SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Superdrug Pick Up / Tesco Health Energy Tablets / Sainsbury's Energy Extra Tablets / Energystore Extra Tablets / Wilko Energy Extra Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredient	mg/tablet
Caffeine EP	50.0
Dextrose Monohydrate EP	130.0

3 PHARMACEUTICAL FORM

Compressed Tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the fast relief of temporary fatigue and drowsiness

4.2 Posology and method of administration

Adults: 1 to 2 tablets before meals three times a day.

(Maximum dose 300mg of caffeine or 6 tablets)

Children: do not give to children under the age of 12 years.

As caffeine is found naturally in tea, coffee and chocolate, and in some carbonated drinks there is the potential for users to take more than the recommended 400mg of caffeine per day. Therefore users should take account of dietary sources of caffeine and ensure that they do not exceed the stated dose.

Typical amounts of caffeine available in dietary sources are:

Brewed coffee:	50 – 100mg/ml*
Instant coffee and tea:	20 – 73mg/ml*
Carbonated drinks (cola):	9 – 19mg/ml*

Chocolate: 5 – 20mg/ml*

* 100ml is equivalent to about 1 small cup of fluid

4.3 Contraindications

Hypersensitivity to caffeine or any of the ingredients.

This product should not be used by people who have been diagnosed with hypertension or who are receiving antihypertensive medication, or who have a history of cardiac arrhythmia.

This product should not be used by patients recovering from chronic alcoholism who are taking disulfiram.

This product should not be used if antidepressants (including lithium carbonate), clozapine, anxiolytics or sedatives are being used, or by persons with anxiety disorders.

This product should not be used by any persons who are also taking ephedrine

Caffeine shares the same metabolic pathway as theophylline and therefore, this product should not be used concurrently with theophylline.

(See also section 4.5).

4.4 Special warnings and precautions for use

Keep away from children.

If symptoms worsen or do not improve within 7 days, seek medical advice.

4.5 Interaction with other medicinal products and other forms of interaction

As caffeine is found naturally in tea, coffee and chocolate, and in some carbonated drinks there is the potential for users to take more than the recommended 400mg/day of caffeine per day. Therefore, users should take account of dietary sources of caffeine and also ensure that they do not exceed the maximum stated dose of 6 tablets, (see section 4.2).

Xanthine derivatives such as caffeine can weaken the vasodilating effect of substances used for myocardial imaging such as adenosine and dipyridamole. Therefore, caffeine should be avoided for 24 hours before myocardial imaging.

Caffeine, a CNS stimulant, has an antagonistic effect towards the action of sedatives and tranquilizers, (see section 4.3).

Caffeine exerts a competitive inhibition of the metabolism of c1ozapine. Therefore, clozapine and caffeine must not be used concurrently, (see section 4.3).

Caffeine can increase blood pressure and counters the hypotensive action of Beta blockers such as Atenolol, Metoprolol, Oxprenolol and Propranolol. This product should not be used at the same time as beta blockers, (see section 4.3)

Disulfiram increases caffeine clearance by up to 50%. Concomitant use of disulfiram and caffeine should be avoided, (see section 4.3).

Use of lithium carbonate and caffeine may cause a small to moderate rise in serum lithium levels. Concomitant use should be avoided, (see section 4.3).

Monoamine oxidase inhibitors may increase the stimulant effects of caffeine.

Methoxsalen reduces clearance of caffeine and may increase the effects of caffeine.

Phenytoin doubles caffeine clearance, although caffeine does not affect the metabolism of phenytoin.

Theophylline and caffeine share the same metabolic pathway, leading to increased clearance times for theophylline when used concurrently with caffeine. Concomitant use should be avoided, (see section 4.3).

Levothyroxin, like caffeine can increase blood pressure, and therefore these two active ingredients should not be used concurrently.

Ephedrine and caffeine interact to produce significant cardiovascular effects. Therefore caffeine should be avoided when ephedrine is being taken, (see section 4.3).

4.6 Fertility, pregnancy and lactation

Avoid taking any medicines during pregnancy and lactation unless prescribed by your doctor.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

At doses up to 300mg per day undesirable effects are not normally observed in healthy individuals. However, some users who are caffeine naive, have abstained from caffeine for a period or who are more sensitive to caffeine may experience effects more commonly seen at higher doses. These include tremor, insomnia,

nervousness, irritability, anxiety, headache, tinnitus, arrhythmia, and tachycardia, diuresis, gastrointestinal disturbances and elevated respiration. Individuals who experience these effects must stop taking this product and any other dietary caffeine.

Following regular use of caffeine, cessation of intake may lead to withdrawal symptoms which may last for up to a week and which include headache, tiredness and decreased alertness.

Reporting of suspected adverse reactions.
Reporting suspected adverse reactions after authorisation 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 the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard.

4.9 Overdose

Nausea, vomiting, abdominal pain, anxiety and insomnia, restlessness, palpitations. Severe overdose can lead to hyperexcitation, convulsions and death. Fatal dose of caffeine 10g (martindale). Treatment of over-dosage seek emergency medical advice. Gastric lavage, activated charcoal and circulatory and ventilatory support.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group (ATC CLASSIFICATION)

5.2 Pharmacokinetic properties

None stated

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose
Yellow Iron Oxide
Silicon Dioxide
Magnesium Stearate

6.2 Incompatibilities

None

6.3 Shelf life

Shelf-life of product as packed for sale
36 months

Shelf-life after dilution or reconstitution according to the directions
Not relevant.

Shelf-life after first opening the container
36 months

6.4 Special precautions for storage

No special storage precautions required

6.5 Nature and contents of container

Strip pack in cellophane containing 60 tablets
Blister Pack containing 30 tablets

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Brunel Healthcare Manufacturing Limited
William Nadin Way
Swadlincote
Derbyshire
DE11 0BB

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 20894/0031

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13/04/1972

10 DATE OF REVISION OF THE TEXT

22/10/2018