1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

DIPRIVAN 2 % 50 ml Infusion (parenteral)

DIPRIVAN 2 % PFS 10 ml Intravenous infusion

DIPRIVAN 2 % PFS 50 ml Intravenous infusion

Propofol

Sugar free

Read all of this leaflet carefully before DIPRIVAN is administered to you

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

What is in this leaflet

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

1. What DIPRIVAN is and what it is used for

DIPRIVAN 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).

DIPRIVAN will be administered to you as an injection by a doctor.

DIPRIVAN is used to:

- Help to put you to sleep before an operation or other procedure and to keep you asleep during the procedure.
- Sedate you if you are an adult and in intensive care for periods up to 72 hours.

2. What you need to know before DIPRIVAN is administered to you

DIPRIVAN should not be administered to you:

- if you are hypersensitive (allergic) to propofol or any of the other ingredients of DIPRIVAN.
- if you are allergic to peanut or soya. This is because DIPRIVAN contains soya oil.
- if your child is younger than 3 years of age.
- if your child has croup (your child might have an upper airway infection that blocks breathing and has a distinctive barking cough) or epiglottitis (swelling around the windpipe) and is in intensive care in hospital.
- for sedation in intensive care if you are 16 years of age or younger.
- if you are pregnant.

Warnings and precautions

Take special care with DIPRIVAN:

- if you have breathing problems or are using any medicines that assist with your breathing.
- if you have ever had a fit or convulsion or have been told previously by your healthcare provider that you have epilepsy.
- if you have any other health problems, such as problems with your heart, breathing, kidneys or liver.
- if you are debilitated (weak).
- if you have ever been told that you have high fat levels in your blood or that your body struggles to use fat.
- if you are elderly.
- if you or your child suffer from severe systemic disease that is a constant threat to life (ASA Grades 3 or 4 patients), which has caused you or your child to be unwell for some time.
- if your healthcare provider has informed you that you are hypovolaemic. Symptoms include, but are not limited to dizziness, nausea and you feel very thirst.
- if you have a serious head injury.
- if you have mitochondrial disease (poor growth, development delays, muscle weakness, decreased oxygen delivery, seizures, unexplained pain, partial or complete paralysis (as these are signs of serious neurological injury)), fever with chills, very low body temperature, urinating less than usual, rapid pulse and breathing, nausea, vomiting (as these are signs of sepsis) as these are risk factors for developing propofol infusion syndrome.
- if you or your child have a zinc shortage and use medication to treat this, especially if you have suffered from burns or had diarrhoea.

Your healthcare provider will continually monitor you and allow sufficient time to ensure full consciousness before you are discharged. Your healthcare provider will also advise that somebody accompany you when your leave the place of administration of DIPRIVAN and on the use of any other medicine that may cause sedation.

Children and adolescents

DIPRIVAN is not recommended for induction and maintenance of anaesthesia in children aged less than 3 years.

DIPRIVAN must not be used in patients of 16 years of age or younger for sedation for intensive care.

Other medicines and DIPRIVAN

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Rifampicin: used to treat TB (tuberculosis).
- Valproate: used to treat epilepsy and bipolar disorder.
- Morphine, meperidine and fentanyl (narcotics): used to relieve pain.
- Benzodiazepines, barbiturates or droperidol (combination of opioids or sedatives): used for the treatment of panic attacks and anxiety, trouble sleeping.

Pregnancy, breastfeeding and fertility

You should not be given DIPRIVAN if you are pregnant or breastfeeding your baby.

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 healthcare provider for advice before receiving this medicine.

Driving and using machines

DIPRIVAN has major influence on the ability to drive and use machines.
It is not always possible to predict to what extent DIPRIVAN may interfere with the daily activities of a patient. You should ensure that you do not engage in the above activities until you are aware of the measure to which DIPRIVAN affects you (see section 4).

DIPRIVAN contains disodium edetate and soya-bean oil

If you are allergic to peanut or soya, DIPRIVAN should not be administered to you. During prolonged use of DIPRIVAN for intensive care, you may need to be given a zinc (a mineral) supplement.

3. How DIPRAVIN will be administered to you

DIPRIVAN 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 dose of DIPRIVAN varies from one patient to another. The amount of DIPRIVAN that you need depends on your age, weight, physical fitness and the level of sleepiness or sleep that you need. Your 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. Your doctor will decide which medicines you need and when you need them.

If you have the impression that the effect of DIPRIVAN is too strong or too weak, tell your doctor or pharmacist.

You will not be expected to give yourself DIPRIVAN. It will be given to you by a person who is qualified to do so.

If you receive more DIPRIVAN than you should

Since a healthcare provider will administer DIPRIVAN, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive a dose of DIPRIVAN

Since a healthcare provider will administer DIPRIVAN, it is unlikely that the dose will be missed.

4. Possible side effects

DIPRIVAN can have side effects.

Not all side effects reported for DIPRIVAN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while been given or after been given DIPRIVAN, please consult your healthcare provider for advice.

The below listed side effects can happen during anaesthesia when DIPRIVAN is administered. Your healthcare provider will be monitoring you during your procedure and will ensure that appropriate treatment is given to you if needed.

