

## Consumer Medicine Information

### 1. What is in this leaflet

This leaflet contains some common questions about Propofol-Lipuro.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risk of you taking this medicine against the benefits they expect it will have for you.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

### 2. What is Propofol-Lipuro used for?

It is a short-acting sleep inducing medicinal product used to start and sustain a general anaesthesia.

It is used to induce sleep or lower your level of consciousness (as a sedative) during intensive care or during diagnostic or surgical procedures.

### 3. Before you are given Propofol-Lipuro

#### *When you must not be given Propofol-Lipuro*

Do not use Propofol-Lipuro:

- if you are allergic (hypersensitive) to Propofol or any of the other ingredients of Propofol-Lipuro
- if you are allergic (hypersensitive) to soya or peanut

#### *Take special care with Propofol-Lipuro if:*

- you have a disorder in which your body does not handle fat properly
- you have any other health problems which require much caution in the use of fat emulsions
- you are very overweight
- your blood volume is too low (hypovolaemia)
- you are very weak or have heart, circulatory, kidney or liver problems
- you have high pressure within the skull and low blood pressure in the arteries
- you have problems with your breathing
- you have epilepsy
- you are undergoing some procedures where spontaneous movements are particularly, undesirable.

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

Do not give Propofol-Lipuro in children of one month of age or younger as a general anaesthetic.

Do not give Propofol-Lipuro 2% in children under 3 years of age.

Do not give Propofol-Lipuro in children 16 years or younger as a sedation during intensive care.

The use of Propofol-Lipuro is not recommended in newborn infants

It will not be used when you are receiving electroconvulsive therapy (electric shock treatment in cases of severe long lasting epileptic attacks).

If you are receiving other lipids by a drip into your vein at the same time your doctor will pay attention to your total daily fat intake.

Propofol will be administered to you by a physician trained in anaesthesia or intensive care. You will be constantly monitored during anaesthesia and waking-up time.

If you experience signs of the so called 'propofol infusion syndrome' (a doctor must be called if the following happen) your doctor will decrease the dosage of propofol or will switch to an alternative drug.

#### *Taking or using other medicines*

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines may depress your breathing or your blood circulation when combined with Propofol or prolong the effect of Propofol:

Painkillers, benzodiazepine tranquillisers, narcotic gases, some local anaesthetics, fentanyl, other medicinal products usually given before operations.

On the other hand, the sedative effect of some of these medicinal products may become stronger.

When given together with Propofol, certain medicines used for muscle relaxation (suxamethonium) or as antidote (neostigmin) may depress heart function.

Occurrence of a specific organic changes in the brain (leucoencephalopathy) has been reported in patients having received fat emulsions such as Propofol-Lipuro together with ciclosporin (a medicine used to suppress rejection reactions after organ transplantation and to suppress overreactions of the immune system).

Make sure that your doctor knows if you are taking any of these medicinal products.

#### *Using Propofol-Lipuro with food and drink*

Alcohol and Propofol make the sedative effects of each other stronger. Therefore you should not drink alcohol just before or just after you have Propofol-Lipuro.

#### *Pregnancy and breast-feeding*

Ask your doctor or pharmacist for advice before taking any medicine.

Propofol-Lipuro should not be used during pregnancy.

If you are breast-feeding your child you should stop nursing and discard breast milk for 24 hours after you have received Propofol-Lipuro. Studies in breast-feeding women showed that Propofol is excreted in small amounts into the milk.

#### *Driving and using machines*

You should not drive or operate machinery for a while after you have had an injection or infusion of Propofol-Lipuro. Your doctor will tell you how long you must wait before you drive or use machinery again.

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 tranquillizing drugs (e.g. tranquillizers, strong pain killers, alcohol).

#### *Important information about some of the ingredients of Propofol-Lipuro*

This medicinal product contains less than 1 mmol (23 mg) sodium in 100 mL, that is, it is essentially 'sodium free'.

### 4. How to use Propofol-Lipuro

Propofol-Lipuro will only be given by anaesthetists or by specially trained doctors in an intensive care unit.

#### *Dosage*

The dose you are given will vary depending on your age, body weight and physical condition.

The doctor will give 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).

The doctor will also observe limits of the time of application, if necessary.

Propofol-Lipuro will usually be given by injection when used to induce general anaesthesia and by continuous infusion (a slower, longer injection) when used to maintain general anaesthesia. It may given as an infusion either diluted or undiluted. When used as a sedative it will usually be given by infusion.

Propofol-Lipuro will only be given for a maximum of 7 days.

#### *Method of administration*

You will receive Propofol-Lipuro by intravenous injection or infusion, that is, through a needle or small tube placed in one of your veins.

Because Propofol-Lipuro does not contain preservatives, an infusion from one vial or bottle of Propofol-Lipuro will not last longer than 12 hours..

Your circulation and breathing will be constantly monitored while you are being given the injection or infusion.

