PATIENT INFORMATION LEAFLET FOR PROPOFOL 1 % PS FRESENIUS

SCHEDULING STATUS: S5

PROPOFOL 1 % PS FRESENIUS

Emulsion for injection or infusion in pre-filled syringe

Propofol

Contains sugar (as Glycerol 22,5 mg/mL)

Contains soybean oil (refined) 50 mg/mL

Read all of this leaflet carefully before you are given PROPOFOL 1 % PS FRESENIUS

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

What is in this leaflet:

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

1. What PROPOFOL 1 % PS FRESENIUS is and what it is used for

PROPOFOL 1 % PS FRESENIUS 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).

PROPOFOL 1 % PS FRESENIUS is used to:

- induce and maintain general anaesthesia in adults, adolescents and children,
- sedate patients older than 16 years of age receiving artificial respiration in the intensive care unit (ICU),
- sedate you during diagnostic and surgical procedures, alone or in combination with local or regional anaesthesia.

2. What you need to know before you are given PROPOFOL 1 % PS FRESENIUS

PROPOFOL 1 % PS FRESENIUS should not be administered:

- if you are hypersensitive (allergic) to propofol or any of the other ingredients of PROPOFOL 1 % PS FRESENIUS (listed in section 6),
- if you are allergic to soya bean oil or peanuts,
- in children younger than 3 years of age,
- for sedation of children of all ages with croup or epiglottitis (inflammation of the glottis) receiving intensive care,
- in patients of 16 years of age or younger for sedation in intensive care.

Warnings and precautions

Special care should be taken with PROPOFOL 1 % PS FRESENIUS.

Tell your doctor or healthcare provider before being given the injection:

- if you have advanced heart failure or heart disease;
- if you have lung disease, severe breathing problems (respiratory failure);
- if you have kidney disease;
- if you have liver disease;
- if your body has lost lots of water (you are hypovolaemic);
- if you have seizures (epilepsy);

- if you have altered levels of fat in the blood. If you are receiving total parenteral nutrition (feeding through a vein), the levels of fat in your blood must be monitored;
- if you are receiving electroconvulsive therapy (ECT, a treatment for psychiatric problems);
- if you have a raised pressure inside the skull (raised intracranial pressure). In combination with low blood pressure the amount of blood reaching the brain may be decreased;
- if you have been told you have mitochondrial disease (a genetic disorder).

PROPOFOL 1 % PS FRESENIUS may increase the risk of:

- epileptic seizures;
- a nervous reflex that slows the heart rate (bradycardia).

Very occasionally, after anaesthesia, there may be a period of unconsciousness associated with stiffness of the muscles. This requires observation by the medical staff, but no other treatment. It will resolve spontaneously.
The injection of PROPOFOL 1 % PS FRESENIUS can be painful. Your doctor may use a local anaesthetic to reduce the pain.
You will not be allowed to leave the hospital until you are fully awake. If you are able to go home shortly after receiving PROPOFOL 1 % PS FRESENIUS, you should not go home unaccompanied.
PROPOFOL 1 % PS FRESENIUS may interfere with daily activities for up to 24 hours. You should not make any legal/contractual decisions for 24 hours after receiving anaesthesia/sedation.
In general, PROPOFOL 1 % PS FRESENIUS should be given with caution to elderly or weak patients.

Children and adolescents

The use of PROPOFOL 1 % PS FRESENIUS is not recommended in children less than 3 years of age (see “PROPOFOL 1 % PS FRESENIUS should not be administered”).
PROPOFOL 1 % PS FRESENIUS must not be given to children and adolescents younger than 16 years of age for sedation in the intensive care unit, since its safety has not been demonstrated in this patient group for this indication.

Other medicines and PROPOFOL 1 % PS FRESENIUS

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).
Tell your doctor if you are taking/receiving any of the following medicines:

- premedications (your anaesthetist will know which medicines can be influenced by PROPOFOL 1 % PS FRESENIUS);
- other anaesthetics, including general, regional, local and inhalational anaesthetics. (Lower doses of PROPOFOL 1 % PS FRESENIUS may be required);
- painkillers (analgesics);
- strong painkillers (fentanyl or opioids);
- benzodiazepines (medicines used to treat anxiety);
- suxamethonium, atracurium, mivacurium (muscle relaxants);
- rifampicin (an antibiotic used in tuberculosis (TB));
- alcohol-containing medicines or beverages;
- neostigmine (medicine used to treat a disease called myasthenia gravis);
- ciclosporin (medicine used to prevent transplant rejections);
- valproate (medicine used to treat epilepsy or mental disorders).

