SUMMARY OF PRODUCT CHARACTERISTICS

B. Braun Melsungen AG · 34209 Melsungen, Germany

1. NAME OF THE MEDICINAL PRODUCT

Etomidate-Lipuro 2 mg/ml emulsion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of emulsion for injection contains 2 mg of etomidate
10 ml of emulsion for injection (= 1 ampoule) contain 20 mg of etomidate

Excipients with known effect:

One ampoule (10 ml) of emulsion for injection contains:

Soya-bean oil, refined	1.0 g
Sodium (as sodium oleate)	0.23 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.

Milky-white oil-in-water emulsion	
pH	6.0 – 8.5

4. CLINICAL PARTICULARS

4.1 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.

4.2 Posology and method of administration

Posology

In all patients, the dosage should be adjusted according to the individual response and the clinical effect.

The following dosage guidelines should be followed:

Adults and adolescents

As a rule, the effective hypnotic dose is 0.3 mg of etomidate per kg body weight, corresponding to 0.15 ml of Etomidate-Lipuro 2 mg/ml per kg body weight.

Therefore, in an adult patient one ampoule usually suffices for a sleep duration of 4–5 min.

Hypnosis can be prolonged by additional injections of Etomidate-Lipuro 2 mg/ml.

Do not exceed the total amount of 3 ampoules (30 ml).

Paediatric population

In children under 15 years the dosage may need to be increased: a supplementary dose of up to 30% of the normal dose for adults is sometimes necessary to obtain the same depth and duration of sleep as obtained in adults.

Elderly patients

Elderly patients should be given a single dose of 0.15 to 0.2 mg of etomidate per kg body weight and the dose should be further adjusted according to effects (see section 4.4).

Other special patient groups

In patients with liver cirrhosis or those who have already received neuroleptic, opiate or sedative medication, the dose of etomidate should be reduced.

Method of administration

Intravenous use

Etomidate-Lipuro 2 mg/ml must be injected strictly intravenously and slowly, usually over approximately 30 seconds, in fractions if required.

Intra-arterial injection must be avoided. Paravenous injection causes severe local pain.

The use of narcotic analgesics or diazepam as premedication and during surgery will reduce the uncontrolled spontaneous muscle movements (myoclonus) shown by some patients after Etomidate-Lipuro 2 mg/ml administration (see section 4.4 and 5.1).

Since etomidate has no analgesic effect, it is recommended to administer a suitable opioid, e.g. fentanyl intravenously 1–2 min before the injection of Etomidate-Lipuro 2 mg/ml (see section 4.4 and 5.1).

The product must only be used by physicians trained in endotracheal intubation. Equipment for artificial respiration must be available (see section 4.4).

4.3 Contraindications

Hypersensitivity to etomidate, soya, peanut or to any of the excipients listed in section 6.1 (see also section 4.8).

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.

4.4 Special warnings and precautions for use

Special warnings

An injection of Etomidate-Lipuro 2 mg/ml should only be administered intravenously.

Induction with Etomidate-Lipuro 2 mg/ml may be accompanied by a slight and transient drop in blood pressure due to a reduction of the peripheral vascular resistance (especially after previous administration of droperidol). In debilitated patients in whom hypotension may be hazardous, the following measures should be taken:

1. Before induction, intravenous access should be obtained for the management of circulatory blood volume.
2. Other inducing agents should be avoided to the extent possible.
3. The induction should be carried out with the patient supine.
4. The drug should be injected slowly (e.g. 10 ml in 1 min.).

Etomidate inhibits the adrenocortical biosynthesis of steroids. Induction doses of etomidate have been associated with a reduction in plasma cortisol and aldosterone concentrations, unresponsive to ACTH administration. When etomidate is used for induction, the postoperative rise of serum cortisol observed after thiopentone induction is delayed for approximately 2 – 6 hours (see section 5.1).

Where concern exists for patients undergoing severe stress, particularly those with adrenocortical dysfunction, supplementation with exogenous cortisol (e.g. 50 – 100 mg hydrocortisone) should be considered. In such situations stimulation of the adrenal gland with ACTH is not useful.

