**SUMMARY OF PRODUCT CHARACTERISTICS**

**Etomidate-Lipuro 2 mg/ml**

**Emulsion for injection.**

1 ml of emulsion for injection contains:

**Etomidate**

2 mg

**Emulsion**

Without surfactants or preservatives.

**PH 6.0 – 8.5**

**Incompatibilities**

- With other medicines:
  - Monoamine oxidase inhibitors (MAOI, substances used to treat mental depression or Parkinson's disease)
  - Verapamil
  - Alpha-blockers and other agents used to lower the blood pressure
  - Monoamine oxidase inhibitors (MAOI)

**Special warnings and precautions for use**

- **Hypersensitivity to etomidate**:
  - The use of narcotic analgesics or diazepam as premedication and during surgery will reduce the uncontrolled stress-related stimulation of the adrenal gland with ACTH.

**Pharmacological properties**

- **Pharmacodynamic properties**: Etomidate is a synthetic corticosteroid with a powerful ability to induce a general anaesthesia without any premedication. It originates its anaesthetic effect in the brain and spinal cord.

**Pharmacokinetic properties**

- **Absorption, distribution and metabolism**: Etomidate is rapidly metabolized in the liver.

**Clinical use**

- **Indications**:
  - Induction of general anaesthesia. Etomidate-Lipuro 2 mg/ml may be used only by a doctor skilled in endotracheal intubation.

**Contraindications**

- **Hypersensitivity to etomidate**, **clofazimine** or any of its excipients.

**Adverse effects**

- **Very rare (< 1/10,000)**
  - Respiratory apnoea
  - Hypotension

**Elderly patients**

- Usually respond to 0.15 to 0.2 mg per kg bodyweight.

**Pregnancy and lactation**

- Not recommended during pregnancy.

**Children**

- There are no data demonstrating that it is safe to use etomidate during pregnancy, so doctors only use it in obstetric anaesthesia when it is absolutely necessary.

**Overdose**

- **Symptoms**: respiratory depression, central apnoea, hypotension, hypotension, bradycardia.

**Driving and use of machines**

- After the anaesthetic effect has worn off, the patient's ability to drive and use machines may still be impaired. Therefore, the patient should not drive or use machines until his/her ability to do so has returned to normal. A final decision must be taken by the post-anaesthesiology treatment team.

**Drug interactions**

- **Monoamine oxidase inhibitors (MAOI)**
  - When you take Verapamil in combination with etomidate your blood pressure may decrease. Moreover your heart rate may increase. In these cases the dose of etomidate must be reduced.

**Interactions with other medicinal products and other forms of etomidate**

- **Etomidate with alcohol**
  - When you take Etomidate-Lipuro with alcohol you may feel drowsy, dizzy and have a headache. This can be avoided by refraining from alcohol on the day of surgery.

**Package leaflet: INFORMATION FOR THE USER**

**Etomidate-Lipuro 2 mg/ml Emulsion for Injection**

**What is in this leaflet:**

- This leaflet has been written for you by the manufacturer and the health professionals responsible for your care.

**What is Etomidate-Lipuro?**

- Etomidate-Lipuro 2 mg/ml is an emulsion of etomidate for injection.

**When you can use Etomidate-Lipuro?**

- Etomidate-Lipuro 2 mg/ml contains less than 1 mmol (23 mg) sodium (as sodium oleate) per ampoule, i.e. it is sodium-free.

**How to take Etomidate-Lipuro?**

- Etomidate-Lipuro 2 mg/ml is suitable for use during general anaesthesia. In children with a weight of up to 60 kg, it may also be used for induction in the operating theatre or for temporary sedation. In other situations stimulation of the adrenal gland with ACTH is not useful.

**Possible side effects**

- **Very rare (< 1/10,000)**
  - Respiratory apnoea
  - Hypotension

**Driving and use of machines**

- After the anaesthetic effect has worn off, the patient's ability to drive and use machines may still be impaired. Therefore, the patient should not drive or use machines until his/her ability to do so has returned to normal. A final decision must be taken by the post-anaesthesiology treatment team.

**Drug interactions**

- **Monoamine oxidase inhibitors (MAOI)**
  - When you take Verapamil in combination with etomidate your blood pressure may decrease. Moreover your heart rate may increase. In these cases the dose of etomidate must be reduced.
• Pain around the injection site
• Hypoventilation

Uncommon (may affect up to 1 in 100 people):
• Rash
• Low blood pressure

Common:
• Jerky movements

Very common:
• Shock

Other side effects include:
• Slow or irregular heartbeat

Not known:
• Skin rashes
• Low blood pressure

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

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

The treatment of such events depends on the severity of symptoms. In general, to manage such occurrences, all
medical treatments are listed under sections of the SmPC.

There are no pre-clinical data of relevance to the prescriber that are additional to those already stated in other
sections of the SmPC.

5.3 Preclinical safety data
Accumulation has not been observed.

About 75% of the administered dose of etomidate appear in the urine within 24 hours, primarily as metabolites.
The total volume of distribution is about 4.5 l/kg.

5.2 Pharmacokinetic properties
The effect of etomidate starts at short notice and the duration of the hypnotic effect is short as a result of
redistribution and metabolic inactivation. A single dose of 0.3 mg/kg body weight leads to loss of consciousness in
30-60 seconds and to narcosis of 3 – 5 minutes duration, followed by sleep.

Other pharmacological effects
- Moderate anxiolytic effect
- Anticonvulsant effect
- Hypotensive effect
- Moderate sedative effect
- Moderate respiratory depression
- Hypoxic damage.

4.8 Side effects

Overdosage may depress cortical secretion. This may be associated with disorientation and delayed awakening.

An overdose of etomidate, administered as a bolus, deepens sleep and may cause respiratory depression and even
apnoea. On the other hand, etomidate administered as a continuous infusion may cause hypotension.

4.9 Overdose

Symptoms

- Overdosage
- Slow awakening
- Hypotension
- Dysphoria
- Confusion
- Numbness and tingling of hands and feet
- Hypothermia
- Hypokalaemia
- Increased intraocular pressure
- Loss of vision
- Diuresis
- Arterial hypotension
- Bradycardia
- Hypoventilation
- Apnoea
- Intraocular pressure increase
- Respiratory failure
- Myoclonus
- Diuresis
- Hyperkalaemia
- Hypoglycaemia
- Reduction of plasma glucose levels
- Seizures
- Hypertension
- Hypotension
- Shock

5.4 Overdose

Overdosage may depress cortical secretion. This may be associated with disorientation and delayed awakening.

If you have received more Etomidate-Lipuro than you should

If you receive more than the correct dosage, you should:

- Immediately contact your doctor or pharmacist.
- Keep the ampoule to help identify the dosage.
- Follow your doctor's instructions.

This leaflet was last revised in 2014.