NAME OF THE MEDICINAL PRODUCT

Etomidate-Lipuro 2 mg/ml Emulsion for Injection

COMPOSITION

The emulsion for injection contains:

1 ml	2 mg etomidate
in 1 ampoule of 10 ml	20 mg etomidate

Excipients with known effect:
Each 10 ml ampoule (10 ml) contains 1.0 g Soya-bean oil, refined and 0.23 mg Sodium (as sodium oleate).

Excipients:
Soya-bean oil, refined, medium-chain triglycerides, glycerol, egg lecithin, sodium oleate, water for injection.

THERAPEUTIC INDICATIONS

Etomidate-Lipuro 2 mg/ml is indicated for the induction of general anaesthesia in adults, infants and toddlers older than 6 months, children and adolescents.

CONTRAINDICATIONS

Hypersensitivity to etomidate, soya, peanut or to any of the excipients listed.

Neonates and infants up to the age of 6 months should be excluded from treatment with Etomidate-Lipuro 2 mg/ml except for imperative indications during in-patient treatment.

UNDESIRABLE EFFECTS

Like most general anaesthetics, etomidate may affect respiratory and vascular functions. Like some other general anaesthetics, etomidate may cause involuntary muscle movements. Besides this, etomidate frequently affects adrenocortical functions.

Undesirable effects are listed according to their frequencies as follows:

Very common: (≥ 1/10)
Common: (≥ 1/100 to < 1/10)
Uncommon: (≥ 1/1 000 to < 1/100)
Rare: (≥ 1/10 000 to < 1/1000)
Very rare: (<1/10 000)
Not known: (cannot be estimated from the available data)

System Organ Class	Adverse Drug Reactions				
	Frequency Category				
	Very Common (≥1/10)	**Common** (≥1/100 to <1/10)	**Uncommon** (≥1/1 000 to <1/100)	**Rare** (≥1/10 000 to <1/1 000)	**Not Known** (cannot be estimated from the available data)
Immune System Disorders					Hypersensitivity[1] (such as anaphylactic shock, anaphylactic reaction, anaphylactoid reaction)
Endocrine Disorders	Cortisol decreased				Adrenal insufficiency
Nervous System Disorders	Dyskinesia	Myoclonus	Hypertonia, Muscle contractions involuntary, Nystagmus, Shivering		Convulsion (including grand mal convulsion)
Cardiac Disorders			Bradycardia, Extrasystoles, Ventricular extrasystoles		Cardiac arrest, Atrioventricular block complete
Vascular Disorders		Hypotension	Hypertension		Shock
Respiratory, Thoracic and Mediastinal Disorders		Apnoea[2], Hyperven-tilation, Stridor	Hypoventilation, Hiccups, Cough	Laryngo-spasm	Respiratory depression[2], Bronchospasm (including fatal outcome)
Gastrointestinal Disorders		Vomiting, Nausea	Salivary hypersecretion		
Skin and Subcutaneous Tissue Disorders		Rash	Erythema		Stevens-Johnson syndrome, Urticaria
Musculoskele-tal and Connective Tissue Disorders			Muscle rigidity		Trismus
General Disorders and Administration Site Conditions			Injection site pain		

System Organ Class	Adverse Drug Reactions				
	Frequency Category				
	Very Common (≥1/10)	**Common** (≥1/100 to <1/10)	**Uncommon** (≥1/1 000 to <1/100)	**Rare** (≥1/10 000 to <1/1 000)	**Not Known** (cannot be estimated from the available data)
Injury, Poisoning and Procedural Complications			Anaesthetic complication, Delayed recovery from anaesthesia, Inadequate analgesia, Procedural nausea		

1) After administration of etomidate, release of histamine has been noted.
   Etomidate-Lipuro 2 mg/ml contains soya-bean oil, which may very rarely cause severe allergic reactions.
2) Respiratory depression and apnoea may occur especially after administration of higher doses of etomidate in combination with central depressant drugs. In patients of 55 years of age or older, respiratory depression and apnoea may occur especially after doses exceeding the recommended maximum dose of 0.2 mg of etomidate per kg body weight.

WARNINGS

Keep out of the sight and reach of children. Contains no antimicrobial preservatives.
For single use only. Discard unused contents.

NOTE

Prescription only

Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

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