Prolonged suppression of endogenous cortisol and aldosterone may occur as a direct consequence of etomidate when given by continuous infusion or in repeated doses. Use of etomidate for maintenance of anaesthesia should therefore be avoided. In such situations stimulation of the adrenal gland with ACTH is not useful.

Etomidate should be used with caution in patients with underlying cortico-adrenal insufficiency such as patients with sepsis.

In patients with liver cirrhosis, or in those who have already received neuroleptic, opiate, or sedative agents, the dose of etomidate should be reduced.

Spontaneous movements may occur in one or more groups of muscles, particularly when no premedication has been administered (see also section 4.8). These movements have been ascribed to subcortical disinhibition (see section 5.1). They can be largely prevented by the intravenous administration of small doses of fentanyl, with droperidol or diazepam 1–2 min before induction with Etomidate-Lipuro 2 mg/ml (see also section 4.2).

Myoclonus and local pain on injection, which is usually mild, is observed during the administration of Etomidate-Lipuro 2 mg/ml especially when it is injected undiluted into a small vein. This can largely be avoided by intravenous application of a small dose of suitable opioids, e.g. fentanyl, 1 to 2 minutes before induction. To minimise the risk of local pain, larger veins should be used.

Etomidate-Lipuro 2 mg/ml should be used with caution in elderly patients, since the potential exists for decreases in cardiac output, which have been reported with doses greater than recommended (see section 4.2).

In animal experiments, Etomidate-Lipuro 2 mg/ml has been shown to possess a porphyrogenic potential. Therefore it should not be administered to patients with hereditary disorder of haem biosynthesis, unless there is no safer alternative.

Precautions for use

Since Etomidate-Lipuro 2 mg/ml has no analgesic action, appropriate analgesics should be used during surgical procedures. If used for short-term narcosis, a strong analgesic, e. g. fentanyl, must be given prior to or simultaneously with Etomidate-Lipuro 2 mg/ml (see section 4.2). Attention should be paid also to instructions given in sections 4.5 and 6.6.

Etomidate-Lipuro 2 mg/ml may be used only by a doctor skilled in endotracheal intubation.

When Etomidate-Lipuro 2 mg/ml is used, resuscitation equipment should be readily available to manage respiratory depression and the possibility of apnoea.

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

4.5 Interactions with other medicinal products and other forms of interaction

The hypnotic effect of etomidate may be enhanced by:

- neuroleptic drugs
- opioids
- sedatives
- alcohol.

Induction with etomidate may be accompanied by a slight and transient reduction in peripheral resistance which may enhance the effect of other drugs reducing blood pressure.

Alfentanil

Co-administration of etomidate with alfentanil has been reported to decrease the terminal half-life of etomidate to approximately 29 minutes. Caution should be used when both drugs are administered together as the concentrations of etomidate may drop below the hypnotic threshold.

Fentanyl

The total plasma clearance and volume of distribution of etomidate is decreased by a factor of 2 to 3 without a change in half-life when administered with fentanyl intravenously. When etomidate is co-administered with fentanyl intravenously, the dose may need to be reduced.

Ketamine

Co-administration of etomidate and ketamine appears to have no significant effect on the plasma concentrations or pharmacokinetic parameters of ketamine or its principal metabolite, norketamine.

Adrenergic neurone blockers, alpha blockers

Combination with general anaesthetics leads to an enhancement of the hypotensive effect of these substances.

Calcium channel blockers (Verapamil, Diltiazem)

Combination with general anaesthetics results in an enhancement of the hypotensive effect and also AV delay.

Monoamine oxidase inhibitors (MAOI)

Because of hazardous interactions between general anaesthetics and MAOIs, MAOIs should normally be stopped 2 weeks before surgery.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety of the use of Etomidate-Lipuro 2 mg/ml during pregnancy has not yet been established. In animals etomidate has no primary effect on fertility, nor primary embryotoxic nor teratogenic effects. At maternally toxic doses in rats, decreased survival was noted.

