Directions for Use

B. Braun Melsungen AG, Mistelweg 2, 12357 Berlin, 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 hereditarydisorder of hem biosynthesis, unless the indication for administration of etomidate has been definitely established after careful consideration of its potential risksand 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 skilledin 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.

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.

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 givena single dose of 0.15 to 0.2 mg of etomidate, corresponding to 0.075 to 0.1 ml of Etomidate-®Lipuro per kg bodyweight. 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.

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 benzodiazepinesis 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 underaseptic 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 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 datestated on the labelling.

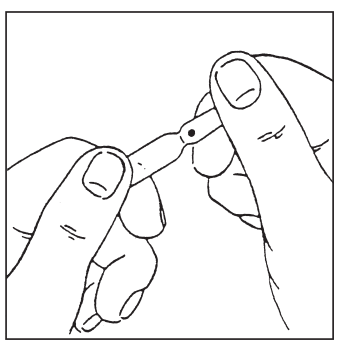
Storage

Protect from light! Do not store above 25 °C.

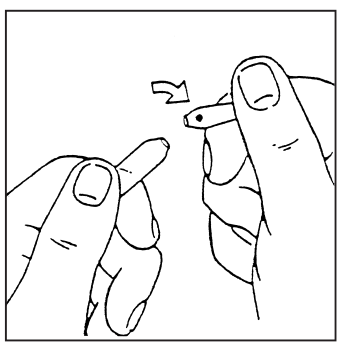
Date of last revision: 11.95

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.

402/12629141/0521

Directions for Use

Etomidate-®Lipuro

“柏朗”安得力多
靜脈注射液
Etomidate-®Lipuro
衛署藥輸字第022558號
本藥限由醫師使用

B. Braun Melsungen AG
Mistelweg 2, 12357 Berlin,
Germany

Approval for Printing

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“柏朗”安得力多靜脈注射液

Etomidate-Lipuro

衛署藥輸字第022558號

本藥限由醫師使用

成份
每 10 ml 乳劑含
Etomidate 20 mg

賦形劑：
大豆油、中鏈三酸甘油脂、甘油、卵磷脂質、油酸鈉、注射用水。

劑型
10 ml 玻璃安瓿裝之注射乳劑

藥理分類
全身麻醉劑

適應症
靜脈注射麻醉劑

注意：
短期麻醉時須與止痛劑合用。

禁忌
Etomidate-Lipuro 不可使用於已知對 Etomidate、大豆油或本產品其他成份有過敏反應之患者。
新生兒及六個月內之嬰兒不應使用 Etomidate-Lipuro，除非於住院治療期間，該適應症有使用之必要。
懷孕期之使用請參考下節中之 懷孕及授乳期“之使用。

特殊警語與使用注意事項
動物實驗顯示 Etomidate 可能導致紫質生成。因此它不可使用於對血液合成有遺傳性障礙之患者，除非給予 Etomidate 之適應症經仔細評估已確認其風險與預期益處。
尤其使用高劑量並與中樞抑制藥物合用時，Etomidate 可能導致短暫性呼吸暫停。
大豆油並不常引起嚴重的過敏反應。
長時間持續性地投予 Etomidate 會有短暫性腎上腺皮質異常之危險。在長時間手術或腎上腺皮質功能受損的情況下，可能需要皮質醇的預防性投藥，例如 50 – 100 mg 的氫化可體松（hydrocortisone）。
Etomidate-Lipuro 無止痛效果。若作短期麻醉時，必須事先或同時給予如 Fentanyl 之強效止痛劑，亦須注意後述 交互作用“ 所提供之詳細資訊。

對開車或操作機械能力之影響：
即使依指示給予 Etomidate-Lipuro，投藥後至少 24 小時內不得開車或操作機械。

懷孕及授乳期
Etomidate-Lipuro 使用於妊娠期之安全性尚未確立，因此只有在特殊且無安全替代方案的情況下，方可給予懷孕婦女 Etomidate-Lipuro 之投藥。
Etomidate 會分泌至乳汁中。若必須於授乳期給予 Etomidate-Lipuro，投藥後 24 小時內不得授乳，此期間分泌之乳汁應予丟棄。

交互作用
Etomidate 的麻醉作用會因精神抑制藥(Neuroleptics)、鴉片類藥物、鎮靜劑及酒精的作用而增強。
Etomidate-Lipuro 未做相容性測試前，不得與其他注射液混合。
此外，除非已確認相容性，否則 Etomidate-Lipuro 不得同時與其他注射液以同一輸液管給予；需要合併給予之藥物如止痛劑，則必需以同一輸液管或個別靜脈插管接續給藥。
Etomidate-Lipuro 可注入已暫時停止注射生理食鹽水 (Isotonic sodium chloride) 之輸液管中。

