Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Effico Tonic, Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml oral solution contains:

Thiamine Hydrochloride	0.18	mg
Caffeine	20.20	mg
Nicotinamide	2.10	mg
Compound Gentian Infusion	0.31	ml

Excipients: Each 5 ml dose contains ethanol 90mg and sucrose 2g.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Solution.
Clear colourless/light straw coloured slightly viscous oral solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an adjunct during convalescence, especially in the aged.

4.2 Posology and method of administration

Adults: 10ml immediately before meals, three times a day.

Children: 2.5 to 5 ml immediately before meals three times a day.

If preferred Effico Tonic can be diluted with water.

4.3 Contraindications

Use in patients who are hypersensitive to any of the ingredients.

4.4 Special warnings and precautions for use

None stated.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Fertility, pregnancy and lactation

This product should not be used in pregnancy.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

None stated.

4.9 Overdose

None stated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Caffeine is a mild CNS stimulant and its inclusion in the formulation helps counteract symptoms of tiredness and listlessness after a weakening illness or hospitalisation.

Thiamine and nicotinamide are present as vitamin supplements. Deficiencies of these two vitamins produce symptoms including fatigue and lethargy with anorexia or loss of appetite.

5.2 Pharmacokinetic properties

Nicotinamide is readily absorbed from the gastrointestinal tract. It has a short half-life and after low doses, the principle metabolites are the N-methyl, 2- and 4- pyridone derivatives.

Thiamine is absorbed from the gastrointestinal tract and widely distributed to most body tissues. It is not stored in the body and amounts in excess of the body’s requirements are excreted in the urine as unchanged thiamine or as metabolites.

Caffeine is absorbed readily after oral administration. The average half-life is reported to be 3.5 hours. Peak plasma concentrations of 1.5 to 1.8 mg/litre have been measured after a 100mg oral dose.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96%
Sodium benzoate (E211)
Citric acid (E330)
Hydrochloride acid
Sucrose
H & R Summer Fruit Flavour 288234
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

Clear colourless glass bottle: 3 years
Orange polyethylene terephthalate (PET) bottle: 2 years

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original package.

6.5 Nature and contents of container

Clear, colourless glass bottle with food grade polypropylene tamper-evident cap, pigmented with titanium dioxide containing 200 ml, 250 ml, 300 ml or 500 ml, or orange polyethylene terephthalate (PET) bottle with food grade polypropylene tamper-evident cap pigmented with titanium dioxide containing 300 ml or 500 ml.

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

Forest Laboratories UK Limited
Riverbridge House
Anchor Boulevard
Crossways Business Park
Dartford
Kent
DA2 6SL

8 MARKETING AUTHORISATION NUMBER

PA 100/45/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of last authorisation: 27 November 1992

Date of last renewal: 27 November 2007

10 DATE OF REVISION OF THE TEXT

September 2009