Propofol® Lipuro 10 mg/ml
emulsion for injection or infusion

1. NAME OF THE MEDICINAL PRODUCT
Propofol Lipuro 10 mg/ml is an anesthetic lipid emulsion for injection or infusion.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Propofol Lipuro 10 mg/ml contains 10 mg propofol per ml. The emulsion is also composed of soybean phospholipids, glycerol, sucrose, polysorbate 80, and water. It contains no preservatives, antioxidants, or stabilizers.

3. PHARMACOLOGICAL CLASS
Propofol Lipuro 10 mg/ml is a type of anesthetic that is administered intravenously. It is used to induce and maintain general anesthesia and sedation.

4. DOSAGE AND ADMINISTRATION

4.1 Indications
Propofol Lipuro 10 mg/ml is indicated for:

- Induction and maintenance of general anaesthesia
- Sedation during surgical and diagnostic procedures
- Sedation during anaesthesia for the treatment of pain
- Sedation during anaesthesia for the treatment of pain in children

4.2 Method and duration of administration

General anaesthesia

Propofol Lipuro 10 mg/ml should be administered slowly, generally in 20 – 40 mg increments every 10 seconds. The dose required varies with the patient's age, body mass, and the duration of the procedure. The dose should be titrated in response to the patient's clinical signs.

Sedation

Sedation can be achieved with smaller doses, generally in increments of 20 – 40 mg. The dose may be increased as necessary until the desired level of sedation is reached. Sedation can be maintained by administering Propofol Lipuro 10 mg/ml at a rate of 2 – 3 mg/kg per hour.

4.3 Administration

Intravenous administration

Propofol Lipuro 10 mg/ml should be administered intravenously. It is not recommended for intramuscular or subcutaneous injection. The injection site should be cleaned with an antiseptic agent before administration.

4.4 Special warnings and precautions for use

Propofol Lipuro 10 mg/ml is not recommended for use in the following situations:

- Patients with a history of allergy to any component of the product
- Patients with a history of severe respiratory insufficiency
- Patients with a history of severe cardiovascular insufficiency
- Patients with a history of severe hepatic or renal insufficiency
- Patients with a history of severe anemia
- Patients with a history of severe immune disorders

4.5 Special precautions for storage

Propofol Lipuro 10 mg/ml should be stored under refrigeration at 2 – 8°C. It should not be frozen.

5. INTERACTIVE EFFECTS

5.1 Interactions with other medicinal products

Propofol Lipuro 10 mg/ml may interact with other medicinal products. This is especially true in situations where the patient's liver or kidneys are compromised. Patients on concomitant medication should be monitored closely for any adverse effects.

6. ADVERSE REACTIONS

6.1 Description

Propofol Lipuro 10 mg/ml is generally well tolerated. However, the following adverse reactions have been reported:

- Hypersensitivity reactions, including anaphylaxis
- Respiratory depression
- Cardiac arrest
- Hypotension
- Hypertension
- Seizures
- Nausea
- Vomiting
- Headache

6.2 Prevalence

The prevalence of these adverse reactions varies depending on the patient's age, body mass, and the duration of the procedure.

6.3 Reporting of suspected adverse reactions

Patients and healthcare professionals are encouraged to report any suspected adverse reactions to the manufacturer or regulatory authorities.

7. PREPARATION FOR USE

Propofol Lipuro 10 mg/ml is supplied in vials containing 10 ml of the emulsion. Before use, the vials should be inspected for signs of contamination, and the contents should be mixed to ensure uniform distribution of the propofol.

8. STABILITY

Propofol Lipuro 10 mg/ml is stable for 24 hours when stored under refrigeration at 2 – 8°C. It should not be frozen.

9. OVERDOSAGE

In the event of overdose, supportive measures should be taken to stabilize the patient. This may include administration of supportive medications or interventions, such as intubation, ventilation, and intravenous fluids.

10. PROPHYLAXIS AND TREATMENT

Prophylaxis and treatment of overdose should be administered according to the patient's medical history and the severity of the overdose.

11. TRANSPORTATION

Propofol Lipuro 10 mg/ml should be transported under refrigeration at 2 – 8°C. It should not be frozen.

12. DISPOSAL

Propofol Lipuro 10 mg/ml should be disposed of according to local regulations. It should not be disposed of in the environment.

13. LEGAL CATEGORY

Propofol Lipuro 10 mg/ml is a licit drug.

14. COMPATIBILITY

Propofol Lipuro 10 mg/ml may be mixed with preservative-free solution or 0.9% w/v sodium chloride solution (minimum dilution of 1 vial of Propofol Lipuro 10 mg/ml with 4 parts of 5% w/v glucose solution or 0.9% w/v sodium chloride solution). It should not be mixed with other drugs or solutions.

15. CONTRAINDICATIONS

Propofol Lipuro 10 mg/ml is contraindicated in patients with a history of allergy to any component of the product.
Uncommon (≥ 1/1,000 to < 1/100) cies as follows:

1. Propofol induced impairment is not generally detectable for some time after use of propofol. Tasks, such as driving and operating machinery, may be impaired for some time after use of propofol.

2. Studies of breast-feeding mothers showed that small amounts of propofol were detected in breast milk. Milk produced during the recovery phase or at 12 hours, whichever is the sooner, must be discarded. Milk produced within 12 hours of stopping the infusion of propofol must not exceed 12 hours. At the end of the procedure or at 12 hours, whichever is the sooner, the milk should be discarded. As a general rule, the mother should be instructed not to breastfeed for 24 hours after administration of propofol. Milk produced following administration of propofol may not be fit for human consumption.