Etomidate-Lipuro 2 mg/ml should be used during pregnancy only if the potential benefit justifies the risks to the foetus.

During obstetric anaesthesia, etomidate may cross the placenta. The Apgar scores of the newborns whose mothers have received etomidate are comparable with those of infants born after the use of other hypnotic agents.

A transient fall in cortisol levels lasting about 6 hours was observed in the neonate after the mother was given etomidate. The decreased values remained within the normal range.

Breast-feeding

Etomidate is excreted into human milk. Caution should be exercised when Etomidate-Lipuro 2 mg/ml is administered to a nursing mother.

If Etomidate-Lipuro 2 mg/ml must be given during the lactation period, nursing is to be interrupted and not to be resumed 24 hours after administration; breast milk secreted during this period must be discarded.

4.7 Effects on ability to drive and use machines

Etomidate has a major influence on the ability to drive and use machines.

It is not recommended to use potentially dangerous machines or to drive a car during the first 24 hours after administration.

The return of normal alertness may vary according to the duration of the operation, the total dose of etomidate administered and concomitant medication used. Hence, a decision to allow for driving or operating machinery must be a judgment made by the post-anaesthesiology treatment team.

4.8 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 < 1/1,000)
Very rare (< 1/10,000)
Not known (frequency 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					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], Hyperventilation, Stridor	Hypoventilation, Hiccups, Cough	Laryngospasm	Respiratory depression[2], Bronchospasm (including fatal outcome)
Gastrointestinal Disorders		Vomiting, Nausea	Salivary hypersecretion		
Skin and Subcutaneous Tissue Disorders		Rash	Erythema		Stevens-Johnson syndrome, Urticaria
Musculoskeletal and Connective Tissue Disorders			Muscle rigidity		Trismus
General Disorders and Administration Site Conditions			Injection site pain		
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.

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Etomidate-Lipuro 2 mg/ml Emulsion for Injection

Etomidate

Read all of this leaflet carefully before using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1.What Etomidate-Lipuro is and what it is used for
2.What you need to know before you use Etomidate-Lipuro
3.How to use Etomidate-Lipuro
4.Possible side effects
5.How to store Etomidate-Lipuro
6.Contents of the pack and other information

1. What Etomidate-Lipuro is and what it is used for

Etomidate-Lipuro belongs to a group of medicines called general anaesthetics. It is used to induce a general anaesthesia, that is, to put patients to sleep before operations and other procedures, so they do not feel anything. It is injected into a vein.

Etomidate-Lipuro is used in adults, adolescents and children older than 6 months.

2. What you need to know before you use Etomidate-Lipuro

Do not use Etomidate-Lipuro:
- if you are allergic to etomidate, soya, peanut or any of the other ingredients of this medicine (listed in section 6).
- It should not be used in children who are under 6 months old, unless the case is a hospital emergency.

Warnings and precautions

Talk to your doctor or pharmacist before using Etomidate-Lipuro.

Only doctors trained in putting tubes down into patients' windpipes should use Etomidate-Lipuro. Life-saving respiration equipment should always be available during the use of this product.

Your doctor may give you painkillers first, in order to prevent pain during injection of etomidate. To minimise the risk of local pain, your doctor should use larger veins for injection.

In most cases your doctor will give you some medicines helping to prevent uncontrolled muscle spasms.

Because etomidate does not affect pain but only puts you to sleep, your doctor will give you a strong painkiller with etomidate for short operations.

Your doctor will give you lower doses of etomidate:
- if you have problems with your liver
- if you received drugs for the treatment of mental illness (neuroleptic drugs)
- if you received strong painkillers (so-called opioids) or sedatives (see also section 3).

In elderly patients, etomidate may reduce cardiac output and therefore will be administered with caution (see also section 3).

The use of etomidate may lead to a drop in blood pressure. Your doctor will take special care if you are very weak (debilitated), because low blood pressure can be dangerous in this case.

Doctors should not administer etomidate to patients with an inborn disorder of production of the red blood pigment (haem) unless there is no safer anaesthetic.

