

Package leaflet: Information for the user

Hypnomidate® 2 mg/ml Injection etomidate

Hypnomidate is a registered trademark

Read all of this leaflet carefully before you start 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 nurse
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If you get side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Hypnomidate is and what it is used for

Hypnomidate contains a medicine called etomidate. It is used as a general anaesthetic.

2. What you need to know before you use Hypnomidate

Do not have Hypnomidate if:

- You are allergic to anything in Hypnomidate (listed in section 6 below)

If you are not sure if this applies to you, talk to your doctor or nurse before having Hypnomidate.

Take special care with Hypnomidate

Check with your doctor or nurse before being given this medicine if you have ever had:

- Problems with your liver
- Low blood pressure
- Long-term treatment with strong painkillers
- Problems with your drinking (alcoholism)
- Problems with your adrenal glands not working properly

Also tell your doctor if you are suffering from a serious infection in your blood (sepsis).

Your doctor will carefully monitor the amount of Hypnomidate they give you or you may need other medication. If you are not sure if any of the above applies to you, talk to your doctor or nurse before having Hypnomidate.

Before your anaesthetic, you will normally be given another medicine, known as a 'pre-med'. This will probably make you feel drowsy and will also help stop any uncontrollable muscle twitches which can occur.

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.

Special monitoring

Hypnomidate may make you breathe more slowly. Your breathing will be carefully monitored until it returns to normal.

Taking other medicines

Please tell your doctor or nurse if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

The effect of Hypnomidate may be altered when it is received together with

- Strong medicines for pain called 'opioid analgesics' such as morphine, codeine, fentanyl or alfentanil
- Medicines to calm you down (also called 'sedatives')
- Medicines to improve thoughts, feelings and/or behaviour (also called 'neuroleptics')
- Alcohol

Talk to your doctor before having Hypnomidate if you are taking any of these medicines. They may have to change the amount of Hypnomidate you are given.

Pregnancy and breast-feeding

You must tell your doctor before having Hypnomidate if you are pregnant, think you may be pregnant or might become pregnant.

You may still be able to have Hypnomidate if your doctor thinks you need to.

You should stop breast-feeding during and for a period of 24 hours after treatment with Hypnomidate.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

Do not drive or use any tools or machines for at least 24 hours after having Hypnomidate. You may be less alert than usual. Ask your doctor or pharmacist for advice.

Important information about an ingredient of Hypnomidate

- Hypnomidate contains propylene glycol that may cause alcohol-like symptoms

Hypnomidate contains propylene glycol

- This medicine contains 3626 mg propylene glycol in 10 ml.
- If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.
- If you are pregnant or breast-feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.
- If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

3. How to use Hypnomidate

Hypnomidate is given by a doctor experienced in using this type of medicine. Check with your doctor or nurse if you are not sure about anything.

How Hypnomidate is given

- Hypnomidate is given into a vein by slow injection or as a drip (infusion).
- It may be diluted before use with a sodium chloride or a dextrose solution
- Hypnomidate does not stop pain so you may be given a painkiller at the same time

How much Hypnomidate is given

Your doctor will decide how much Hypnomidate you need. This may depend on:

- Your body weight in kilograms
- Your general health

- Your age
- The type of operation you are having

Adults and children

The usual dose is 0.3 mg/kg. No more than 3 ampoules will be used.

Elderly patients

Less Hypnomidate may be used in patients that are elderly or weak due to ill health.

If you have too much Hypnomidate

It is unlikely that you will be given too much Hypnomidate. This will be monitored during your operation.

4. Possible side effects

Like all medicines, Hypnomidate can cause side effects, although not everybody gets them. If side effects occur, they usually do so while you are asleep. Your doctor will monitor these effects during your operation.

The following side effects have been reported:

Very common (affects more than 1 in 10 people)

- Muscle twitching or jerking, with difficulty moving your body
- Cortisol decreased

Common (affects less than 1 in 10 people)

- Pain or discomfort along the vein where the injection was given
- Dizziness and fainting. These are signs of lowered blood pressure but are mild and do not usually last long
- Breathing stops for a short period of time. If necessary, your breathing will be helped by a machine (ventilator)
- Breathing faster and/or deeper than normal
- Noisy breathing
- Being sick
- Feeling sick
- Rash

Uncommon (affects less than 1 in 100 people)

- Unusual muscle stiffness causing poor control of movement
- Heart beats more slowly
- Extra heartbeats
- Unusual fast heartbeat
- Swelling, redness and clotting in a vein, which is extremely tender when touched
- High blood pressure
- Breathing more slowly or weakly than usual
- Hiccups
- Cough
- Too much saliva
- Redness of the skin
- Pain where the injection was given. To prevent this happening, your doctor or nurse may inject a small amount of painkiller just before giving you Hypnomidate
- Complications with the anaesthetic
- Delayed recovery from the anaesthetic
- Not enough painkiller
- Involuntary movements of the eye

Other side effects

- Allergic reactions including rare cases of serious allergic reaction which may cause difficulty in breathing, wheezing or coughing, and hives or nettle rash (urticaria)
- Adrenal glands not working properly – you may feel weak, more tired than usual and lose weight
- Fits or convulsions
- Heart attack
- Heart problems
- A dangerous decrease of blood pressure which, if untreated, may lead to collapse, coma and death
- Inflammation of the blood vessels
- Shallow, slow or weak breathing
- Difficulty in breathing or wheezing, which could be fatal
- Rare skin condition, with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- Pinkish, itchy swellings on the skin
- Problems using your jaw muscles

You may still have some of these effects when you wake up.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hypnomidate

Hypnomidate is kept out of the reach and sight of children. It is stored in the hospital pharmacy. Do not store above 25°C.

Hypnomidate will not be used after the expiry date stated on the label. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

The active substance in Hypnomidate is etomidate. Each millilitre (ml) contains 2 milligrams (mg) of etomidate.

The other ingredients are propylene glycol and water. It may also contain very small amounts of sodium hydroxide and hydrochloric acid.

What Hypnomidate looks like and contents of the pack

Hypnomidate is supplied in a clear glass ampoule containing 10 ml of liquid in packs of 5 and 10 ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Piramal Critical Care Limited
 Suite 4, Ground Floor
 Heathrow Boulevard - East Wing,
 280 Bath Road,
 West Drayton
 UB7 0DQ
 United Kingdom

Manufacturer:

Piramal Critical Care Limited
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280 Bath Road,
West Drayton
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Or

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