PATIENT INFORMATION LEAFLET

PROPOFOL-PF 1% 200 mg/20 ml Emulsion for I.V. Injection/Infusion

Intravenous administration.

Sterile

• ***Active substance****:* Propofol 10 mg/ml

• ***Excipients****:* Refined soybean oil, egg phospholipid, oleic acid, glycerol, sodium hydroxide, water for injection.

Read all of this PATIENT INFORMATION LEAFLET carefully before you start using this medicine because it contains important information for you.

- *Keep this **PATIENT INFORMATION LEAFLET.** You may need to read it again.*
- *If you have any additional questions, please contact your physician or pharmacist.*
- *This medicine has been prescribed personally for you. Do not pass it on to others.*
- *When you go to doctor or hospital while using this medicine, tell your doctor that you are using this medicine.*
- *Please completely follow the instructions in this information leaflet. Do not use **higher** or **lower** doses other than what is recommended to you.*

In this leaflet:

The titles are included.

1. What is *PROPOFOL-PF 1%* and what is it used for?

PROPOFOL-PF 1% is a white emulsion presented in packages containing 5 x 20 ml ampoules.

PROPOFOL-PF 1% 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)

2. What you need to know before you use *PROPOFOL-PF 1%*

Do not use *PROPOFOL-PF 1%* in the following conditions:

- If you are allergic to Propofol or any of the other ingredients of this medicine
- If you are allergic to soya or peanut
- It should not be used during pregnancy or lactation and at birth (obstetrics) (except for miscarriage).
- in patients of 1 month younger for general anaesthesia.
- in patients of 16 years of age or younger for sedation in intensive care

TAKE SPECIAL CARE with *PROPOFOL-PF 1%* in the following conditions

If:

- you have advanced heart failure and have any other serious disease of the heart
- you are receiving electroconvulsive therapy (ECT, a treatment for psychiatric problems)

The use of PROPOFOL-PF 1%is not recommended in children younger than 1 month.Special care should also be observed when administering PROPOFOL-PF 1% to children less than 3 years of age. However, evidence now available does not suggest that this is any less safe than in children older than 3 years.

The usage of sedation for children 16 years and younger can lead to serious and sometimes fatal side effects.

In general, PROPOFOL-PF 1 %, should be given with caution to elderly or weak patients. Before receiving PROPOFOL-PF 1 %, tell your anaesthetist or intensive care doctor if you have:

- Heart disease
- Lung disease
- Kidney disease
- Liver disease
- Seizures (Epilepsy)
- 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.)
- Altered levels of fat in the blood. (If you are feeding through a vein, the levels of fat in your blood must be monitored.)

If you have any of the following conditions, they must be treated before you receive PROPOFOL-PF 1 %:

- Heart failure
- When there is insufficient blood reaching the tissues (circulatory failure)
- Severe breathing problems (Respiratory Failure)
- Dehydration (Hypovolaemia)
- Seizures (Epilepsy)

PROPOFOL-PF 1 % may increase the risk of the following conditions:

- Epileptic seizures
- A nervous reflex that slows the heart rate (Vagotonia,)
- Slow heart rate (Bradycardia)
- Changes in the blood flow to the organs of the body (effects on the cardiovascular system) if you are overweight and receive high doses of Propofol.

Involuntary movements can occur during sedation with PROPOFOL-PF 1 %. The doctors will take into account how this might affect surgical procedures and will take the necessary precautions.

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-PF 1 % can be painful. A local anaesthetic can be used to reduce this pain but can have its own side effects.

You will not be allowed to leave the hospital until you are fully awake.

Please consult your doctor if these warnings are valid for you, even at any time in the past.

Using *PROPOFOL-PF 1%* with food and drink

After you have been given PROPOFOL-PF 1% , you should not consume alcohol until fully awake.

Pregnancy

Before using this medicine consult your doctor or pharmacist.

PROPOFOL-PF 1% should not be given to pregnant women unless necessary.

If you notice that you have been pregnant during treatment, consult immediately your doctor or pharmacist.

Breastfeeding

Before using this medicine consult your doctor or pharmacist.

You should stop breast-feeding and discard any breast milk for 24 hours after receiving PROPOFOL-PF 1%.

Driving and using machinery

If you are able to go home after receiving PROPOFOL-PF 1%, do not drive a car or go home unaccompanied.

Important information on some excipients present in *PROPOFOL-PF 1%*

PROPOFOL-PF 1% contains soya-bean oil.Tell your doctor if you know that you have allergic reactions to soya-bean oil or peanut.

This medicinal product contains less than 1 mmol (23 mg) sodium so it is essentially sodium-free.

Taking with other medicines

You must take special care if you are also taking/receiving any of the following medicines:

- Premedications (Your anaesthetist will know which medicines can be influenced by PROPOFOL-PF 1%)
- Other anaesthetics, including general, regional, local and inhalational anaesthetics (Lower doses of PROPOFOL-PF 1% may be required. Your anaesthetist will know this.)
- Analgesics (Painkillers)
- Muscle relaxants such as Suxamethonium
- Benzodiazepines used to treat anxiety
- Drugs that affect many of the internal body functions such as the heart rate (e.g. atropine)
- Strong painkillers such as fentanyl
- Alcohol
- Neostigmine used to treat myasthenia gravis
- Cyclosporine used to prevent transplant rejections

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

3. How to use *PROPOFOL-PF 1%* ?

Instructions for proper use and dosage/administration frequency:

Your doctor will determine the dosage of your drug depending on your illness and will apply it to you.

It will only be given to you in hospitals or suitable therapy units by or under the direct supervision of your anaesthetist or intensive care doctor.

Route and method of administration:

PROPOFOL-PF 1% 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). An infusion pump may be used to give the injection for long operations and for use in intensive care.

- **In adults:**

The dose of PROPOFOL-PF 1% you are given will vary depending on your age, body weight and physical condition or your sleep. Most people need 1.5 - 2.5 mg propofol per kg body weight to make them go to sleep (induction of anaesthesia), and then 4-12 mg propofol per kg body weight per hour after this to keep them asleep (maintenance of anaesthesia). For sedation, doses of 0.3-4.0 mg propofol per kg body weight per hour are usually sufficient.

When used for sedation, PROPOFOL-PF 1% must not be administered for more than 7 days. If you have any further information ask your doctor or pharmacist.

Different age groups:

- **Use in children:**

Usually slightly higher doses are needed to start and maintain anesthesia in children. The dose should be adjusted according to your child age and body weight.

- **In elderly:**

Elderly and weak patients may require lower doses.

Special conditions of use:

It does not have any special usage.

If you have the impression that the effect of PROPOFOL-PF 1% is too strong or weak, Added with your doctor or pharmacist.

If you receive more *PROPOFOL-PF 1%* than you should:

It is invalid.

If you receive more PROPOFOL-PF 1% than you should, tell your doctor or pharmacist.

If you miss a dose of *PROPOFOL-PF 1%*:

It is invalid.

Do not take double dose to make up the dose you have missed.

Effects that may occur if you stop taking *PROPOFOL-PF 1%*:

PROPOFOL-PF 1% will be given to you by your doctor.
Tell your doctor or pharmacist if you have any further question about the usage of PROPOFOL-PF 1%.

4. Possible side effects

Like all medicines, PROPOFOL-PF 1% may cause side effects in patients sensitive to its ingredients.

Side effects are listed as defined by following categories:
Very common: may be seen in at least one of 10 patients;
Common: may be seen in less than one of 10 patients but more than one of 100 patients;
Uncommon: may be seen in less than one of 100 patients but more than one of 1.000 patients;
Rare: may be seen less than 1 in 1,000 patients, but more than 1 in 10,000 patients.
Very rare: may be seen in at least one of 10.000 patients;
Not known: Cannot be estimated from the available data.

If any of the following reactions happen, tell your doctor immediately:

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

- A feeling of pain at the site of the injection

Common (may be seen in less than one of 10 patients but more than one of 100 patients)

- Increased blood fat level (hypertriglyceridemia)

The following side effects may occur during the initiation of anesthesia:

- Involuntary movements
- Myoclonus
- Tic (Minimal excitation)
- Low blood pressure (Hypotension)
- Low Heartbeat (Bradycardia)
- Fast Heartbeat (Tachycardia)
- Hot flush
- Increased breathing (Hyperventilation)
- Respiration of breathing (Temporary apnea)
- Hiccups, cough

Uncommon (may be seen in less than one of 100 patients but more than one of 1.000 patients*)*

- Significant decrease in blood pressure (Hypotension)
- Cough
- Slow pulse (Progressive bradycardia)

Rare(may be seen less than 1 in 1,000 patients, but more than 1 in 10,000 patients)

- Severe hypersensitivity reactions (Anaphylaxis), which can be seen with the following symptoms:
- Swelling of the face, mouth and larynx (Angioedema)
- Narrowed airways in the lung (Bronchospasm), which makes breathing difficult.
- Skin rash (Erythema)
- Low blood pressure (Hypotension)
- Headache
- Dizziness (Vertigo)
- Involuntary movements similar to epileptic seizures (epileptiform movements), including convulsions (involuntary, severe contraction in muscles) and opistotonus (contraction where legs and arms are stretched while the body and head are sliding backwards)
- Blood clot (Thrombosis)
- Inflammation in the veins (phlebitis)
- Unusual colour of urine
- Fever following surgery

The following rare symptoms may occur during the awakening period:

- Feeling good (Euphoria) and sexual disinhibition (The person's inability to show obstacle impulses in normal time)
- Chills and sensations of cold
- Irregular heart beat (Arrhythmia)
- Cough

- Nausea and vomitting
- Postoperative fever

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

- Delayed epileptiform seizures (involuntary movements similar to epileptic seizures seen after awakening)
- Convulsions in enpilepsy patients (involuntary, severe contraction in the muscles)
- Being unconscious after the anesthesia
- Fluid accumulation in the lungs (Pulmonary edema)
- Inflamed pancreas (pancreatitis)
- Severe tissue responses as a result of accidental injection to the tissue
- Rhabdomyolysis (a muscle disease)
- Change in acidity level in the blood (Metabolic acidosis)
- Increased level of potassium in the blood (Hyperkalaemia)
- Heart failure

When PROPOFOL-PF 1% is administered in combination with lidocaine ,a local anaesthetic used to reduce the pain at the site of injection, certain side effects may occur rarely:

- Dizziness
- Vomiting
- Sleepiness
- Fits
- A slowing of the heart rate (Bradycardia)
- Irregular heartbeat (Cardiac Arrhythmias)
- Shock

Tell your doctor or pharmacist if you notice any other effects not listed in this leaflet.

5. How to store *PROPOFOL-PF 1%:*

Store PROPOFOL-PF 1% in original packaging and keep out of the reach and sight of children.
Store at room temperature below 25°C, do not freeze.
After opening the product must be used immediately.

Use in compliance with the expiry date.

Do not use PROPOFOL-PF 1% after the expiry date/ Use it before the expiry date.
Do not throw away drugs that have expired or are not used! Deliver to the collection system determined by the Ministry of Environment and Urbanism.

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This patient leaflet was approved on 24.01.2020.

THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY

PROPOFOL-PF 1 % should not be mixed prior to administration with injection or infusion solutions other than 5 % glucose, 0.9 % sodium chloride 1% lidocaine injection solution. Final propofol concentration must not be below 2 mg/ml.

For single use. Any unused emulsion must be discarded.

It should be shaken before use.
If two layers can be seen after shaking the emulsion should not be used.
Use only homogeneous preparations and undamaged products.

Prior to use, the ampoule neck should be cleaned using an alcohol. After use, tapped package must be discarded.

PROPOFOL-PF 1% is administered only by anesthesiology and / or emergency medicine specialists in hospitals or appropriate treatment units.

Circulation and breathing functions should be followed (eg by ECG, pulse oximeter).
In general anaesthesia, aid equipments and resuscitation devices should keep ready.

PROPOFOL-PF 1% may be administered undiluted or diluted in 5 % glucose or 0.9 % sodium chloride solutions.

5 % glucose, 0.9 % sodium chloride or 4 % dextrose and 0.18 % sodium chloride intravenous infusion solution may be given through the same infusion set. PROPOFOL-PF 1% must not be mixed with any other solutions for infusion or injection. Co-administration of other medicinal products with PROPOFOL-PF 1% infusion line must occur close to the cannula site using a Y-piece connector.

PROPOFOL-PF 1% is a lipid containing emulsion without antimicrobial preservatives and may support rapid growth of microorganisms.

The emulsion must be drawn aseptically into a sterile syringe or giving set immediately after opening the ampoule. Administration must commence without delay.

Asepsis must be maintained for both PROPOFOL-PF 1% and the infusion equipment throughout the infusion period. PROPOFOL-PF 1% must not be administered through a microbiological filter.

Infusion of undiluted PROPOFOL-PF 1%

The use of a burette, drop counter, syringe pump or volumetric infusion pump to control the infusion rate is recommended when PROPOFOL-PF 1% is infused undiluted.

As usual for fat emulsions, the infusion of PROPOFOL-PF 1% via one infusion system must not exceed 12 hours. The infusion set for PROPOFOL-PF 1% must be changed at least every 12 hours.

Infusion of diluted PROPOFOL-PF 1%

Burettes, drop counters or volumetric infusion pumps should always be used to control infusion rates. The maximum dilution must not exceed 1 part of PROPOFOL-PF 1 % with 4 parts of 5 % glucose or 0.9 % sodium chloride solution (minimum concentration 2 mg PROPOFOL-PF 1 % per ml).
The mixture should be prepared aseptically immediately prior to administration and must be administered within 6 hours after preparation.

Muscle relaxants like atracurium and mivacurium should only be administered after flush of the same infusion site used for PROPOFOL-PF 1 % .

Lidocaine may be added to the solution (20 parts of PROPOFOL-PF 1 % with up to 1 part of 1 % lidocaine solution for injection) to reduce pain at the site of injection of PROPOFOL-PF 1 % .
Lidocaine must not be used in patients with hereditary acute porphyria.

This mixture must be administered within 6 hours after preparation.