Patient Information Leaflet for B. Braun Etomidate 2 mg/ml

SCHEDULING STATUS

S5

B. BRAUN ETOMIDATE 2 mg/ml

2 mg/mL emulsion for injection

(etomidate)

(Sugar free)

This product contains less than 1 mmoL of sodium (see section 6).

Read al of this leaflet carefully before you are given B. BRAUN ETOMIDATE 2 mg/ml.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.

What is in this leaflet

1. What B. BRAUN ETOMIDATE 2 mg/ml is and what it is used for

B. BRAUN ETOMIDATE 2 mg/ml belongs to a group of medicines called general anaesthetics. General anaesthetics are used to cause unconsciousness (sleep) so

that surgical operations or other procedures can be performed. They can also be used to sedate you (so that you are sleepy but not completely asleep).

B. BRAUN ETOMIDATE 2 mg/ml is used to:

- Put you to sleep before an operation
- Sedate you during diagnostic and surgical procedures.

2. What you need to know before you are given B. BRAUN ETOMIDATE 2 mg/ml

B. BRAUN ETOMIDATE 2 mg/ml should not be administered

- If you are allergic to etomidate, soya, peanut or to any of the other ingredients of this medicine (see section 6)
- If you have a condition called Porphyria
- If you are pregnant or breastfeeding
- If you are in labour and delivery
- To neonates and infants up to the age of 6 months except for imperative indications during in hospital treatment.

Tell your doctor if this applies to you.

Warnings and precautions

Special care should be taken with B. BRAUN ETOMIDATE 2 mg/ml

Tell your doctor or health care provider before being given the injection:

- If you have impaired adrenocortical function
- If you have liver disease or have had it in the past
- If you have taken medication to treat and manage symptoms of a psychiatric disorder
- If you have taken medication to put you to sleep
- If you have taken medication to treat strong pain (so-called opiods)
- If you are over 65

- If you have a mitochondrial disease (genetic disorder) which affects the production of haem (a precursor to haemoglobin, which is necessary to bind oxygen in the bloodstream).

Please tell your doctor if you have one of these diseases or conditions.

The return of normal alertness may vary according to the duration of the operation, the total dose of etomidate and other pain or sedative medication administered to you.

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).

The interference with daily activities may continue for up to 24 hours and no legal/contractual devisions should be entered for 24 hours after receiving anaesthetic/conscious sedation.

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.
Single induction doses of etomidate can lead to transient adrenal insufficiency and decreased serum cortisol levels.
Etomidate should be used with caution in critically ill patients, including patients with sepsis as it has been associated with an increased risk of mortality in some studies in these patient groups.

Other medicines and B. BRAUN ETOMIDATE 2 mg/ml

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.) B. BRAUN ETOMIDATE 2 mg/ml may affect other medicines or be affected by them.

Some medicines enhance the effect of B. BRAUN ETOMIDATE 2 mg/ml

It is especially important that you tell your doctor if you have recently taken:

- antipsychotic medication
- strong pain killers (opiods e.g. fentanyl)
- tranquillizers
- alcohol.

Some medicines influence the effect of B. BRAUN ETOMIDATE 2 mg/ml

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 medicines are administered together as the concentrations of etomidate may drop below the hypnotic threshold.

B. BRAUN ETOMIDATE 2 mg/ml can

- Enhance the effect of medicines indicated in reducing blood pressure
- Additionally, safe use has been demonstrated in combination with Ketamine (medication used for general anaesthesia).

You should not take Monoamine oxidase inhibitors (MAOI, medicines used to treat mental depression or Parkinson’s disease) at least two weeks before a treatment with etomidate. Otherwise this could harm your health .

B. BRAUN ETOMIDATE 2 mg/ml with alcohol

You should avoid alcohol until you are full recovered. Your doctor will advise you further on the consumption of alcohol before and after the use of B. BRAUN ETOMIDATE 2 mg/ml. The use of alcohol should be avoided for 24 hours following B. BRAUN ETOMIDATE 2 mg/ml.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before being given this medicine.

B. BRAUN ETOMIDATE 2 mg/ml crosses the placenta and may depress vital functions of the newborn. So doctors only use it in exceptional cases if there is no safer alternative available.

You may still be given B. BRAUN ETOMIDATE 2 mg/ml, but you need to discuss it first.

Your doctor will help you decide whether to stop breast-feeding, or whether to abstain from etomidate therapy, considering the benefit of breast-feeding to the baby and the benefit of etomidate to the mother. If you are breast-feeding your child you should stop nursing and discard breast milk for 24 hours after you have received B. BRAUN ETOMIDATE 2 mg/ml.

Driving and using machines

You should not drive or operate machinery for 24 hours after you have received B. BRAUN ETOMIDATE 2 mg/ml.

Your doctor will advise you

- if you should be accompanied when you are leaving
- when you can drive and use machinery again
- on the use of other tranquilizing medicines (e.g. tranquillizers, strong pain killers, alcohol).