Receiving PROPOFOL 1 % PS FRESENIUS with food and drink

After you have been given PROPOFOL 1 % PS FRESENIUS, you should not eat, drink or consume alcohol until fully recovered.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor or other healthcare provider for advice before receiving PROPOFOL 1 % PS FRESENIUS.

PROPOFOL 1 % PS FRESENIUS should not be given to pregnant women.

You should stop breastfeeding and discard any breast milk for 24 hours after receiving PROPOFOL 1 % PS FRESENIUS.

Driving and using machinery

After having PROPOFOL 1 % PS FRESENIUS you may still feel sleepy for some time. Do not drive, operate machinery, or work in dangerous situations.

If you are able to go home shortly after receiving PROPOFOL 1 % PS FRESENIUS, do not go home alone.

Ask your doctor when you can start doing these activities again and when you can go back to work.

PROPOFOL 1 % PS FRESENIUS contains soya-bean oil and sodium

PROPOFOL 1 % PS FRESENIUS contains soybean oil. This can cause severe hypersensitivity (allergic) reactions. If you are allergic to peanuts or soya, do not use this product. Tell your doctor if you know that you are allergic to soya-bean oil or peanuts.

PROPOFOL 1 % PS FRESENIUS contains sodium (less than 1 mmol (23 mg) sodium per 100 ml, i.e., essentially “sodium-free”).

3. How PROPOFOL 1 % PS FRESENIUS will be given to you

You will not be expected to give yourself PROPOFOL 1 % PS FRESENIUS. It will only be given to you in hospitals or suitable therapy units by a person who is qualified to do so.

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 (such as 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.

Children and adolescents over 3 years of age:

The use of PROPOFOL 1 % PS FRESENIUS is not recommended in children younger than 3 years of age.

The dose should be adjusted according to age and/or body weight.

PROPOFOL 1 % PS FRESENIUS must not be given to children and adolescents younger than 16 years of age for sedation in the intensive care unit, since its safety has not been demonstrated in this patient group for this indication.

Method of administration:

PROPOFOL 1 % PS FRESENIUS is for intravenous use, usually on the back of your hand or in the forearm. Your anaesthetist may use a needle or cannula (a fine plastic tube).

PROPOFOL 1 % PS FRESENIUS will be injected into a vein either manually or by electric pumps.

When used for sedation, PROPOFOL 1 % PS FRESENIUS must not be administered for more than 72 hours.

If you received more PROPOFOL 1 % PS FRESENIUS than you should

Since a healthcare provider will administer PROPOFOL 1 % PS FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

However, different people need different doses and if you do receive too much for you, your anaesthetist may need to take measures to make sure your heart and breathing are adequately supported. This is why anaesthetics are only administered by doctors trained in anaesthesia or in the care of patients in intensive care.
If you have any further questions on the use of this medicine, ask your anaesthetist or intensive care doctor.

If you missed a dose of PROPOFOL 1 % PS FRESENIUS

Since a healthcare provider will administer PROPOFOL 1 % PS FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

PROPOFOL 1 % PS FRESENIUS can have side effects.
Not all side effects reported for PROPOFOL 1 % PS FRESENIUS are included in this leaflet.
Should your general health worsen or if you experience any untoward effects while receiving PROPOFOL 1 % PS FRESENIUS, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, tell your doctor immediately in order to stop administering PROPOFOL 1 % PS FRESENIUS:

- Serious allergic reaction which causes swelling of the lips, face and throat, difficulty in breathing, swollen and reddened skin, hot flushes;
- Build-up of fluid in the lungs which can make you feel breathless (may also happen when you wake up);
- Inflamed pancreas (pancreatitis) which causes severe stomach pain;
- Kidney failure (decreased urine output, swelling, shortness of breath).

These are all very serious side effects. If you have them, you may have had a serious reaction to PROPOFOL 1 % PS FRESENIUS. You may need urgent medical attention or further hospitalisation.

Tell your doctor or healthcare provider if you notice any of the following:

Frequent side effects:

- Headache;
- Slow or fast heartbeat;
- Low blood pressure;
- Changes in your breathing pattern, hiccups;
- Cough;
- Feeling sick (nausea), being sick (vomiting);
- A feeling of pain at the site of the injection (while the injection is being given, before you fall asleep).

