

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nature's Bounty Lemon Balm Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains:

171 mg of extract (as dry extract) from *Melissa officinalis* L., folium (equivalent to 684 mg – 1026 mg of Lemon Balm leaf).

Extraction solvent: Ethanol 50 % v/v

For the full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Capsule, hard

Two piece clear hard capsules with green/brown fill.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A traditional herbal medicinal product used for the temporary relief of symptoms of mild mental stress, to aid sleep and for mild digestive complaints such as bloating and flatulence, exclusively based upon long-standing use.

4.2 Posology and method of administration

For oral short-term use only

Adults and older people

Take 2 capsules 3 times daily.

Swallow the whole capsule with water.

Do not exceed the stated dose.

Duration of use:

If symptoms persist, worsen or do not improve after 2 weeks use of Nature's Bounty Lemon Balm Hard Capsules, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

Not recommended for use in children under 18 years (see 4.4 Special warnings and precautions for use).

4.3 Contraindications

Do not use in cases of known hypersensitivity to Lemon Balm or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

- Do not exceed the stated dose
- The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.
- If symptoms worsen or persist, or if new symptoms develop whilst taking this medicinal product, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

4.5 Interaction with other medicinal products and other forms of interactions

Although no data is available additive effects with hypnotics and other sedatives cannot be excluded and therefore as a general precaution comedication is not recommended.

4.6 Fertility, pregnancy and lactation

There is limited data available on the use of Lemon Balm in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). Nature's Bounty Lemon Balm Hard Capsules is not recommended during pregnancy and in women of child-bearing potential not using contraception.

There is insufficient information on the excretion of Lemon Balm in human milk. A risk to new-borns/infants cannot be excluded. Therefore, Nature's Bounty Lemon Balm Hard Capsules should not be used during breast-feeding.

Studies on fertility have not been performed.

4.7 Effects on ability to drive and use machines

May impair the ability to drive and use machines. If affected, patients should not drive or operate machinery.

4.8 Undesirable effects

None known. If adverse reactions occur, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: <http://www.hpra.ie/>; E-mail: medsafety@hpra.ie.

4.9 Overdose

No cases of human overdose have been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not required as per Article 16c(l)(a)(iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data

Non-clinical in vitro bacterial mutagenicity tests (Ames test) did not reveal mutagenic concern. Tests on reproductive toxicity, mammalian genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Herbal Preparation:

Maltodextrin

Colloidal Anhydrous Silica

Capsule Contents:

Calcium Hydrogen Phosphate Dihydrate
Magnesium Stearate
Colloidal Hydrated Silica

Capsule shell:

Hypromellose

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.
Keep the bottle tightly closed in order to protect from light and moisture.

6.5 Nature and contents of container

Green polyethylene terephthalate (PET) bottle with a polypropylene cap and an inner seal liner made up of polyester, polymer adhesive layer, polyolefin-foam and aluminium foil.
Pack size: 30 capsules
Not all packs 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 REGISTRATION HOLDER

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8 REGISTRATION NUMBER(S)

TR23157/006/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th September 2014

10 DATE OF REVISION OF THE TEXT

February 2021