B. BRAUN ETOMIDATE 2 mg/ml contains sodium and soya-bean oil

This medicine contains less than 1 mmoL sodium (23 mg) in 10 mL that is to say essentially 'sodium free'.

B. BRAUN ETOMIDATE 2 mg/ml contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

3. What you need to know before you are given B. BRAUN ETOMIDATE 2 mg/ml

B. BRAUN ETOMIDATE 2 mg/ml will only be given to you by your anaesthetists or under the care of your anaesthetist.

The anaesthetist or healthcare professional will administer your correct dose.

Dosage

Your anaesthetist will work out the dose of B. BRAUN ETOMIDATE 2 mg/ml you need based on your age, body weight and physical condition. The doctor will give the correct dose to start or to achieve the required level of sedation, by carefully watching your responses and vital signs (pulse, blood pressure, breathing, etc.)

The usual dose is 0,2 to 0,3 mg per kg (0,1 and 0,15 mL per kg) body weight.

The dose of B. BRAUN ETOMIDATE 2 mg/ml in children (under 15 years old) should be increased up to 30 % of the normal dose for adults to achieve the same depth and duration of sleep as obtained in adults.

The usual dose of B. BRAUN ETOMIDATE 2 mg/ml in the elderly (> 65 years old), is 0,15 to 0,20 mg per kg body weight. Your doctor may adjust your dose according to the depth and duration of sleep achieved.

Your doctor may reduce your dose if you have or have had liver disease in the past, or if you have recently taken medication indicated for psychiatric disorder, strong pain killers or tranquillizers.

How B. BRAUN ETOMIDATE 2 mg/ml is given

B. BRAUN ETOMIDATE 2 mg/ml will be given to you by your anaesthetist by slow intravenous injection that is, through a needle or small tube placed in one of your veins. Your doctor will tell you how long your treatment with B. BRAUN ETOMIDATE 2 mg/ml will last.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If more B. BRAUN ETOMIDATE 2 mg/ml is given to you than recommended

As your anaesthetist will be monitoring your condition carefully, it is unlikely that you will be given too much B. BRAUN ETOMIDATE 2 mg/ml. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use B. BRAUN ETOMIDATE 2 mg/ml

Since a health care provider will administer B. BRAUN ETOMIDATE 2 mg/ml, it is unlikely that the dose will be missed.

4. Possible side effects

B. BRAUN ETOMIDATE 2 mg/ml can have side effects.

Not all side effects reported for B. BRAUN ETOMIDATE 2 mg/ml are included in this leaflet. Should your general health worsen or if you experience any untoward effects while being given B. BRAUN ETOMIDATE 2 mg/ml, please consult your healthcare provider for advice.

If these side effects occur while you are under anaesthesia, they will be seen and treated by your anaesthetist. The following side effects may be serious and, therefore, require immediate treatment:

- breathing may slow down or stop for a short time
- slow or irregular heartbeat
- cramp-like closure of the voice box
- allergic (medicine hypersensitivity) reactions - such as a rash, red skin, swelling of your tongue and/or throat, shortness of breath, changes in blood pressure or heart rate, sometimes resulting in a serious decrease of blood pressure. Severe allergic or allergic-like reactions can be life threatening.
- shock
- difficulty breathing, which can be fatal.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- jerky movements
- cortisol decreased
- muscle twitching,
- hypotension (low blood pressure)
- increased breath sounds
- increased breathing (hyperventilation)
- nausea (feeling sick)

- vomitting
- rash.

Less frequent side effects:

- unusual muscle stiffness and involuntary muscle contractions
- involuntary eye movements (nystagmus)
- shivering
- high blood pressure
- reduced breathing (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).

Frequency unknown side effects:

- problems with your adrenal glands (glands attached to the kidneys)
- seizures
- 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 you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor , pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://primaryreporting.who-umc.org/ZA.

By reporting side effects, you can help provide more information on the safety of B. BRAUN ETOMIDATE 2 mg/ml.

5. How B. BRAUN ETOMIDATE 2 mg/ml is stored

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 ºC.

Do not freeze.

For single use only. Discard any unused portion.

Keep the ampoules in the outer carton until required for use.

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

Do not use if the ampoule shows sign of damage.

Do not use if two separate layers can be seen after shaking the product.

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.

6. Contents of the pack and other information

What B. BRAUN ETOMIDATE 2 mg/ml contains

The active ingredient is etomidate.

The other ingredients are:

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

What B. BRAUN ETOMIDATE 2 mg/ml looks like and contents of the pack

B. BRAUN ETOMIDATE 2 mg/ml is a milky-white oil-in-water emulsion packed in a 10 mL Type I, clear, colourless glass ampoule. 5 ampoules will be packed in a clear PVC tray and 2 trays each containing 5 ampoules will be packed into an outer cardboard container.

Holder of Certificate of Registration

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