Less frequent side effects:

- Twitching and shaking of your body, or fits (may also happen when you wake up);
- Dizziness, shivering, chills and sensations of cold;
- Being unconscious after the operation (when this has happened, the patients have recovered without problems);
- Swelling and redness or blood clots at the vein along the injection site;
- Unusual colour of urine (may also happen when you wake up);
- Fever following surgery.

Frequency not known (frequency cannot be estimated from the available data):

- Feeling euphoric (intense excitement);
- Feeling sexually aroused (inappropriate sexual behaviour);
- Medicine abuse, dependence, mostly by healthcare professionals;

- Involuntary movements;
- Irregular heartbeat, changes in ECG;
- Respiratory depression (you may experience shallow breathing and shortness of breath);
- Increase in liver size (your doctor will conduct tests to determine this);
- Breakdown of muscle cells (rhabdomyolysis) – you may notice muscle weakness, pain and dark red or brown urine;
- Increase in acidity of your blood, high potassium and fat levels in your blood, heart failure (your doctor will conduct blood tests to determine this);
- Prolonged erection;
- Pain and swelling, following accidental injection into the tissue around the vein.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) available on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PROPOFOL 1 % PS FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store PROPOFOL 1 % PS FRESENIUS

Store all medicines out of reach of children.

Store at or below 25 °C. Do not freeze. For single use. Any unused emulsion must be discarded. Do not throw away any medicines via wastewater or household waste.

Do not use this medicine after the expiry date which is stated on the syringe and the outer packaging after EXP. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What PROPOFOL 1 % PS FRESENIUS contains

- The active substance is propofol.

Each mL of the emulsion contains 10 mg propofol.

Each 10 mL syringe contains 100 mg propofol.

Each 20 mL syringe contains 200 mg propofol.

Each 50 mL syringe contains 500 mg propofol.

- The other ingredients are soybean oil, medium-chain triglycerides, purified egg phosphatides, glycerol, oleic acid, sodium hydroxide (for pH adjustment), water for injections.

What PROPOFOL 1 % PS FRESENIUS looks like and contents of the pack

PROPOFOL 1 % PS FRESENIUS is a white, homogeneous oil-in-water emulsion in a pre-filled syringe.

PROPOFOL 1 % PS FRESENIUS is available in plastic and glass pre-filled syringes.

Pack sizes:

Packs containing 5 glass pre-filled syringes with 10 mL emulsion

Packs containing 6 plastic pre-filled syringes with 10 mL emulsion

Packs containing 5 glass pre-filled syringes with 20 mL emulsion

Packs containing 6 plastic pre-filled syringes with 20 mL emulsion

Packs containing 1 plastic pre-filled syringe with 50 mL emulsion

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Registration number

49/2.1/1233

Access to the corresponding Professional Information

The professional information will be printed and packaged with the product.

PASIËNTINLIGTINGSBLAD VIR PROPOFOL 1 % PS FRESENIUS

SKEDULERINGSTATUS: **S5**

PROPOFOL 1 % PS FRESENIUS

Emulsie vir inspuiting of infusie in vooraf-gevulde spuit

Propofol

Bevat suiker (as Gliserol 22,5 mg/mL)

Bevat sojaboonolie (geraffineerd) 50 mg/mL

Lees die hele inligtingsblad aandagtig deur voordat PROPOFOL 1 % PS FRESENIUS aan jou gegee word

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer wil lees.
- Indien jy verdere vrae het, raadpleeg asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.

Wat is in hierdie inligtingsblad:

1. Wat PROPOFOL 1 % PS FRESENIUS is en waarvoor dit gebruik word
2. Wat jy moet weet voordat PROPOFOL 1 % PS FRESENIUS aan jou gegee word
3. Hoe PROPOFOL 1 % PS FRESENIUS aan jou gegee sal word
4. Moontlike newe-effekte
5. Hoe om PROPOFOL 1 % PS FRESENIUS te bewaar
6. Inhoud van die pakkie en ander inligting

1. Wat PROPOFOL 1 % PS FRESENIUS is en waarvoor dit gebruik word

PROPOFOL 1 % PS FRESENIUS behoort tot 'n groep medisyne genaamd "algemene narkosemiddels". Algemene narkosemiddels word gebruik om bewusteloosheid (slaap) te

veroorsaak sodat chirurgiese of ander prosedures uitgevoer kan word. Dit kan ook gebruik word om jou te kalmeer (sodat jy lomerig word, maar nie heeltemal slaap nie).