Etomidate should not be used for keeping people under anaesthesia because etomidate may cause a drop in a hormone called cortisol, especially when administered over a longer time. To prevent a drop of the cortisol level below normal values, the doctor may need to give cortisol to some patients (especially those undergoing severe stress) before etomidate.

Your doctor will take special care if your adrenal glands (glands attached to the kidneys) are not working properly, e.g. if you suffer from blood poisoning (sepsis).

Children and adolescents

Etomidate-Lipuro should not be used in children younger than 6 months unless the doctor considers it necessary (see also "Do not use Etomidate-Lipuro").

Children under 15 years of age may need higher doses of Etomidate-Lipuro to obtain the same depth and duration of sleep as in adults (see also section 3).

Other medicines and Etomidate-Lipuro

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some drugs for treatment of mental illness (neuroleptic drugs), some strong painkillers (so-called opioids) and sedatives can make the anaesthetic effect of etomidate stronger.

Your doctor will take into account, that the required dose of etomidate may change if the strong pain killers alfentanil and fentanyl are given in combination with etomidate.

Alpha-blockers and other agents used to lower the blood pressure

Etomidate-Lipuro may enhance the effect of alpha-blockers and other medicines that reduce your blood pressure.

Calcium channel blockers (e.g. Verapamil, Diltiazem; used to treat high blood pressure and heart diseases)

When you take Verapamil in combination with etomidate your blood pressure may decrease. Moreover your heart function could be affected.

Monoamine oxidase inhibitors (MAOI, substances used to treat mental depression or Parkinson's disease)

You should not take MAOI at least two weeks before a treatment with etomidate. Otherwise this could harm your health.

Etomidate-Lipuro with alcohol

You should not drink any alcoholic beverages before you are given etomidate because this may increase the effect of etomidate.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

There are no data demonstrating that it is safe to use etomidate during pregnancy, so doctors only use it in exceptional cases if there is no safer alternative available.

Like other anaesthetics used in childbirth, etomidate may cross the placenta.

Etomidate passes into breast milk. Do not breast-feed your baby for 24 hours after you have had etomidate. Throw away any milk you express during this time.

Driving and using machines

Do not drive or use machines for at least 24 hours after you received etomidate. Your doctor will tell you when you can drive and use machinery again.

Etomidate-Lipuro contains soya-bean oil and sodium

This product contains soya-bean oil. In rare cases, soya-bean oil may cause severe allergic reactions.

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

3. How to use Etomidate-Lipuro

The doctor will decide on the right dose of Etomidate-Lipuro depending on how you respond.

Adults and adolescents

Normally the dose is 0.3 mg per kilogram (kg) of bodyweight for both adults and adolescents. This is the same as 0.15 ml per kg body weight. No more than 3 ampoules (30 ml) of Etomidate-Lipuro will be given to you.

Use in children

Usually children receive the same dose as adults. There may be cases, however, where children do not sleep sufficiently deeply with this dose. Then more etomidate will have to be given, up to 0.4 mg per kg of body weight, after the doctor is sure that this will not put the patient at a higher risk.

Elderly patients

Elderly patients usually respond to 0.15 to 0.2 mg per kg bodyweight.

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Etomidate-Lipuro 2 mg/ml
Emulsion for Injection

Etomidate

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4.9 Overdose

Symptoms

An overdose of etomidate, administered as a bolus, deepens sleep and may cause respiratory depression and even respiratory arrest, in which case adequate respiratory support is mandatory.

Hypotension has also been observed in such cases.

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

Treatment

Treatment depends on the nature and severity of the symptoms, including, if necessary, respiratory support.

In addition to supportive measures (e.g. of respiration) administration of 50-100 mg hydrocortisone (not ACTH) may be required.

All equipment and medication usually required in general anaesthetic procedures should be available.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other general anaesthetics,

ATC code: N01AX07.

