

## Data Sheet

# Ivelip<sup>®</sup> 10% and Ivelip<sup>®</sup> 20%

*Lipid emulsion for intravenous infusion*

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## Trade Name of the Medicinal Product

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IVELIP 10% and IVELIP 20%

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## Qualitative and Quantitative Composition

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	Ivelip 10%	Ivelip 20%
Purified soybean oil	10.00 g	20.00 g
Purified egg phosphatides	1.20 g	1.20 g
Glycerol	2.50 g	2.50 g
Sodium oleate	0.03 g	0.03 g
Sodium hydroxide	pH=7 to 9	
Water for injectable preparation	q.s 100 ml	
Osmolarity of dispersing phase (approx)	310 mOsm/l	360 mOsm/l
Energy content (approx.)	1100 kcal/l	2000 kcal/l

1 g of lipids = 10 ml = 200 drops of IVELIP 10%

1 g of lipids = 5 ml = 100 drops of IVELIP20%

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## Pharmaceutical Form

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Lipid emulsion for intravenous infusion.

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## Clinical Particulars

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### *Therapeutic indications*

Source of energy and essential fatty acids for patients requiring parenteral nutrition when oral or enteral alimentation is impossible, insufficient or contra-indicated.

## ***Posology and method of administration***

**IV:** the infusion should be slow and progressive

### **Dosage**

Adult patients: 1 to 3 g of lipids/kg/24 hours

Paediatric patients: 0.5 to 4 g of lipids/kg/24 hours

### ***Adult patients***

*Rate of administration:*

Ivelip 10%: 10 to 20 drops/min for the first 10 minutes  
30 to 40 drops/min for the first 20 minutes  
40 to 60 drops/min next.

Ivelip 20%: 5 to 10 drops/min for the first 10 minutes  
20 to 30 drops/min for the first 20 minutes  
30 to 40 drops/min next.

Do not administer 500 ml under 4 hours.

Do not exceed 0.4 g of lipids/kg/hour.

### ***Children***

*Rate of administration:*

Ivelip 10%: 2 drops per minute for the first 15 minutes, then progressively increase.

Ivelip 20%: 1 drop per minute for the first 15 minutes, then progressively increase.

Do not exceed 0.25 g of lipids/kg/hour.

### ***In small for gestational age or premature infants***

Dosage is identical to that for children.

A weaker dosage should be considered to start the treatment.

The dose will be progressively increased according to the clinical tolerance and injected lipid clearance capacities which should be checked daily.

*Rate of administration*

Infusion duration: The infusion should be administered in a continuous manner for 24 hours for gestational age infants under 32 weeks. Over 32 weeks, continuous or discontinuous administration could be used.

### **Use in mixtures**

IVELIP 10 % and IVELIP 20% may be included in the composition of nutritive mixtures combining glucids, amino acids, electrolytes, trace elements, when compatibility and stability are known.

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## **Contra-indications**

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- hyperlipaedemia
- hyperlipaedemia associated with nephrosis syndrome
- hyperlipaedemia associated with acute pancreatic
- severe hepatic insufficiency
- known allergy to egg phosphatides or soy protein

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## **Precautions for use**

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For new born or premature infants with impaired capacity to metabolise fat: the plasmatic clearance of injected lipids is often reduced and accumulation of lipids in pulmonary arteries has been described with some lipidic emulsions. To overcome this risk, it is recommended to respect the route of administration (see Posology), to be assured of plasma clarification before each administration and to practise a daily dosage of serum triglycerides.

For new born infant with neonatal icterus: lipid emulsion must be used carefully because of the moving risk by fatty acids of bilirubin fixed on albumin.

The rate of blood platelet will be daily monitored during the neonatal period and within regular intervals in case of long term administration of IVELIP® 10 % to the child.

Any open bottle should be used immediately and in no case conserved for future use.

### ***Interaction with other medicaments and other forms of interaction***

Any addition of medicines to an IVELIP bottle is strictly warned against.

## ***Effects on ability to drive and to use machines***

Not applicable.

## ***Adverse effects***

As with any lipid emulsion, in exceptional circumstances IVELIP administration could provide acute reactions: hyperthermia, sweating, rigor, headache, dyspnoea. Should such reactions occur the IVELIP infusion should immediately discontinued.

During very long term administration (6 to 8 weeks or more) of lipid emulsions, transient increases of alkaline phosphatases of transaminases and of bilirubin have been noted. Generally, these phenomena return to normal after a reduction in dosage. In unusual cases, hepatomegaly and icterus are observed.

In exceptional cases, severe thrombopenias have been observed with children. In these cases the treatment must be stopped.

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## **Pharmacological Properties**

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### ***Pharmacodynamic properties***

IVELIP is a lipid emulsion providing:

- lipidic calories
- essential fatty acids

Egg phosphatides supply phosphorus (12.6 mmol/l or 400 mg/l) and choline (1.44 g/l). The quantities must be augmented in some cases.

The size of the IVELIP® lipidic globules is similar to that of the natural chylomicrons in serum after a meal.

### ***Pharmacokinetic properties***

The size of the IVELIP lipidic globules is similar to that of chylomicrons; their elimination kinetic is identical.

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## **Pharmaceutical Particulars**

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### **List of excipients**

Egg phosphatides

Glycerol

Sodium oleate

Sodium hydroxide

Water for Injections.

### **Incompatibilities**

The compatibility and stability of nutritive mixtures should be confirmed before administration.

### **Shelf life**

18 months.

### **Special precautions for storage**

Storage temperature should not exceed 25°C.

Protect emulsions from freezing.

### **Nature and contents of container**

#### **Ivelip 10%**

100 ml in glass bottle

500 ml in glass bottle

#### **Ivelip 20%**

100 ml in glass bottle

250 ml in glass bottle

500 ml in glass bottle

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## **Medicine Classification**

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General Sales Medicine

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## **Name and Address**

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Baxter Healthcare Ltd  
33 Vestey Drive

Mt. Wellington  
Auckland

Ph: 09 574 2400

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## **Data of Preparation**

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30 December 2001