PROPOFOL 1 % PS FRESENIUS word gebruik om:

- algemene narkose in volwassenes, adolessente en kinders te induseer en in stand te hou,
- pasiënte ouer as 16 jaar wat kunsmatige asemhaling ontvang in die intensiewe versorgingseenheid (ICU) te kalmeer,
- alleen, of in kombinasie met plaaslike of streeksnarkose, jou te kalmeer tydens diagnostiese en chirurgiese prosedures.

2. Wat jy moet weet voordat PROPOFOL 1 % PS FRESENIUS aan jou gegee word

PROPOFOL 1 % PS FRESENIUS moet nie aan jou toegedien word nie:

- indien jy hipersensitief (allergies) is vir propofol of enige van die ander bestanddele van PROPOFOL 1 % PS FRESENIUS (gelys in afdeling 6),
- indien jy allergies is vir sojaboonolie of grondboontjies,
- in kinders jonger as 3 jarige ouderdom,
- vir kalmering van kinders van alle ouderdomme met kroep of epiglottitis (ontsteking van die glottis) wat intensiewe sorg ontvang,
- in pasiënte van 16 jarige ouderdom of jonger vir kalmering in intensiewesorg.

Waarskuwings en voorsorgmaatreëls

Spesiale sorg moet geneem word met PROPOFOL 1 % PS FRESENIUS.

Lig jou dokter of gesondheidsorgverskaffer in voordat jy ingespuit word:

- indien jy gevorderde hartversaking het, of hartsiekte;
- indien jy longsiekte, erge asemhalingsprobleme (respiratoriese versaking) het;
- indien jy 'n niersiekte het;
- indien jy lewersiekte het;
- indien jou liggaam baie water verloor het (jy hipovolemies is);

- indien jy stuipe (epilepsie) het;
- indien jy veranderde vetvlakke in die bloed het. Indien jy totale parenterale voeding (voeding deur 'n aar) ontvang, moet jou bloedvetvlakke gemonitor word;
- indien jy elektrokonvulsiewe behandeling ontvang (ECT, 'n behandeling vir psigiatriese probleme);
- indien jy 'n verhoogde druk binne die skedel het (verhoogde intrakraniale druk). In kombinasie met lae bloeddruk kan die hoeveelheid bloed wat die brein bereik afneem;
- indien daar vir jou gesê is dat jy mitochondriale siekte ('n genetiese afwyking) het.

PROPOFOL 1 % PS FRESENIUS kan die risiko verhoog van:

- epileptiese aanvalle;
- 'n senuweerefleks wat die harttempo vertraag (bradikardie).

Baie selde kan daar na narkose 'n periode van bewusteloosheid wees, wat geassosieer word met styfheid van die spiere. Dit vereis waarneming deur die mediese personeel, maar geen ander behandeling nie. Dit sal spontaan opklaar.
Die inspuiting van PROPOFOL 1 % PS FRESENIUS kan pynlik wees. Jou dokter kan plaaslike verdowing gebruik om die pyn te verminder.
Jy sal nie toegelaat word om die hospitaal te verlaat voordat jy heeltemal wakker is nie.
Indien jy kort nadat jy PROPOFOL 1 % PS FRESENIUS ontvang het huis toe kan gaan, moet jy nie alleen huis toe gaan nie.
PROPOFOL 1 % PS FRESENIUS kan vir tot 24 uur met daaglikse aktiwiteite inmeng. Jy moet geen wetlike/kontraktuele besluite neem vir 24 uur nadat jy narkose/sedasie ontvang het nie.
Oor die algemeen moet PROPOFOL 1 % PS FRESENIUS met omsigtigheid aan bejaarde of swak pasiënte gegee word.

Kinders en adolessente

Die gebruik van PROPOFOL 1 % PS FRESENIUS word nie aanbeveel in kinders jonger as 3 jarige ouderdom nie (sien "PROPOFOL 1 % PS FRESENIUS moet nie toegedien word nie"). PROPOFOL 1 % PS FRESENIUS moet nie aan kinders en adolessente jonger as 16 jaar toegedien word vir sedasie in die intensiewe versorgingseenheid nie, aangesien die veiligheid daarvan nie in hierdie pasiëntgroep vir hierdie indikasie aangetoon is nie.