Mechanism of action, pharmacodynamic effects

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

Etomidate suppresses the function of the adrenal cortex. Etomidate inhibits adrenal cell cortisol production by reversibly blocking the steroid synthesis enzyme 11-β-hydroxylase. The cortisol suppression is unresponsive to ACTH and lasts up to 8 h after a single 0.3 mg/kg dose of etomidate. The inhibition of cortisol synthesis is reversible and depends on the etomidate concentration in plasma.

Involuntary muscle movements observed after administration of etomidate result from disinhibition of physiological diencephalic excitations, similar to myoclonus during physiological sleep.

Etomidate has been reported to possess anticonvulsive properties and a protective effect on brain cells against hypoxic damage.

Since etomidate has no analgesic effect, concurrent administration of an analgesic is required for all surgical procedures.

5.2 Pharmacokinetic properties

Absorption

Since Etomidate-Lipuro 2 mg/ml is administered intravenously, its bioavailability is 100 %.

Distribution

Etomidate rapidly separates from the oil particles upon injection. This is reflected by the etomidate plasma concentration, which is comparable with that of the aqueous formulation.

The plasma protein binding of etomidate (primarily to albumin) is about 75 %, it is reduced in renal dysfunction or chronic liver damage.

Etomidate is rapidly distributed to the brain and other tissues.

The total volume of distribution is about 4.5 l/kg.

Rapid distribution from the central compartment to a peripheral and a deeper peripheral compartment as well as a high elimination rate cause the plasma concentration to fall rapidly for about 30 minutes after a single administration. Then, the plasma concentration declines more slowly.

Biotransformation and elimination

The primary step of biotransformation is the hydrolysis of the ethyl ester in the liver. A small proportion is also subject to oxidative N-dealkylation. All metabolites discovered are pharmacologically inactive.

The elimination half-life is relatively long (terminal elimination half-life 2 – 5 h) despite a high rate of hepatic extraction due to slow redistribution of etomidate from the deeper peripheral compartment.

About 75 % of the administered dose of etomidate appear in the urine within 24 hours, primarily as metabolites. Other routes of excretion play a minor role.

The major metabolite in the urine (about 80 %) is the hydrolysis product of etomidate, namely R-(+)-1-(α-methylbenzyl)-5-imidazolecarboxylic acid. Only 2 % of etomidate are excreted unchanged via the urine.

The half-life of the lipid particles is short.

Accumulation has not been observed.

5.3 Preclinical safety data

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Soya-bean oil, refined,
Medium-chain triglycerides,
Glycerol,
Egg lecithin,
Sodium oleate,
Water for injections

6.2 Incompatibilities

Etomidate-Lipuro 2 mg/ml must not be mixed with any other product.

6.3 Shelf Life

Unopened
2 years

After first opening
To be used immediately, see section **6.6**.

After reconstitution / dilution
not applicable

6.4 Special precautions for storage

Do not freeze.
Keep ampoules in the outer carton in order to protect from light.

6.5 Nature and contents of container

The product is supplied in colourless glass ampoules (type I glass, Ph. Eur.) containing 10 ml
Pack sizes: packs of 10 ampoules

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

Ampoules should be shaken prior to use to ensure homogenous distribution. Only to be used if the emulsion is homogenous and milky-white after shaking. If two layers can be seen after shaking the ampoule should not be used.

Not to be used if ampoule shows signs of damage.

Etomidate-Lipuro 2 mg/ml 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.

Drugs to be given concurrently with Etomidate-Lipuro 2 mg/ml, e.g. an analgesic, should be administered consecutively through the same line or through separate venous cannulae.

Etomidate-Lipuro 2 mg/ml may be injected into the tubing of an infusion of isotonic sodium chloride having temporarily been stopped.

7. MARKETING AUTHORISATION HOLDER

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34212 Melsungen, Germany

8. MARKETING AUTHORISATION NUMBER(S)

PL 03551/0041

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

11.03.2002 / 31.05.2006

10. DATE OF REVISION OF THE TEXT

05.05.2013

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The dose is less in patients with a liver disease called cirrhosis and in patients who have had special drugs for treatment of mental illness (neuroleptics), strong painkillers (so-called opioids) or sedatives just before etomidate.

