sleep.
Since etomidate has no analgesic action, appropriate analgesics should be used in procedures involving painful stimuli.
Do not exceed a total dose of 30 ml (3 ampoules). Etomidate should only be given by slow intravenous injection.
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

B. Braun Melsungen AG
34209 Melsungen
Germany

Approval for Printing
B BRAUN Melsungen AG

Approved for Printing ☐
Approved for Printing when corrected ☐
New draft required ☐

Date Signature

schwarz

Format = 210 x 298 mm
2 Seiten

Lätus 1053
1053

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GIF (L03)
Standort Berlin

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 necroses 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, unvoluntary 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 first-choice drug for patients with a history of allergy.
There are isolated reports about the occurrence of laryngospasm after etomidate.
A slight and transient drop in blood pressure may occur due to a reduction of the peripheral vascular resistance. In vulnerable patients, special care should be exercised to minimise this effect.
Respiratory depression may occur. Pain can occur after injection into the small veins of the dorsum of the hand. Use of larger veins or an intravenous application of a small dose of fentanyl 1 to 2 minutes before induction reduces pain on injection.

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.

Licence no: 113-84-29554.

License Holder:
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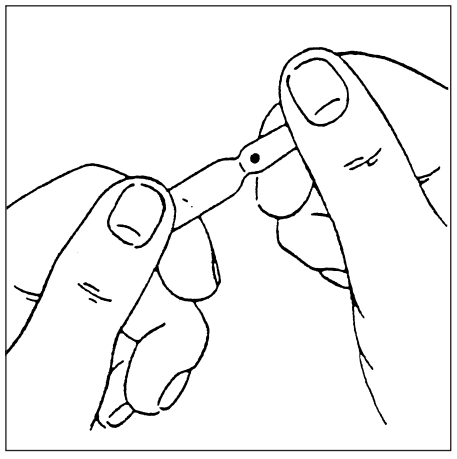
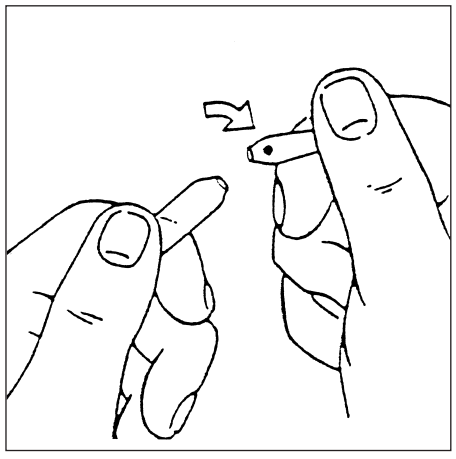
How to open OPC (One Point Cut) ampoules (filing unnecessary)



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.