Ander medisyne en PROPOFOL 1 % PS FRESENIUS

Lig altyd jou gesondheidsorgkundige in as jy enige ander medisyne neem. (Dit sluit in komplementêre of tradisionele medisyne).

Lig jou dokter in as jy die volgende medisyne neem/ontvang:

- premedikasie (jou narkotiseur sal weet watter medisyne deur PROPOFOL 1 % PS FRESENIUS beïnvloed kan word);
- ander narkosemiddels, waaronder algemene, streeks-, plaaslike en inhalasienarkosemiddels. (Laer dosisse PROPOFOL 1 % PS FRESENIUS kan nodig wees);
- pynstillers (analgetika);
- sterk pynstillers (fentaniel of opioïede);
- bensodiasepiene (medisyne wat gebruik word om angstigheid te behandel);
- suksametonium, atrakurium, mivakurium (spierverslappers);
- rifampisien ('n antibiotikum wat gebruik word vir tering (TB));
- medisyne of drankies wat alkohol bevat;
- neostigmien (medisyne wat gebruik word om 'n siekte genaamd miastenie gravis te behandel);
- siklosporien (medisyne wat gebruik word om orgaanverwerping te voorkom);
- valproaat (medisyne wat gebruik word om epilepsie of geestesiektes te behandel).

Ontvang van PROPOFOL 1 % PS FRESENIUS saam met voedsel en vloeistowwe

Nadat PROPOFOL 1 % PS FRESENIUS aan jou gegee is, moet jy nie eet, drink of alkohol inneem totdat jy heeltemal herstel het nie.

Swangerskap en borsvoeding

Indien jy swanger is of borsvoed, dink jy is dalk swanger, of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy PROPOFOL 1 % PS FRESENIUS ontvang.

PROPOFOL 1 % PS FRESENIUS moet nie aan swanger vrouens gegee word nie.

Jy moet ophou borsvoed en alle borsmelk weggooi, vir 24 uur nadat jy PROPOFOL 1 % PS FRESENIUS ontvang het.

Bestuur en gebruik van masjinerie

Nadat jy PROPOFOL 1 % PS FRESENIUS ontvang het kan jy nog vir 'n geruime tyd lomerig voel. Moet nie bestuur, masjinerie gebruik of in gevaarlike situasies werk nie.

Indien jy kort nadat jy PROPOFOL 1 % PS FRESENIUS ontvang het huis toe kan gaan, moet jy nie alleen huis toe gaan nie.

Vra jou dokter wanneer jy weer hierdie aktiwiteite kan hervat en wanneer jy weer kan teruggaan werk toe.

PROPOFOL 1 % PS FRESENIUS bevat sojaboonolie en natrium.

PROPOFOL 1 % PS FRESENIUS bevat sojaboonolie. Dit kan ernstige hipersensitiwiteits (allergiese) reaksies veroorsaak. Moet nie hierdie produk gebruik nie indien jy allergies is vir grondboontjies of soja.. Lig jou dokter in indien jy weet dat jy allergies is vir sojaboonolie of grondboontjies.

PROPOFOL 1 % PS FRESENIUS bevat natrium (minder as 1 mmol (23 mg) natrium per 100 mL, d.w.s., in wese "natriumvry").

3. Hoe PROPOFOL 1 % PS FRESENIUS aan jou gegee sal word

Daar sal nie van jou verwag word om PROPOFOL 1 % PS FRESENIUS aan jouself toe te dien nie. Dit sal slegs deur gekwalifiseerde personeel in hospitale of geskikte behandelingsfasiliteite aan jou gegee word.

Die dosis wat aan jou toegedien word, sal wissel afhangende van jou ouderdom, liggaamsgewig en fisiese toestand. Die dokter sal die korrekte dosis gee om die narkose te begin en dit vol te hou, of om die vereiste vlak van sedasie te bereik, deur jou reaksies en lewenstekens (soos polsslag, bloeddruk, asemhaling, ens.) sorgvuldig dop te hou.

Jy mag verskeie verskillende medisyne nodig hê om jou aan die slaap of slaperig te hou, pynvry te hou, jou te help om behoorlik asem te haal en jou bloeddruk stabiel te hou. Jou dokter sal besluit watter medisyne jy nodig het en wanneer jy dit nodig het.