Your doctor will usually give the injection slowly over about 30 seconds, or as a number of very small injections, into the vein. Your doctor will avoid to inject this medicine into an artery.

Before giving etomidate, the doctor will usually give the patient a drug such as diazepam, which depresses the central nervous system and reduces uncontrolled muscle spasms.

If you have received more Etomidate-Lipuro than you should

In such a case the sleeping period may be extended and breathing may stop for a short time. Your blood pressure may also be lowered.

The treatment of such events depends on the severity of symptoms. In general, to manage such occurrences, all equipment and medicines usually required in general anaesthetic procedures (especially breathing support) will be available.

Overdosage may also affect the function of your adrenal glands. In such cases your doctor may give you a medicine called hydrocortisone.

4. Possible side effects

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

Most likely, etomidate may affect breathing and circulation. Uncontrolled muscle movements may occur. Besides this, etomidate may also affect the function of the adrenal glands.

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

Common (may affect up to 1 in 10 people):
- Breathing may slow down or stop for a short time. This can be easily managed by your anaesthetist.

Uncommon (may affect up to 1 in 100 people):
- Slow or irregular heartbeat

Rare (may affect up to 1 in 1,000 people):
- Spasm of the voice box

Not known (frequency cannot be estimated from the available data):
- Allergic reactions have been observed. A special type of hypersensitivity reaction, the so-called anaphylactoid reaction, has been observed, too.
- Shock
- Difficulty in breathing that may be fatal

Other side effects include

Very common (may affect more than 1 in 10 people):
- Jerky movements

Common (may affect up to 1 in 10 people):
- Muscle twitching
- Low blood pressure
- Wheezing
- Hyperventilation
- Feeling sick, vomiting
- Rash

Uncommon (may affect up to 1 in 100 people):
- Unusual muscle stiffness and involuntary muscle contractions
- Involuntary eye movements (nystagmus)
- Shivering
- High blood pressure
- Hypoventilation
- Coughing
- Hiccups
- Too much saliva
- Redness of the skin
- Pain around the injection site
- Complications associated with general anaesthesia (delayed wake-up, sensation of pain due to insufficient painkilling effect, feeling sick)

Not known (frequency cannot be estimated from the available data):
- Problems with your adrenal glands (glands attached to the kidneys)
- Convulsions
- Heart attack
- Severe problems with your heart
- Hives
- Severe allergic reaction of the skin and mucous membranes accompanied by blistering and reddening of the skin (Erythema), which might in very severe cases affect inner organs and might be life threatening (Stevens-Johnson syndrome)
- Lockjaw

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Etomidate-Lipuro

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the ampoule label and the carton. The expiry date refers to the last day of that month.

Ampoules should be shaken before use. This medicine must only be used if it is homogenous and milky-white after shaking. The product must not be used if two separate layers can be seen after shaking the ampoule. The doctor or nurse will check that the ampoule is not damaged.

Keep ampoules in the outer carton in order to protect from light. Do not freeze.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Etomidate-Lipuro contains

– The active substance is Etomidate
Each millilitre of the emulsion contains 2 mg of Etomidate.
Each ampoule (10 millilitres) contains 20 mg of Etomidate.

– The other ingredients are:
Soya-bean oil
Medium-chain triglycerides
Glycerol
Egg lecithin
Sodium oleate
Water for injections

– pH: 6.0 – 8.5

What Etomidate-Lipuro looks like and contents of the pack

Etomidate-Lipuro is a milky-white emulsion of oil in water.

It comes in colourless glass ampoules containing 10 ml of sterile emulsion.

It is available in packs of 10 ampoules.

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

The Netherlands: Etomidaat-Lipuro 2 mg/ml, emulsie voor injectie
Portugal: Etomidato-Lipuro 2 mg/ml, emulsão injectável
Spain: Etomidato-Lipuro 2 mg/ml, emulsión inyectable
United Kingdom: Etomidate-Lipuro 2 mg/ml, emulsion for injection

This leaflet was last revised in 05/2013.

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