If any of the following happens during your procedure, DIPRIVAN must be stopped. If you experience the below after your procedure tell your healthcare provider immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing (angioedema),
- rash or itching (erythema).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DIPRIVAN. You may need urgent medical attention or hospitalisation.

Tell your healthcare provider immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- if you have pain, tightness, and a feeling of constriction in the chest and back with difficulty getting enough air or breathing (bronchospasm),
- changes in your breathing pattern (respiratory depression),
- slow or abnormally fast heartbeat (bradycardia, tachycardia) or abnormal heart rhythm (premature ventricular contractions),
- build-up of fluid in the lungs which can make you very breathless (pulmonary oedema),
- if you stop breathing for a period of 20 seconds or longer means you could have suffered from transient apnoea during induction,
- if you have been told that you have a chronic condition in which your heart doesn't pump blood as well as it should or you have shortness of breath, fatigue, swollen legs and rapid heartbeat, as you could suffer from cardiac failure,
- if you notice that you are going to urinate less than usual and you notice that you are swelling due to fluid retention and have nausea, fatigue and shortness of breath, this could mean that you have renal failure,

- you struggle to be woken up after the procedure has been completed (postoperative unconsciousness),
- you could have temporary loss of consciousness caused by a fall in blood pressure (syncope).

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:

- pain where the drip for the anaesthesia was inserted (local pain on induction),
- your blood pressure has increased (hypertension) or you could have a drop in your blood pressure (hypotension),
- headaches during the recovery phase,
- your child could have a change in body temperature from hot to cold or cold to hot (flushing in children),
- you could feel nauseous or vomit while recovering from the procedure,
- children may experience withdrawal symptoms.

Less frequent side effects:

- If your skin is red, swollen, tender and warm to the touch in the affected area you could have phlebitis (inflammation of a vein),
- if you have leg pain or swelling of the legs, you could have thrombosis (clotting of your blood),
- twitching and shaking of your body, or a fit (epileptiform movements) or body movements that you cannot control (involuntary movement),
- unusual colour of urine (urine discolouration),
- you have a fever after the procedure,

- you have short sudden pain in your abdomen/back with nausea, or vomiting and loss of appetite you could have pancreatitis,
- you do not have the need or desire to be sexually active (sexual disinhibition),
- you feel very tired, weak with dizziness, vomiting, nausea and have a fever with chills and sweating, as you could be suffering from tissue necrosis.

Side effects with an unknown frequency:

- if you or your child are/is breathing fast with confusion and vomiting, you could be suffering from metabolic acidosis,
- if you or your child are/is tired, weak, nauseous, vomiting and have chest pain you could be suffering from hyperkalaemia,
- if you or your child have a feeling of always being happy and that nothing can go wrong (euphoric moods),
- you notice that you are taking medication more than usual to function through the day and can't cope without taking unnecessary medication you might have a drug abuse problem or might have developed a drug dependency problem,
- your body parts such as your arms, legs move without you being aware of them doing so this could be involuntary movement,
- you have dark, reddish urine, a decreased amount of urine, weakness and muscle aches (rhabdomyolysis),
- you have previously had blood tests done and your doctor advised that you have hyperlipidaemia (high cholesterol),
- your doctor could tell you that you have a Brugada type ECG,
- you have pain where DIPRIVAN was given to you, with swelling in the area (local pain),
- you could suffer from an enlarged liver (hepatomegaly),

- you have an abnormal feeling or happiness and need to celebrate (excitation),
- you have continuous hiccups,
- involuntary muscle contractions that cause repetitive or twisting movements (dystonia) or abnormality or impairment of voluntary movement (dyskinesia),
- a prolonged erection of the penis, usually without sexual arousal (priapism).

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://www.sahpra.org. za/Publications/Index/8

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of DIPRIVAN.

5. How to store DIPRIVAN

Store all medicines out of reach of children.

Store at or below 25 °C. Do not freeze.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DIPRIVAN contains

The active substance is 20 mg/mL of propofol.

The other ingredients are disodium edetate (anhydrous) 0,005 % *m/v*, glycerol, purified egg phosphatide, sodium hydroxide (for pH adjustment), soya-bean oil and water for injection.

Sugar free

What DIPRIVAN looks like and contents of the pack

DIPRIVAN is a white or almost white, homogenous emulsion, practically free from extraneous particulate contamination and large oil droplets. Slight creaming may be visible on prolonged standing.

DIPRIVAN 2 % 50 ml: 1 x 50 ml colourless, clear Type 1 glass vial with an aluminium seal, grey bromobutyl rubber stopper and a polypropylene snap off cap. 1 vial is packed in an outer cardboard carton.

DIPRIVAN 2 % PFS 10 ml: 1 x 10 ml pre-filled glass syringe, plunger rod and luer connector pack. 1 pre-filled syringe is packed in an outer cardboard carton.

DIPRIVAN 2 % PFS 50 ml: 1 x 50 ml pre-filled glass syringe, plunger rod and luer connector pack. 1 pre-filled syringe is packed in an outer cardboard carton.

Not all strengths, packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 118 088

This leaflet was last revised in

12 April 2023

Registration numbers

DIPRIVAN 2 % 50 ml: 36/2.1/0084

DIPRIVAN 2 % PFS 10 ml: 36/2.1/0085

DIPRIVAN 2 % PFS 50 ml: 36/2.1/0086

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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