<u>Kinders en adolessente ouer as 3 jaar:</u>

Die gebruik van PROPOFOL 1 % PS FRESENIUS word nie aanbeveel in kinders jonger as 3 jaar nie.

Die dosis moet volgens ouderdom en/of liggaamsgewig aangepas word.

PROPOFOL 1 % PS FRESENIUS moet nie aan kinders en adolessente jonger as 16 jaar vir sedasie in die intensiewe versorgingseenheid gegee word nie, aangesien die veiligheid daarvan niein hierdie pasiëntgroep vir hierdie indikasie aangetoon is nie.

<u>Metode van toediening:</u>

PROPOFOL 1 % PS FRESENIUS is vir binneaarse gebruik, gewoonlik op die agterkant van jou hand of in die voorarm. Jou narkotiseur kan 'n naald of kannule ('n dun plastiekbuisie) gebruik. PROPOFOL 1 % PS FRESENIUS sal of met die hand of deur 'n elektriese pomp in 'n aar gespuit word.

Wanneer dit vir kalmering gebruik word, moet PROPOFOL 1 % PS FRESENIUS nie vir langer as 72 uur toegedien word nie.

Indien jy meer PROPOFOL 1 % PS FRESENIUS ontvang het as wat jy moes

Aangesien 'n gesondheidsorgverskaffer PROPOFOL 1 % PS FRESENIUS sal toedien, sal hy/sy die dosis beheer. In geval van oordosering sal jou dokter egter die oordosering behandel.

Die dosis verskil egter van persoon tot persoon; as jy ‘n te hoë dosis ontvang, sal jou narkotiseur moontlik maatreëls moet tref om te verseker dat jou hart en asemhaling voldoende ondersteuning ontvang. Dit is waarom narkosemiddels slegs toegedien word deur dokters wat opgelei is in narkose of in die versorging van pasiënte in intensiewesorg.

Indien jy verdere vrae het oor die gebruik van hierdie medisyne, raadpleeg jou narkotiseur of intensiewesorg dokter.

Indien jy 'n dosis van PROPOFOL 1 % PS FRESENIUS oorgeslaan het

Aangesien 'n gesondheidsorgverskaffer PROPOFOL 1 % PS FRESENIUS sal toedien, is dit onwaarskynlik dat 'n dosis oorgeslaan sal word.

4. Moontlike newe-effekte

PROPOFOL 1 % PS FRESENIUS kan newe-effekte hê.

Nie alle newe-effekte wat vir PROPOFOL 1 % PS FRESENIUS aangemeld is, is in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl jy PROPOFOL 1 % PS FRESENIUS ontvang, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgkundige vir advies.

Indien enige van die volgende gebeur, lig jou dokter dadelik in, sodat toediening van PROPOFOL 1 % PS FRESENIUS gestaak kan word:

- Ernstige allergiese reaksie wat swelling van die lippe, gesig en keel kan veroorsaak, moeilike asemhaling, geswelde en rooi vel, warmgloede;

- Ophoping van vloeistof in die longe wat jou uitasem kan laat voel (dit kan ook gebeur as jy wakker word);
- Ontsteekte pankreas (pankreatitis) wat erge maagpyn kan veroorsaak;
- Nierversaking (verminderde urienuitskeiding, swelling, kortasemheid).

Dit is alles baie ernstige newe-effekte. Indien jy enige hiervan ervaar, het jy moontlik 'n ernstige reaksie op PROPOFOL 1 % PS FRESENIUS gehad. Jy kan dringende mediese aandag of verdere hospitalisering benodig.

Lig jou dokter of gesondheidsorgverskaffer in as jy enige van die volgende waarneem:

Gereelde newe-effekte:

- Hoofpyn;
- Stadige of vinnige hartklop;
- Lae bloeddruk;
- Veranderinge in jou asemhalingspatroon, hik;
- Hoes;
- Mislike gevoel (naarheid) en opbring (braking);
- 'n Seer gevoel by die plek van die inspuiting (terwyl die inspuiting gegee word, voordat jy aan die slaap raak).

Minder gereelde newe-effekte:

- Spiertrekkings en bewerigheid van jou liggaam, of stuipe (kan ook gebeur as jy wakker word);
- Duiseligheid, bewing, kouekoors en voel koud;
- Om bewusteloos te wees na die operasie (waar dit gebeur het, het pasiënte sonder enige probleme herstel);
- Swelling en rooiheid of bloedklonte in die aar by die plek van inspuiting;
- Ongewone kleur van die uriene (kan ook gebeur wanneer jy wakker word);

- Koors na die operasie.