#### *Overdose*

#### *If you received more Propofol-Lipuro than you should*

It is unlikely that this occurs because the doses you receive are very carefully controlled.

If you accidentally got an overdose, this could lead to depression of heart function, circulation and breathing. In this case your doctor will employ any necessary treatment immediately.

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

### 5. Possible Side Effects

Like all medicines, Propofol-Lipuro emulsion for injection or infusion can cause side effects, although not everybody gets them.

*Common (may affect up to 1 in 10 people):*

- Low blood pressure that might occasionally need infusion of fluids and reduction of the speed of administration of propofol.
- Too low heartbeat that might be serious in rare cases.

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

- Convulsions like in epilepsy

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

- Allergic reactions including swelling of the face, tongue or throat, wheezing breath, skin redness and low blood pressure
- There have been cases of unconsciousness occurring after operations. You will therefore be carefully observed during the waking-up time.
- Water on lungs (lung oedema) after administration of propofol
- Inflammation of the pancreas.

*Not known (frequency cannot be estimated from the available data):*

- There have been reports of isolated cases of severe adverse reactions presenting as a combination of the following symptoms: breakdown of muscle tissue, accumulation of acidic (sour) substances in the blood, abnormally high blood potassium level, high blood fat levels, abnormalities in the electrocardiogram (Brugada-type ECG), liver enlargement, irregular heart-beat, kidney failure and heart failure. This has been called the "propofol infusion syndrome". Some of the affected patients eventually died. These effects have only been seen in patients in intensive care with doses higher than 4 mg of propofol per kg body weight per hour. See also section 2, 'Warnings and precautions'.

**Other side effects are:**

*Very common (affects more than 1 treated patient of 10):*

- Pain at the injection site occurring during the first injection. The pain may be reduced by injecting propofol into larger veins of the forearm. Injection of lidocaine (a local anaesthetic) and propofol at the same time also helps to reduce the pain at the injection site.

*Common (may affect up to 1 in 10 people):*

- Short interruption of breathing
- Headache during the time of recovery
- Sickness or vomiting during the time of recovery

*Uncommon (may affect up to 1 in 100 people):*

- Blood clots in veins or inflammation of veins

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

- Loss of sexual control during the time of recovery
- Abnormal colour of urine after longer lasting administration of propofol
- Cases of fever after an operation

*Not known (frequency cannot be estimated from the available data):*

- Involuntary movements
- Abnormally good mood

- Drug abuse
- Failure of the heart
- Breakdown of muscle tissue has been reported very rarely in cases where propofol has been given at greater doses than recommended for sedation in intensive care units

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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## 6. Storage

Keep out of the reach and sight of children.

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

Keep ampoules in the outer carton in order to protect from light. Store below 25°C. Do not freeze.

Propofol-Lipuro must be used immediately after opening the ampoule, vial or bottle.

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

*The following information is intended for medical or healthcare professionals only:*

The containers are for single use in one patient only.

Any unused emulsion must be thrown away at the end of administration.

The containers must be shaken before use.

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## 7. Product Description

*What Propofol-Lipuro looks like*

It is a milky-white oil-in water emulsion which comes in the following:

**Propofol-Lipuro 1%:**

20mL glass ampoule

20mL colourless glass vial, sealed with a grey rubber stopper and aluminium seal with a blue polypropylene flip-off insert

50mL colourless glass infusion bottles, sealed with a grey rubber stopper and aluminium seal with a blue polypropylene flip-off insert

100mL colourless glass infusion bottles, sealed with a grey rubber stopper and aluminium seal with a blue polypropylene flip-off insert

**Propofol-Lipuro 2%:**

50mL colourless glass infusion bottles, sealed with a grey rubber stopper and aluminium seal with a red polypropylene flip-off insert

**Ingredients:**

**Propofol-Lipuro 1%**

Active ingredient:

Propofol

1 mL contains 10 mg of Propofol.

Inactive ingredients:

Soya oil,

Medium-chain triglycerides,

Egg lecithin,

Glycerol,

Sodium oleate,

Water for injections

**Propofol-Lipuro 2%**

Active ingredient:

Propofol

1 mL contains 20 mg of Propofol.

Inactive ingredients:

Soya oil,

Medium-chain triglycerides,

Egg lecithin,

Glycerol,

Sodium oleate,

Water for injections

Australian registration number:

**Propofol-Lipuro 1%:**

20mL ampoule AUST R 142906

20mL vial AUST R 220082

50mL bottle AUST R 220083

100mL bottle AUST R 220081

**Propofol-Lipuro 2%:**

50mL bottle AUST R 220084

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## 8. Sponsor Details

B. Braun Australia Pty Ltd

Level 5, 7-9 Irvine Place

Bella Vista NSW 2156

Australia

Toll Free Number: 1800 251 705

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## 9. Date of Information

This leaflet was updated in July 2019