劑量
劑量可依個別反應及臨床作用予以調整。

依下列劑量指示給藥：
Etomidate 一般達到麻醉作用之有效量為每公斤體重0.15 至 0.3 mg，相當於每公斤體重 0.075至0.15 ml 之 Etomidate-Lipuro。
15 歲以下之兒童及年長患者，其單一劑量為 0.15 至 0.2 mg 之 Etomidate，相當於每公斤體重0.075 至 0.1 ml 之 Etomidate-Lipuro。同屬此年齡層之患者，投藥之精確劑量必須依臨床反應予以調整。
肝硬化及已投予精神抑制藥 (Neuroleptics) 之患者則須減少用量。
於中止癲癇症狀態或中止癲癇症持續發作之特殊麻醉情況下，應於 10 秒內快速予以輸注足量 Etomidate (0.3 mg/每公斤體重，相當於 0.15 ml 之 Etomidate-Lipuro)。若有必要，可以此劑量重複數次。

投藥方法
Etomidate-Lipuro 僅能由靜脈輸注，通常緩慢地輸注單一劑量所需時間約 30 秒，若有必要，可分段給予。
Etomidate-Lipuro 之使用應避免由動脈輸注而造成組織壞死之危險。靜脈周邊之輸注則會引起劇烈疼痛。
投予 Etomidate-Lipuro 前應適度前驅給藥以避免肌陣攣的發生。建議於 Etomidate-Lipuro 投藥前 1 小時以肌肉注射或 10 分鐘前以靜脈注射方式投予 Benzodiazepine 類之藥物如 Diazepam。
明顯癲癇症或抽筋傾向升高之患者，須在數秒內快速予以輸注 Etomidate-Lipuro，以避免延緩 Etomidate 進入腦部作用之時間。Etomidate 良好的生體利用率及其能在腦部迅速地分佈，可防止發生抽筋現象。
Etomidate-Lipuro 需由熟練氣管插管技術之醫師在可提供心肺復甦設備的情況下使用。

用藥過量
一旦用藥過量，特別是 Etomidate 與吸入性麻醉劑併用時，沉睡期將會延長且有呼吸短暫停頓之現象發生。
當使用 Etomidate-Lipuro 時，一般麻醉過程中所需之設備與藥品均應備妥。

不良反應
此部分常用術語之定義：
非常常見：≥ 接受治療患者之 10 %
常見：< 接受治療患者之 10 %、≥ 接受治療患者之 1 %
不常見：< 接受治療患者之 1 %、≥ 接受治療患者之 0.1 %
罕見：< 接受治療患者之 0.1 %、≥ 接受治療患者之 0.01 %
非常罕見：< 接受治療患者之 0.01 %，包含個別病例

與一般全身麻醉相同，Etomidate 會影響呼吸系統及心血管系統的功能。另外像其他一些全身麻醉一樣，Etomidate 可能導致不自主的肌肉運動。此外，Etomidate 常會影響腎上腺皮質功能。特別是在使用 Etomidate 期間已觀察到下列不良反應：

免疫系統異常
非常罕見： **已有過敏反應、少數支氣管痙攣與過敏性反應的報告。Etomidate 投藥後注意到有組織胺的釋出。**

內分泌異常
非常常見： **Etomidate 會抑制固醇類腎上腺皮質的生合成。給予單一劑量 Etomidate 後，腎上腺皮質對壓力源之反應明顯地減少約 3 – 6 小時。請參見 注意事項“ 部分。**

神經系統異常
非常常見： **給予單一劑量 Etomidate 後，特別是在未前驅給藥的患者身上可觀察到不自主的肌肉運動(myocloni)。若前驅給藥投予鴉片類藥物或 Benzodiazepine 類藥物則可避免其發生。**
不常見： **顫抖**
非常罕見： **抽搐**

心臟異常
罕見： **心律不整**

血管異常
常見： **因周邊血管阻力減少，可能發生輕微及短暫的血壓降低。**

呼吸、胸和縱膈異常
常見： **特別是在給予較高劑量 Etomidate 及與中樞鎮靜藥物併用時，可能發生呼吸抑制與呼吸暫停現象。**
罕見： **咳嗽、喉頭痙攣**

腸胃道系統異常
常見： **Etomidate 投藥後可能出現噁心及嘔吐，但這主要是因同時給予鴉片類藥物或在前驅給藥時給予鴉片類藥物而引起。**
罕見： **打嗝**

全身性異常和注射部位狀況
常見： **注射過程中的局部疼痛通常是輕微的，且主要是在未先給予 Fentanyl 而將未稀釋藥物注射入小靜脈的情況下才會發生局部疼痛。注射於較大的靜脈可降低局部疼痛的風險。**

注意
若發生任何此手冊中未提到的不良反應請通知醫師或藥師。

保存期限
本產品在標籤上之有效期限過後請勿再使用。

儲存 / 使用 / 操作需知
儲存溫度不可超過 25 °C，不可冷凍。
將安瓿貯存於原包裝外盒中以避光。
安瓿只可單次使用。剩餘部份應丟棄。
Etomidate-Lipuro 不含抗菌防腐劑。因為脂肪乳劑會促進微生物生長，安瓿開瓶後應於無菌狀態下立即以注射器抽出並輸注。剩餘部份應丟棄。
使用前搖晃安瓿已確定是否分佈均勻。
若乳劑搖晃後變色或不均質則不應使用。

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