

Patient Information Leaflet
Blafol
(Propofol Injection BP 1% w/v)

Read all of this leaflet carefully before you start taking this medicine:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- 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 any side of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

What is in this leaflet?

1. What Blafol is and what it is used for
2. Before you use Blafol
3. How to use Blafol
4. Possible side effects
5. How to store Blafol
6. Further information

1. What Blafol is and what it is used for

Blafol contains a medicine called Propofol. This 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).

Blafol will be given to you as an injection by a doctor.

In adults and children over 1 month of age it is used to:

- Help put you to sleep **before** an operation or other procedure.
- Keep you asleep **during** an operation or other procedure.
- Sedate you during diagnostic and surgical procedures, alone or in combination with local or regional anaesthesia.

In people over 16 years of age it is also used to:

- Sedate you when receiving artificial respiration in an Intensive Care Unit (ICU).

2. Before you use Blafol

Do not use Blafol:

- If you are allergic to Propofol or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to peanut or soya. This is because Blafol contains soya oil.
- If you are 16 years of age or younger for sedation in intensive care.

If any of the above apply to you, do not have Blafol and tell your doctor, anaesthetist or nurse.

If you are not sure, talk to one of these people before having Blafol.

Take special care with Blafol

- If you have ever had a fit or convulsion.
- If you have ever been told that you have very high levels of fat in your blood.
- If you have ever been told that your body has problems using fat.
- If your body has lost lots of water (you are dehydrated).
- If you have any other health problems, such as problems with your heart, breathing, kidneys or liver.
- If you have been generally unwell for some time.
- If you have mitochondrial disease.

If you are not sure if any of the above apply to you, talk to your doctor or nurse before having Blafol.

Taking other Medicines

Please tell your health care provider if you are taking or have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

In particular, tell your doctor, anaesthetist or nurse if you are taking any of the following medicines:

- Rifampicin (for tuberculosis - TB)

Pregnancy and breast-feeding

Do not have Blafol if you are pregnant unless absolutely necessary.

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.

Driving and using machines

Do not drive or use any tools or machines until you are sure the effects have worn off. After having Blafol, you may still feel sleepy for some time.

- If you are able to go home shortly after having Blafol, do not drive a car or use any tools or machines.
- Ask your doctor when you can start doing these activities again and when you can go back to work.

Important information about some of the ingredients of Blafol

Blafol contains sodium. If you are on a sodium controlled diet, you will need to take this into account.

Blafol contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

Blafol contains disodium edetate. During prolonged use of Blafol for intensive care, you may need to be given a zinc (a mineral) supplement.

3. How to use Blafol

You will be given Blafol by a doctor. It will be given to you as an injection into a vein. This is usually in the back of your hand or in your forearm.

- The doctor will give you the injection using a needle or through a fine plastic tube called a 'cannula'.
- The doctor can also use an electric pump to control how fast the injection is given. This may be done if you are having a long operation or if you are in an Intensive Care Unit.

The dose of Blafol varies from one patient to another. The amount of Blafol that you need depends on your age, size, physical fitness and the level of sleepiness or sleep that you need.

The doctor will give you the correct dose to start and to sustain anaesthesia or to achieve the required level of sedation, by carefully watching your responses and vital signs (pulse, blood pressure, breathing etc.).

You may need several different medicines to keep you asleep or sleepy, free from pain, breathing in a healthy way and to keep your blood pressure steady. The doctor will decide which medicines you need and when you need them.

4. Possible side effects

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

Side effects that can happen during anaesthesia

The following side effects can happen during anaesthesia (while the injection is being given to you or when you are sleepy or asleep). Your doctor will be looking out for these. If they happen, your doctor will give you appropriate treatment.

Very common (may affect more than 1 in 10 people)

- A feeling of pain at the site of the injection (while the injection is being given, before you fall asleep).

Common (may affect up to 1 in 10 people)

- Low blood pressure.
- Changes in your breathing pattern.
- Slow heartbeat.

Rare (may affect up to 1 in 1,000 people)

- Twitching and shaking of your body, or a fit (may also happen when you wake up).
- Unusual colour of urine (may also happen when you wake up).

Very rare (may affect up to 1 in 10,000 people)

- Allergic reactions.
- Stopping of your heart beat.
- Build-up of fluid in the lungs which can make you very breathless (may also happen when you wake up).

Not known: frequency cannot be estimated from the available data:

- Shallow breathing.
- Prolonged, often painful erection (priapism).

Side effects that can happen after anaesthesia

The following side effects can happen after anaesthesia (when you are waking up or after you have woken up).

Common (may affect up to 1 in 10 people)

- Feeling sick (nausea).
- Being sick (vomiting).
- Headache.

Uncommon (may affect up to 1 in 100 people)

- Swelling and redness along a vein or blood clots.

Very rare (may affect up to 1 in 10,000 people)

- Feeling sexually aroused.
- High temperature (fever).
- Redness or soreness where the injection was given.
- Being unconscious after the operation. (When this has happened, the patients have recovered without problems.)
- Tissue damage.

Not known: frequency cannot be estimated from the available data

- A feeling of pain at the site of the injection.
- Swelling at the site of injection.
- Prolonged, often painful erection (priapism)

Other possible side effects

The following side effects have been seen when Blafol is used in intensive care at higher doses than recommended.

Very rare (may affect up to 1 in 10,000 people)

- Heart failure.
- Inflamed pancreas (pancreatitis) which causes severe stomach pain.
- Too much acid in your blood. This may make you breathe more quickly.
- Increased amount of potassium in your blood.
- High blood level of a type of fat called lipids.
- Abnormal heart beat.
- Enlargement of the liver.
- Kidney failure.

The following side effects have been seen in children in intensive care when Blafol has been stopped suddenly.

Common (may affect up to 1 in 10 people)

- ‘Withdrawal symptoms’. These include unusual behaviour, sweating, shaking and feeling anxious.
- Flushing of the skin.

Do not be concerned by this list of possible side effects. You may not get any of them.

Not known: frequency cannot be estimated from the available data

- Euphoric mood.

- Involuntary movements.
- Drug abuse and dependence on Blafol, mostly by healthcare professionals.
- Abnormal ECG.
- Breakdown of muscle cells (rhabdomyolysis).

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

5. How to store Blafol

Keep out of the reach and sight of children.

The doctor and hospital pharmacist are responsible for storing, using and disposing of Blafol correctly.

Store below 30°C. Do not freeze.

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Blafol contains:

- The active substance is propofol. There is 10 mg of propofol in each ml.
- The other ingredients are Soyabean Oil, Egg Phospholipid (Lipoid E 80), Glycerol, Disodium Edetate, Sodium Oleate B, Sodium Hydroxide.

What Blafol looks like and contents of the pack

A milky white emulsion, packed in 10 ml 20 mm Flint Tubular USP Type-I (Schott Fiolax Tubing) Vials, with Rubber Stopper Grey Bromo Butyl RFU & Aluminium Seal Lacq 20mm F/O Top Transparent yellow.

Marketing Authorisation Holder and Manufacturer

Bliss GVS Pharma Ltd.

102, Hyde Park, Saki Vihar Road, Andheri (E), Mumbai - 400 072, INDIA.

Tel: +91 – 22 – 4216 0000 / 28505387

Fax: + 91 – 22 – 28563930

Leaflet revision and issue date - June 2020.