1. **NAME OF THE MEDICINAL PRODUCT**

**Propofol-Lipuro 10 mg/ml** emulsion for injection or infusion

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**

Propofol-Lipuro 10 mg/ml contains:

- Propofol 10 mg/ml
- Lipid

- Lipid injection 10 mg/ml contains:
  - Monoolein 3.7 mg/ml
  - Stearoyl-L-α-Phosphatidylcholine 1.8 mg/ml

- Lipid injection 50 mg/ml contains:
  - Monoolein 18.5 mg/ml
  - Stearoyl-L-α-Phosphatidylcholine 9.2 mg/ml

3. **PHARMACOLOGICAL PROPERTIES**

3.1. **Therapeutic indications**

- Propofol-Lipuro 10 mg/ml emulsion for injection or infusion is used for:
  - Induction of anaesthesia
  - Maintenance of general anaesthesia
  - Sedation during operative procedures
  - Sedation in patients in intensive care

3.1.1. **Dosages and administration method for induction of anaesthesia**

- Patient older than 55 years and in patients of ASA grades II, III, IV, or V:
  - Dosage: 1 mg/kg body weight
  - Administration: by rapid infusion

- Adults and children > 1 month:
  - Dosage: 1 mg/kg body weight
  - Administration: by rapid infusion

3.1.2. **Dosages and administration method for maintenance of general anaesthesia**

- Patients over 8 years of age:
  - Dosage: 20 – 40 mg of propofol every 10 minutes
  - Administration: by infusion

- Children under 8 years:
  - Dosage: 40 – 60 mg of propofol every 10 minutes
  - Administration: by infusion

3.2. **Pharmacokinetics**

- Absorption: rapid absorption
- Distribution: rapid distribution
- Metabolism: rapid metabolism
- Excretion: rapid excretion

3.3. **Pharmacodynamics**

- Onset of anaesthesia: within 10 seconds
- Duration of anaesthesia: 5 – 10 minutes

4. **PHARMACOLOGICAL INCOMPATIBILITY**

- Any solutions containing chlorhexidine or benzalkonium chloride delivered concurrently, a reduction in quantity should be made because these solutions are incompatible with propofol.

5. **PHARMACOLOGICAL INTERACTIONS**

- No significant pharmacological interactions are known.

6. **CLINICAL PARTICULARS**

6.1. **Contraindications**

- Contraindicated in patients who are hypersensitive to any component in the formulation.

6.2. **Precautions for use**

- Patients with a history of epilepsy or a risk of seizures may be at increased risk of developing a seizure.

6.3. **Special warnings and precautions for use**

- Patients should be observed closely for signs of sensitivity to the propofol injection.

7. **OVERDOSAGE**

- Overdosage may result in a fatal respiratory depression.

8. **PACKAGING AND STORING**

- Propofol-Lipuro 10 mg/ml contains no antimicrobial preservatives.

9. **REPLACEMENT OF LOST LABELS**

- If labels are lost, a new carton of Propofol-Lipuro 10 mg/ml should be obtained.

10. **TEXTBOOK OF MEDICINE**

- This product should be used under medical supervision.

11. **SUMMARY OF PRODUCT CHARACTERISTICS**

- This product should be used under medical supervision.

12. **TERMS OF SUPPLY AND STORAGE**

- This product should be used under medical supervision.

13. **WHOLESALE AND RETAIL PACKAGING**

- This product should be used under medical supervision.

14. **COMPATIBILITY**

- This product should be used under medical supervision.
### Table of Adverse Drug Reactions

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Adverse Drug Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very common (≥ 1/10)</td>
<td>Bradycardia (1), Hypotension (1), Nausea (1), Rigors (1), Tissue necrosis (10)</td>
</tr>
<tr>
<td>Common (≥ 1/100 to &lt; 1/10)</td>
<td>Bradycardia (1), Hypotension (1), Nausea (1), Rigors (1), Tissue necrosis (10)</td>
</tr>
<tr>
<td>Rare (≥ 1/1,000 to &lt; 1/100)</td>
<td>Bradycardia (1), Hypotension (1), Nausea (1), Rigors (1), Tissue necrosis (10)</td>
</tr>
<tr>
<td>Very rare (&lt; 1/1,000)</td>
<td>Bradycardia (1), Hypotension (1), Nausea (1), Rigors (1), Tissue necrosis (10)</td>
</tr>
</tbody>
</table>

### 4.8 Undesirable effects

1. **Bradycardia and hypotension** occasionally occur during the administration of propofol. These effects are pharmacologically predictable side effects of an anesthetic/sedative agent, such as hypotension. These effects usually do not persist beyond 12 hours (please see section 4.4).

2. **Respiratory depression** should be treated by artificial ventilation."