Frekwensie onbekend (frekwensie kan nie uit die beskikbare gegewens geskat word nie):

- Euforiese gevoel (intense opgewondenheid);
- Voel seksueel geprikkel (ontoepaslike seksuele gedrag);
- Misbruik van medisyne, afhanklikheid, meestal deur gesondheidsorgkundiges;
- Onwillekeurige bewegings;
- Onreëlmatige hartklop, veranderinge in die EKG;
- Asemhalingsonderdrukking (jy kan vlak asemhaling en kortasemheid ervaar);
- Vergroting van die lewer (jou dokter sal toetse uitvoer om dit te bepaal);
- Afbraak van spierselle (rabdomiolise) – jy kan spierswakheid, pyn en donkerrooi of bruin uriene opmerk;
- Verhoogde suurgraad van jou bloed, hoë kalium- en vetvlakke in jou bloed, hartversaking (jou dokter sal bloedtoetse uitvoer om dit te bepaal);
- Langdurige ereksie;
- Pyn en swelling na onbedoelde inspuiting in die weefsel rondom die aar.

Indien jy enige newe-effekte ondervind wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte

Indien jy newe-effekte ervaar, bespreek dit met jou dokter, apteker of verpleegkundige. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die Med Safety APP (Medsafety X SAHPRA) en die eReporting-platform (who-umc.org) op die SAHPRA webwerf. Deur newe-effekte aan te meld, kan jy help om meer inligting rakende die veiligheid van PROPOFOL 1 % PS FRESENIUS te verskaf.

Pasiënte word gevra om enige vermoedelike ongunstige newe-effekte van geneesmiddels aan hulle gesondheidsorgverskaffer of die Houer van die Registrasiesertifikaat by die

volgende e-posadres aan te meld: safety.fksa@fresenius-kabi.com en aan die betrokke medisyne se regulatoriese owerheid in die land waar die produk bemark word.

5. Hoe om PROPOFOL 1 % PS FRESENIUS te bewaar

Bewaar alle medisyne buite bereik van kinders.

Bewaar by, of benede 25 °C. Moet nie vries nie. Vir enkelgebruik. Enige ongebruikte emulsie moet weggegooi word. Moet nie medisyne in afvalwater of huishoudelike afval weggooi nie. Moet nie hierdie medisyne gebruik ná die vervaldatum wat na "Exp/Verv." op die spuit en karton gedruk is nie. Die vervaldatum verwys na die laaste dag van daardie maand.

6. Inhoud van die pakkie en ander inligting

Wat PROPOFOL 1 % PS FRESENIUS bevat

- Die aktiewe bestanddeel is propofol.

Elke mL emulsie bevat 10 mg propofol.

Elke 10 mL spuit bevat 100 mg propofol.

Elke 20 mL spuit bevat 200 mg propofol.

Elke 50 mL spuit bevat 500 mg propofol.

- Die ander bestanddele is: sojaboonolie, mediumketting trigliseriede, gesuiwerde eierfosfatiede, gliserol, oleïensuur, natriumhidroksied (vir pH-instelling), water vir inspuiting.

Hoe PROPOFOL 1 % PS FRESENIUS lyk en inhoud van die pakkie

PROPOFOL 1 % PS FRESENIUS is 'n wit, homogene olie-in-water emulsie in 'n vooraf-gevulde spuit.

PROPOFOL 1 % PS FRESENIUS is beskikbaar in plastiek- en glas vooraf-gevulde spuite.

<u>Verpakkingsgroottes:</u>

Pakke met 5 vooraf-gevulde glas spuite met 10 mL emulsie

Pakke met 6 vooraf-gevulde plastiek spuite met 10 mL emulsie

Pakke met 5 vooraf-gevulde glas spuite met 20 mL emulsie

Pakke met 6 vooraf-gevulde plastiek spuite met 20 mL emulsie

Pakke met 1 vooraf-gevulde plastiek spuit met 50 mL emulsie

Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat

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Hierdie inligtingsblad is voorheen hersien op

30 Januarie 2025

Registrasienommer

49/2.1/1233

Toegang tot die ooreenstemmende Professionele Inligting

Die professionele inligting sal gedruk word en saam met die produk verpak word.