Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Minadex Tonic Oral Emulsion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Vitamin A (Retinol)	0.433	mg (650 I.U.)
Colecalciferol	0.065	mg (65 I.U.)
Iron (as Green Ferric Ammonium Citrate)	12.000	mg
Potassium Glycerophosphate solution	2.250	mg
Calcium glycerophosphate	11.250	mg
Manganese Sulphate.	0.380	mg
Copper Sulphate, pentahydrate	0.500	mg

Excipients: each 5ml also contains:

Glucose	0.655	g
Sucrose	2.8417	g
Soya Bean Oil	36.5	mg
Sodium Methyl Parahydroxybenzoate	10.0	mg
Sodium Metasulphite	10.0	mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral emulsion.
Yellowish to green translucent oral emulsion with an odour and taste of orange.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a treatment for vitamin and mineral deficiency and as an appetite stimulant during and after illness.

4.2 Posology and method of administration

Method of administration: Oral

Dosage:

Children 6 months to 3 years:	5 ml (1 teaspoonful) twice daily
Children 3 years to 12 years:	5 ml (1 teaspoonful) three times daily
Adults:	10 ml (2 teaspoonsful) three times daily
Elderly Patients:	10 ml (2 teaspoonsful) three times daily

4.3 Contraindications

Use in patients hypersensitive to any of the constituents

4.4 Special warnings and precautions for use

1. Minadex contains ferric ammonium citrate which may stain teeth

2. The stated dose should not be exceeded

3. No other medicine containing iron or vitamins A and D should be taken without prior medical consultation

4. This product contains glucose. Patients with rare glucose-galactose malabsorption should not take this medicine. This product also contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

5. This product contains sodium metabisulphite which may rarely cause severe hypersensitivity reactions and bronchospasms.

6. This product contains soya bean oil. If you are allergic to peanut or soya, so not use this product.

Prolonged excessive ingestion of vitamin D can lead to hypervitaminoses states which may occur if foods high in vitamin (for example liver), are ingested in association with recommended doses of this product.

This product contains sodium methyl parahydroxybenzoate (E219) which may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

No data available

4.6 Fertility, pregnancy and lactation

Safety in human pregnancy has not been established. It is not advisable to administer Minadex in pregnancy or to women breast-feeding infants.

Large doses of vitamin A have been found to be teratogenic if administered during the first trimester of pregnancy. Minadex syrup should not be taken in the first 13 weeks of pregnancy. If iron containing products are considered essential during the first 13 weeks of pregnancy they should only be taken under medical supervision.

Vitamin D during the last trimester of pregnancy may cause hypercalcaemia in infants.

It is advised that if possible women receiving vitamin D do not breastfeed their infants as this may lead to the development of hypercalaemia in the infant.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

Side effects to this product are rare, but may include temporary staining of the teeth, rash and mild gastrointestinal disturbance.

4.9 Overdose

No data available. Gross abuse of the product would be necessary to approach toxic levels in which case conservative measures should be adopted.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Minadex provides a readily assimilable source of vitamins A and D together with the essential elements iron, potassium, calcium, manganese and copper. The pharmacological importance of these constituents in the maintenance of normal health is well documented in the literature.

5.2 Pharmacokinetic properties

The active constituents in Minadex are presented in solution and are readily assimilated from the gastrointestinal tract.

5.3 Preclinical safety data

No formal preclinical studies have been conducted. However all the individual ingredients are well documented in the literature and the product has been available for many years with no adverse reports recorded.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acacia
Soya bean oil
Orange oil
Butylhydroxyanisole (E320)
Sodium methyl hydroxybenzoate (E219)
Syrup (Glucose 40%, Sucrose 40%)
Citric acid monohydrate
Glycerophosphoric acid 20% w/w
Sodium metabisulphite (E223)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original container in order to protect from light.

6.5 Nature and contents of container

Type III amber glass bottles with polyolefin screw caps.

Pack sizes: 30ml, 150ml, 200ml, 300ml and 400ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Seven Seas Limited
Hedon Road
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HU9 5NJ
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 417/7/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First date of authorisation: 13 July 1995

Last date of renewal: 13 July 2010

10 DATE OF REVISION OF THE TEXT

October 2011