# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Maxivalen 200 mg/ml emulsion for infusion

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Maxivalen contains:

| | Contents per 1000 ml |
|---|---|
| Refined soya-bean oil | 60 g |
| Medium-chain triglycerides | 60 g |
| Refined olive oil | 50 g |
| Fish oil, rich in omega-3-acids | 30 g |
| Energy: | 2000 kcal |

Excipient with known effect:

1000 ml of Maxivalen contains 2.2 mmol (or 50.2 mg) sodium.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Emulsion for infusion.

White homogenous emulsion.

pH-value: 6.5-9.0

Osmolality: 360-480 mosm/kg

## 4 CLINICAL PARTICULARS

## 4.1 Therapeutic indications

Supply of energy and essential fatty acids and omega-3 fatty acids to patients, as part of a parenteral nutrition regimen, when oral or enteral nutrition is impossible, insufficient or contraindicated.

## 4.2 Posology and method of administration

Posology

The patient's ability to eliminate the fat infused, should govern the dose and infusion rate, see section 4.4.

*Adults*

The standard dose is 1.0-2.0 g fat/kg body weight (b.w.)/day, corresponding to 5-10 ml/kg b.w./day.

The recommended infusion rate is 0.125 g fat/kg b.w./hour, corresponding to 0.63 ml Maxivalen/kg b.w./hour, and should not exceed 0.15 g fat/kg b.w./hour, corresponding to 0.75 ml Maxivalen/kg b.w./hour.

*Paediatric population*

*Neonates and infants*

The initial dose should be 0.5-1.0 g fat/kg b.w./day followed by a successive increase by 0.5-1.0 g fat/kg b.w./day up to 3.0 g fat/kg b.w./day.

It is recommended not to exceed a daily dose of 3 g fat/kg b.w./d, corresponding to 15 ml Maxivalen/kg b.w./day.

The rate of infusion should not exceed 0.125 g fat/kg b.w./hour.

In premature and low birthweight neonates, Maxivalen should be infused continuously over about 24 hours.

Children

It is recommended not to exceed a daily dose of 3 g fat/kg b.w./d, corresponding to 15 ml Maxivalen/kg b.w./day.

The daily dose should be increased gradually during the first week of administration. The infusion rate should not exceed 0.15 g fat/kg b.w./hour.

Method of administration

Intravenous infusion into a peripheral or central vein.

When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed (see section 4.4, 6.3 and 6.6).

## 4.3 Contraindications

- Hypersensitivity to fish-, egg-, soya- or peanut protein, to any of the active substances or to any of the excipients listed in section 6.1.
- Severe hyperlipidemia.
- Severe liver insufficiency.
- Severe blood coagulation disorders.
- Severe renal insufficiency without access to hemofiltration or dialysis.
- Acute shock.
- General contraindications to infusion therapy: acute pulmonary oedema, hyperhydration, decompensated cardiac insufficiency.
- Unstable conditions (e.g. severe post-traumatic conditions, uncompensated diabetes mellitus, acute myocardial infarction, stroke, embolism, metabolic acidosis, severe sepsis and hypotonic dehydration).

## 4.4 Special warnings and precautions for use

The capacity to eliminate fat is individual and should therefore be monitored according to the routines of the clinician. This is in general done by checking the triglyceride levels. Special caution should be taken in patients with a marked risk for hyperlipidema (e.g. patients with high lipid dose, severe sepsis and extremely low birth weight infants). The concentration of triglycerides in serum should in general not exceed 3 mmol/l during infusion. Reduction of the dose or cessation of the lipid emulsion should be considered if serum or plasma triglyceride concentrations during or after infusion exceed 3 mmol/l.

An overdose may lead to fat overload syndrome, see section 4.8.

This medicinal product contains soya-bean oil, fish oil and egg phospholipids, which may rarely cause allergic reactions. Cross allergic reaction has been observed between soya-bean and peanut.

Lipid emulsions should be given with caution in conditions of impaired lipid metabolism, which may occur in patients with renal failure, diabetes mellitus, pancreatitis, impaired liver function, hypothyroidism, and sepsis.

Clinical data in patients with diabetes mellitus or renal failure are limited.

Administration of medium-chain fatty acids alone can result in metabolic acidosis. This risk is to a great extent eliminated by the simultaneous infusion of the long chain fatty acids included in Maxivalen. Concomitant administration of carbohydrates will further eliminate this risk.

Hence, simultaneous infusion of carbohydrate or a carbohydrate-containing amino acid solution is recommended. Laboratory test generally associated with monitoring of intravenous nutrition should be checked regularly. These include blood glucose levels, liver functions tests, acid base metabolism, fluid balance, full blood count and electrolytes.

Any sign or symptom of anaphylactic reaction (such as fever, shivering, rash or dyspnoea) should lead to immediate interruption of the infusion.

Lipid emulsions should be given with caution to neonates and premature neonates with hyperbilirubinemia and cases with pulmonary hypertension. In neonates, particularly premature neonates on long term parenteral nutrition, blood platelet counts, liver function tests and serum triglycerides should be monitored.

Light exposure of solutions for intravenous parenteral nutrition, especially after admixture with vitamins, may have adverse effects on clinical outcome in neonates, due to generation of peroxides and other degradation products. When used in neonates and children below 2 years, lipid solutions should be protected from ambient light until administration is completed (see section 4.2, 6.3 and 6.6).

High levels of lipids in plasma may interfere with some laboratory blood tests, e.g. haemoglobin.

**100 ml, 250 ml bags**:

This medicinal product contains less than 1 mmol sodium (23 mg) per bag, that is to say essentially ‘sodium free’.

**500 ml bag**:

This medicinal product contains 25.1 mg sodium per bag, equivalent to 1.3% of the WHO

recommended maximum daily intake of 2 g sodium for an adult.

The addition of other medicinal products or substances to lipid emulsions should generally be avoided unless compatibility is known (see 6.2 and 6.6).

## 4.5 Interaction with other medicinal products and other forms of interaction

Heparin given in clinical doses causes a transient increase in lipoprotein lipase release into the circulation. This may initially result in increased plasma lipolysis, followed by a transient decrease in triglyceride clearance.

Soya-bean oil has a natural content of vitamin $K_1$. The content is however so low in Maxivalen that it is not expected to significantly influence the coagulation process in patients treated with coumarin derivatives.

## 4.6 Fertility, pregnancy and lactation

There are no data available on exposure of lipid emulsions in pregnant or breast-feeding women. There are no studies available on reproductive toxicity in animals. Parenteral nutrition may become necessary during pregnancy and lactation. Lipid emulsions should only be given to pregnant and breast-feeding women after careful consideration.

## 4.7 Effects on ability to drive and use machines

Not relevant.

## 4.8 Undesirable effects

Undesirable effects observed during the administration of fat emulsions:

| | *Common (≥1/100 to <1/10)* | *Uncommon (≥1/1000 to <1/100)* | *Rare (≥1/10,000 to <1/1000)* | *Very rare (<1/10,000)* |
|---|---|---|---|---|
| *Vascular disorders* | | | Hypotension, hypertension | |
| *Respiratory, thoriacic and mediastinal disorders* | | | Dyspnoea | |
| *Gastrointestinal disorders* | | Lack of appetite, nausea, vomiting | | |

| | *Common (≥1/100 to <1/10)* | *Uncommon (≥1/1000 to <1/100)* | *Rare (≥1/10,000 to <1/1000)* | *Very rare (<1/10,000)* |
|---|---|---|---|---|
| *Reproductive system and breast disorders* | | | | Priapism |
| *General disorders and administration site conditions* | Slight increase in body temperature | Chills | Hypersensitivity-reactions (e.g. anaphylactic or anaphylactoid reactions, skin rash, urticaria, flush, headache), heat or cold sensation, paleness, cyanosis, pain in the neck, back, bones, chest and loins | |

Should these side-effects occur or should the triglyceride level during infusion rise above 3 mmol/l, the infusion of Maxivalen should be stopped or, if necessary, continued at a reduced dose.

Maxivalen should always be a part of a complete parenteral nutritional treatment including amino acids and glucose. Nausea, vomiting and hyperglycemia are symptoms related to conditions indicating parenteral nutrition and may sometimes be associated with parenteral nutrition.

Monitoring of triglycerides and blood glucose levels are recommended to avoid elevated levels, which may be harmful.

Fat overload syndrome

Impaired capacity to eliminate triglycerides can lead to “Fat overload syndrome” which may be caused by overdose. Possible signs of metabolic overload must be observed. The cause may be genetic (individually different metabolism) or the fat metabolism may be affected by ongoing or previous illnesses. This syndrome may also appear during severe hypertriglyceridemia, even at the recommended infusion rate, and in association with a sudden change in the patient’s clinical condition, such as renal function impairment or infection. The fat overload syndrome is characterised by hyperlipemia, fever, fat infiltration, hepatomegaly with or without icterus, splenomegaly, anaemia, leukopenia, thrombocytopenia, coagulation disorder, hemolysis and reticulocytosis, abnormal liver function tests and coma. The symptoms are usually reversible if the infusion of the fat emulsion is discontinued.

Should signs of a fat overload syndrome occur, the infusion of Maxivalen should be discontinued.

**Reporting of suspected adverse reactions**
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme, Website:
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

### 4.9 Overdose

Overdose leading to fat overload syndrome may occur as a result of a too rapid infusion rate, or chronically at recommended rates of infusion in association with a change in the patients clinical conditions e.g. renal function impairment or infection. Overdose may lead to side-effects (see section 4.8). In these cases the lipid infusion should be stopped or, if necessary, continued at a reduced dose.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Blood substitutes and perfusion solutions, solutions for parenteral nutrition

ATC-code: B05BA02

The fat emulsion has a particle size and biological properties similar to those of endogenous chylomicrons. The constituents of Maxivalen; soya-bean oil, medium-chain triglycerides, olive oil and fish oil have except for their energy contents, their own pharmacodynamic properties.

Soya-bean oil has a high content of essential fatty acids. The omega-6 fatty acid linoleic acid is the most abundant (approx. 55-60%). Alpha-linolenic acid, an omega-3 fatty acid, constitutes about 8 %. This part of Maxivalen provides the necessary amount of essential fatty acids.

Medium-chain fatty acids are rapidly oxidised and provide the body with a form of immediately available energy.

Olive oil mainly provides energy in the form of mono-unsaturated fatty acids, which are much less prone to peroxidation than the corresponding amount of poly-unsaturated fatty acids.

Fish oil is characterised by a high content of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). DHA is an important structural component of cell membranes, whereas EPA is a precursor of eicosanoids as prostaglandines, tromboxanes and leucotrienes.

Vitamin E protects unsaturated fatty acids against lipid peroxidation.

Two studies providing home parenteral nutrition in patients in need of long-term nutrition support have been performed. The primary objective in both studies was to show safety. Efficacy was the secondary objective in one of the studies, which was done in paediatric patients. This study was stratified by age groups (1 month - <2 years, and 2-11 years respectively). Both studies showed same safety profile as the comparator (Intralipid 20%). Efficacy in the paediatric study was measured by weight gain, height, body mass index, pre-albumin, retinol binding protein and fatty acid profile. There was no difference between the groups in any of the parameters except the fatty acid profile after 4 weeks treatment. The fatty acid profile in the patients administrated with lipid emulsion revealed an increase in omega-3 fatty acids in plasma lipoproteins and red blood cells phospholipids and hence reflects the composition of the infused lipid emulsion.

## 5.2 Pharmacokinetic properties

The individual triglycerides have different clearance rate but lipid emulsion as a mixture is eliminated faster than long chain triglycerides (LCT) with lower triglyceride levels during infusion. Olive oil has the slowest clearance rate of the components (somewhat slower than LCT) and medium chain triglycerides (MCT) the fastest. Fish oil in a mixture with LCT has the same clearance rate as LCT alone.

## 5.3 Preclinical safety data

In pre-clinical studies no other effects than those expected after high doses of lipids were observed, based on single dose and repeat dose toxicity and genotoxicity studies performed with lipid emulsions. In a local tolerance study in rabbits a slight, transient inflammation after intra-arterial, paravenous or subcutaneous administration was observed. After intra-muscular administration a moderate transient inflammation and tissue necrosis were seen in some animals.

In a test in guinea pigs (Maximisation test) fish oil showed moderate dermal sensitisation. A systemic antigenicity test gave no indication of evidence of anaphylactic potential of fish oil.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Glycerol

Egg phospholipids

all-*rac*-α-Tocopherol

Water for injections

Sodium hydroxide (for pH adjustment)

Sodium oleate

## 6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

## 6.3 Shelf life

2 years

Shelf life after first opening the container

Use immediately.

When used in neonates and children below 2 years, the solution (in bags and administration sets) should be protected from light exposure until administration is completed (see section 4.2, 4.4 and 6.6).

## 6.4 Special precautions for storage

This medicinal product does not require any special temperature storage conditions. Do not freeze.

Store in the overpouch.

Storage after mixing

From a microbiological point of view if additions are made to Maxivalen, the admixtures should be used immediately. If admixtures are not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C, unless additions have taken place in controlled and validated aseptic conditions.

## 6.5 Nature and contents of container

The container consists of an inner bag (primary package) with an overpouch. An oxygen absorber is placed between the inner bag and the overpouch.

- The inner bag is made of a multilayer polymer film.
- The inner bag film consists of polypropylenepolymer. The infusion and additive ports are made of polypropylene.
- The oxygen barrier overpouch consists of polypropylene.
- The oxygen absorber consists of iron powder in a polymer sachet.

The overpouch and the oxygen absorber should be discarded after opening of the overpouch.

Pack sizes:

1 bag x 100 ml, 10 bags x 100 ml

1 bag x 250 ml, 10 bags x 250 ml

1 bag x 500 ml, 12 bags x 500 ml

Not all pack sizes may be marketed.

## 6.6 Special precautions for disposal

Use only if the emulsion is homogeneous.

Inspect the emulsion visually for phase separation prior to administration. Ensure that the final emulsion for infusion does not show any evidence of phase separation.

When used in neonates and children below 2 years, protect from light exposure, until administration is completed. Exposure of Maxivalen to ambient light, especially after admixture with vitamins, generates peroxides and other degradation products that can be reduced by protection from light exposure (see section 4.2, 4.4 and 6.3).

For single use only. Any unused emulsion should be discarded.

Additives

Maxivalen may be aseptically admixed with amino acid, glucose, and electrolyte solutions.

Compatibility for different additives and the storage time of the different admixtures will be available upon request from the marketing authorisation holder.

Additions should be made aseptically.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## 7 MARKETING AUTHORISATION HOLDER

DEMO PHARMA UK LIMITED

2nd Floor Connect 38,

1 Dover Place, Ashford,

Kent, TN23 1FB,

England

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 55035/0036

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14/04/2026

## 10 DATE OF REVISION OF THE TEXT

14/04/2026