

Directions for Use

B. Braun Melsungen AG · 34209 Melsungen, Germany

Composition

10 ml of emulsion contain

Etomidate 20 mg

Excipients:

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

Pharmaceutical form

Emulsion for injection in glass ampoules of 10 ml

Pharmaco-therapeutic group

General anaesthetic

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, soya-bean oil or any other of the constituents of the product.

Neonates 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.

Special warnings and precautions for use

Etomidate has revealed a porphyrogenic potential in animal experiments. Therefore it should not be administered to patients with inherited disorders of haem biosynthesis, unless the indication for administration of etomidate has definitely been established after careful consideration of its risks and potential benefits.

Especially when administered in high doses in combination with centrally depressant drugs, etomidate may cause transient apnoea.

Soya-bean oil may rarely cause severe allergic reactions.

After prolonged continuous administration of etomidate there is a risk of transient adrenocortical failure. During longer lasting operations or in the case of impaired adrenocortical function prophylactic administration of cortisol may be needed, e.g. 50 - 100 mg of hydrocortisone.

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".

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.

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 safer alternative.

Etomidate is secreted into breast milk. 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; breast milk secreted during this period must be discarded.

Etomidate-Lipuro 2 mg/ml Emulsion for Injection

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.

Dosage

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

The following dosage guidelines should be followed:

In general, 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 according to the clinical effect.

In patients with liver cirrhosis and patients having been premedicated with neuroleptics 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 of Etomidate-Lipuro) should be injected quickly, i. e. within 10 sec. This dose may be repeated several times, if required.

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.

Method of administration

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

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

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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.

Etomidate-Lipuro may be used only by a doctor skilled in endotracheal intubation, with equipment for artificial respiration being available.

Overdose

In cases of overdose, 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

Definition of frequency terms used in this chapter:

Very common: $\geq 10\%$ of treated patients

Common: $< 10\%$, $\geq 1\%$ of treated patients

Uncommon: $< 1\%$, $\geq 0.1\%$ of treated patients

Rare: $< 0.1\%$, $\geq 0.01\%$ of treated patients

Very rare: $< 0.01\%$ of treated patients,
including isolated cases

Like most general anaesthetics, etomidate affects respiratory and cardiovascular functions. Also, like some other general anaesthetics, etomidate may cause involuntary muscle movements. Besides this, etomidate frequently affects adrenocortical functions. In particular, the following undesirable effects have been observed during the use of etomidate:

Immune system disorders

Very rare: Allergic reactions, rare cases of bronchospasm and anaphylactoid reactions have been reported.

After administration of etomidate, release of histamine has been noted.

Endocrine disorders

Very common: Etomidate inhibits the adrenocortical biosynthesis of steroids. After a single dose of etomidate the adrenocortical response to stressors is markedly reduced for approx. 3 - 6 hours. See also section "**Special Warnings ...**".

Nervous system disorders

Very common: After a single dose of etomidate, especially in unpremedicated patients, involuntary muscle movements (myocloni) are observable. They can be prevented by premedication with opioids or benzodiazepines.

Uncommon: Shivering

Very rare: Convulsions

Cardiac disorders

Rare: Cardiac arrhythmia

Vascular disorders

Common: A slight and transient drop in blood pressure may occur due to a reduction of the peripheral vascular resistance.

Respiratory, thoracic and mediastinal disorders

Common: Respiratory depression and apnoea may occur especially after administration of higher doses of etomidate combined with centrally depressant drugs.

Rare: Coughing, laryngospasm

Gastrointestinal disorders

Common: After administration of etomidate, nausea and vomiting may occur, which are, however, caused primarily by opioids given simultaneously or as premedication.

Rare: Hiccough

General disorders and administration site conditions

Common: Local pain during injection, which is usually mild and occurs mainly when the drug is injected undiluted into small veins without previous administration of fentanyl. To minimise the risk of local pain, larger veins should be used.

Note

The doctor or pharmacist should be informed of any undesirable effect not mentioned in this leaflet.

Expiry date

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

Instructions for storage / use / handling

Do not store above 25 °C. Do not freeze.

Keep ampoules in the outer carton in order to protect from light.

Ampoules are for single use only. Discard unused contents.

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

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

Not to be used if emulsion is discoloured or not homogenous after shaking.

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