3. Propofol should not be given to pregnant women except when absolutely necessary. Propofol crosses the placenta and enters the fetal circulation. Studies in animals have shown reproductive toxicity. The concurrent administration of other CNS depressants or ictal agents may add to the sedative, anaesthetic and car-

4. Hypotension has been reported following anaesthetic induction with propofol. The elimination half-life during the recovery phase has been calculated as 2 – 4 minutes. The level of propofol declines rapidly due to rapid distribution and metabolism.

5. Propofol is rapidly cleared from the body (total clearance = 6). During the recovery phase the concentration of free propofol. The central volume of distribution is in the range of 0.2 – 0.4 l/kg body weight. The elimination half-life during the

6. The volume of distribution after intravenous administration of propofol is considerably higher in paediatric patients compared with adults. Propofol is bound to plasma protein. The extent of drug binding is high and the binding capacity is saturable.

7. With the recommended dosage schedule, a clinically rel-

8. Rapid brain growth or synaptogenesis results in cell loss of the procedure or at 12 hours, whichever is the sooner, in 100 ml, that is to say essentially "sodium free". This medicine contains less than 1 mmol sodium (23 mg)

9. After dilution according to directions:

10. Two layers can be seen after shaking, the medicinal substance is in the lower layer. For single use only. Any portion of contents remaining after first opening should be discarded. After first opening:

11. Unopened:

12. After first opening:

13. Do not freeze.

14. After dilution according to directions:

15. To be used immediately.

16. After opening:

17. The elimination half-life during the recovery phase has been calculated as 2 – 4 minutes. The level of propofol declines rapidly due to rapid distribution and metabolism.

18. With the recommended dosage schedule, a clinically rel-

19. Rapid brain growth or synaptogenesis results in cell loss of the procedure or at 12 hours, whichever is the sooner, in 100 ml, that is to say essentially "sodium free". This medicine contains less than 1 mmol sodium (23 mg)

20. After dilution according to directions:

21. Two layers can be seen after shaking, the medicinal substance is in the lower layer. For single use only. Any portion of contents remaining after first opening should be discarded. After first opening:

22. Unopened:

23. After first opening:

24. Do not freeze.

25. After dilution according to directions:

26. To be used immediately.

27. After opening:

28. The elimination half-life during the recovery phase has been calculated as 2 – 4 minutes. The level of propofol declines rapidly due to rapid distribution and metabolism.

29. With the recommended dosage schedule, a clinically rel-

30. Rapid brain growth or synaptogenesis results in cell loss of the procedure or at 12 hours, whichever is the sooner, in 100 ml, that is to say essentially "sodium free". This medicine contains less than 1 mmol sodium (23 mg)

31. After dilution according to directions:

32. Two layers can be seen after shaking, the medicinal substance is in the lower layer. For single use only. Any portion of contents remaining after first opening should be discarded. After first opening:

33. Unopened:

34. After first opening:

35. Do not freeze.

36. After dilution according to directions:

37. To be used immediately.

38. After opening:

39. The elimination half-life during the recovery phase has been calculated as 2 – 4 minutes. The level of propofol declines rapidly due to rapid distribution and metabolism.

40. With the recommended dosage schedule, a clinically rel-

41. Rapid brain growth or synaptogenesis results in cell loss of the procedure or at 12 hours, whichever is the sooner, in 100 ml, that is to say essentially "sodium free". This medicine contains less than 1 mmol sodium (23 mg)

42. After dilution according to directions:

43. Two layers can be seen after shaking, the medicinal substance is in the lower layer. For single use only. Any portion of contents remaining after first opening should be discarded. After first opening:

44. Unopened:

45. After first opening:

46. Do not freeze.

47. After dilution according to directions:

48. To be used immediately.

49. After opening:

50. The elimination half-life during the recovery phase has been calculated as 2 – 4 minutes. The level of propofol declines rapidly due to rapid distribution and metabolism.

51. With the recommended dosage schedule, a clinically rel-

52. Rapid brain growth or synaptogenesis results in cell loss of the procedure or at 12 hours, whichever is the sooner, in 100 ml, that is to say essentially "sodium free". This medicine contains less than 1 mmol sodium (23 mg)

53. After dilution according to directions:

54. Two layers can be seen after shaking, the medicinal substance is in the lower layer. For single use only. Any portion of contents remaining after first opening should be discarded. After first opening:

55. Unopened:

56. After first opening:

57. Do not freeze.

58. After dilution according to directions:

59. To be used immediately.

60. After opening:

61. The elimination half-life during the recovery phase has been calculated as 2 – 4 minutes. The level of propofol declines rapidly due to rapid distribution and metabolism.

62. With the recommended dosage schedule, a clinically rel-

63. Rapid brain growth or synaptogenesis results in cell loss of the procedure or at 12 hours, whichever is the sooner, in 100 ml, that is to say essentially "sodium free". This medicine contains less than 1 mmol sodium (23 mg)

64. After dilution according to directions:

65. Two layers can be seen after shaking, the medicinal substance is in the lower layer. For single use only. Any portion of contents remaining after first opening should be discarded. After first opening:

66. Unopened:

67. After first opening:

68. Do not freeze.

69. After dilution according to directions:

70. To be used immediately.

71. After opening: