Holland & Barrett Devil’s Claw Capsules
GNC Live Well Devil’s Claw Capsules
Lifecycle Devil’s Claw Capsules
Nature’s Garden Devil’s Claw Capsules

THR 21710/0005

UKPAR

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The Medicines and Healthcare products Regulatory Agency (MHRA) granted NBTY Europe Limited a Traditional Herbal Registration Certificate for the traditional herbal medicinal products Holland & Barrett Devil’s Claw Capsules, GNC Live Well Devil’s Claw Capsules, Lifecycle Devil’s Claw Capsules and Nature’s Garden Devil’s Claw Capsules (Traditional Herbal Registration number: THR 21710/0005) on 25 February 2011. These products are identical to each other apart from in name and will be collectively referred to as Devil’s Claw Capsules for the remainder of this report. Devil’s Claw Capsules are available without prescription and can be bought from pharmacies and other outlets.

Devil’s Claw Capsules is a traditional herbal medicinal product used for the relief of backache, rheumatic or muscular pain, and general aches and pains in the muscles and joints, based on traditional use only. The active ingredient in Devil’s Claw Capsules comes from Devil’s claw (*Harpagophytum procumbens* D.C. and/or *H. zeyheri* L. Decne) root.

This registration is based exclusively upon the longstanding use of Devil’s claw root as a traditional herbal medicine and not upon data generated from clinical trials. There is no requirement under the Traditional Herbal Registration scheme to prove scientifically that a product works.

No new or unexpected safety concerns arose from this application and it was, therefore, decided that a Traditional Herbal Registration Certificate could be granted.
HOLLAND & BARRETT DEVIL’S CLAW CAPSULES
GNC LIVE WELL DEVIL’S CLAW CAPSULES
LIFECYCLE DEVIL’S CLAW CAPSULES
NATURE’S GARDEN DEVIL’S CLAW CAPSULES
THR 21710/0005

SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal medicine Devil’s Claw Capsules (THR 21710/0005) to NBTY Europe Limited on 25 February 2011. This product is on the general sales list (GSL).

This application was submitted according to Article 16.c of Directive 2001/83 EC, as amended, as part of the Traditional Herbal Medicines Registration Scheme. The product is used for the relief of backache, rheumatic or muscular pain, and general aches and pains in the muscles and joints, based on traditional use only.

The data supplied by the Applicant demonstrate 30 years of traditional use of Devil’s claw root, including at least 15 years of use in the European Community. A satisfactory review of the available safety data on Devil’s claw root has also been provided, together with an Expert Safety Report supporting the proposed product.
**HERBAL SUBSTANCE:**  
**DEVIL’S CLAW**

Scientific name of the plant: *Harpagophytum procumbens* DE Candolle  
*or*  
*Harpagophytum zeyheri* DECNE  
Family: Pedaliaceae  
Synonyms of the herbal substance: Devil’s claw

The Devil’s claw plants used in this product are cultivated in Namibia. The roots are harvested manually from April to October and, following harvesting, the roots are dried in the sun.

Confirmation has been provided that the herbal substance is produced in line with the Guideline on Good Agricultural and Collection Practice (GACP) EMEA/HMPC/246816/2005 and that the herbal substance has not been fumigated or treated with ionizing radiation.

**Control of Herbal Substance**

An appropriate specification based on the Ph Eur monograph for Devil’s claw is applied and is acceptable. The specification is supported by the batch data provided.

**Container Closure System**

Satisfactory details of the container closure system are provided and confirmation has been given that all components of the container closure system comply with Directive 2008/39/EC relating to plastic materials and articles intended to come into contact with foodstuffs.

**Stability**

Confirmation is given that the herbal substance will be tested prior to being used to make the herbal preparation. A shelf-life for the herbal substance is not appropriate because it is only a precursor of the active substance, the herbal preparation. The actual guideline requires stability testing data for the herbal preparation and the herbal product in the application documents and not for the herbal substance.

**HERBAL PREPARATION:**  
**DEVIL’S CLAW ROOT DRY EXTRACT**

Part of the plant used: Root  
Ratio of the herbal substance to the herbal preparation (native): 3.5-5:1  
Extraction solvent: Ethanol 60% (V/V)

**Manufacture**

A satisfactory description of the manufacturing process of the herbal substance and flow diagram has been provided. The in-process controls are satisfactorily detailed. The manufacture of the herbal preparation is considered a standard procedure.
Certificates of analysis for all materials used in the manufacture of the herbal preparation have been provided.

**Control of Herbal Preparation**
A satisfactory specification with appropriate tests and limits has been provided for the herbal preparation.

Satisfactory analytical procedures are used to control the quality of the herbal preparation. Analytical procedures have been validated, as appropriate.

Certificates of analysis have been provided for production batches of the herbal preparation, demonstrating satisfactory compliance with the proposed specification.

**Container Closure System**
Confirmation is provided that all components of the container closure system used to store the herbal preparation comply with Directive 2008/39/EC relating to plastic materials and articles intended to come into contact with foodstuffs.

**Stability**
Stability studies have been performed in accordance with current guidelines. The proposed re-test period for the Devil’s claw root dry extract is acceptable.

**HERBAL PRODUCT: DEVIL’S CLAW CAPSULES**

**Description and Composition of the Herbal Product**
Devil’s Claw Capsules are two-piece, clear hard capsules with a grey/brown powder fill. Each capsule contains 427mg of extract (as dry extract) from Devil’s claw root and the excipients maltodextrin and silica colloidal anhydrous (that are part of the herbal preparation), calcium hydrogen phosphate dehydrate, microcrystalline cellulose, magnesium stearate, silica colloidal hydrated and hypromellose.

The compatibility of the herbal preparation with the excipients is demonstrated by the stability testing results. The excipients are controlled in line with their respective Ph Eur monograph and representative certificates of analysis are provided to demonstrate full compliance with the Ph Eur.

The magnesium stearate used in the product is confirmed to be of vegetable origin.

**Manufacture**
A flow diagram outlining the various stages of the manufacturing process and the in-process controls is provided.

In-process controls are appropriate considering the nature of the product and the method of manufacture. Currently, process validation has not been carried out on commercial batches, however, as the manufacturer has extensive experience and has committed to carry out process validation on commercial batches following an appropriate process validation protocol, this is acceptable.
Control of Herbal Product
The finished product specification is satisfactory. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where appropriate, safety. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification.

Container Closure System
The capsules are stored in green polyethylene terephthalate (PET) bottles with a chiffon green hinge cap (polypropylene), with an inner seal liner designed to lift ‘n’ peel. The inner seal acts as a tamper evident seal under the cap. The inner seal liner is made up of polyester film, polymer adhesive layer, polyester tab, polyolefin foam, aluminium foil and sealable polyester film. The product is available in packs of 50 or 100 capsules.

Suitable specifications have been provided by the packaging suppliers and it has been confirmed that all primary packaging materials comply with Directive 2008/39/EC.

Stability
Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a product shelf-life of 2 years is appropriate when the storage precautions ‘Do not store above 25° C’ and ‘Store in the original package’ are applied.

Pharmaceutical Expert
The Quality Overall Summary has been written by a chemist with suitable experience.

Assessor’s comments on the Summary of Product Characteristics, label and Patient Information Leaflet
All product literature is satisfactory.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

Assessor’s overall conclusions on quality
The grant of a Traditional Herbal Registration is acceptable.
NON-CLINICAL ASSESSMENT

NON-CLINICAL ASPECTS
The Expert Safety Report submitted by the applicant lists relevant references to published work studying the toxicology of Devil’s claw root.

NON-CLINICAL OVERVIEW
The applicant has submitted a literature review with this application. An Expert Safety Report was provided, which included reviews of some non-clinical data. The Expert Safety Report was written by a suitably qualified professional.

The overview submitted in support of this application is satisfactory.

Due to a shortage of published data on Devil’s claw root, it is not possible to assess if the safety package for the phytochemical constituents of these active ingredients is acceptable to the standards of today’s GLP and safety testing requirements. However, the information supplied demonstrating traditional use is acceptable and thus the lack of provision of a complete standard safety package is acceptable and in compliance with guideline EMEA/HMPC/32116/05.

Assurance was provided that the results of genotoxicity testing will be provided before renewal of the registration.

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The SmPC for this product is satisfactory from a non-clinical point of view.

ENVIRONMENTAL RISK ASSESSMENT
An environmental risk assessment is not required for herbal medicinal products according to guidance CPMP/SWP/4447/00.

CONCLUSION
There are no objections to granting of a Traditional Herbal Registration from a non-clinical point of view.
CLINICAL ASSESSMENT

PROPOSED INDICATION
The applicant has submitted the following therapeutic indication:

“A traditional herbal medicinal product used for the relief of backache, rheumatic or muscular pain and general aches and pains in the muscles and joints. This is based on traditional use only.”

The indication is acceptable.

POSOLOGY AND METHOD OF ADMINISTRATION
The applicant has submitted the following:

“For oral use only

Adults and elderly- Take 1 capsule 2 times daily. Swallow the whole capsule with water. Take one capsule in the morning and one in the evening

Not for use in children or adolescents under 18 years (see section 4.4 ‘Special Warnings and Precautions for use’).

Duration of use:
If symptoms worsen or do not improve after 4 weeks, a doctor or a qualified healthcare practitioner should be consulted.”

This is acceptable.

Efficacy
No clinical efficacy data is required for registration of Traditional Herbal Medicinal Products (THMP).

Evidence of Traditional Use
Article 16 c 1 (c) requires the applicant to provide bibliographic or expert evidence to show that the medicinal product in question, or a corresponding product, has been in medicinal use throughout a period of at least 30 years, including at least 15 years within the EU.

The published HMPC assessment report and Community Monograph for Devil’s claw adopted by the HMPC adequately covers the evidence for traditional use of the herbal preparation in the product under assessment for at least 30 years. The requirements of the Directive are considered to be met.

Safety Review
Article 16 c 1 (d) requires the applicant to provide a bibliography of the safety data together with an expert report.
The HMPC Assessment Report for Devil’s claw covers the bibliographic data available and the safety of Devil’s claw has been demonstrated. The SmPC is in line with the HMPC monograph.

PRODUCT LITERATURE
The SmPC, PIL and labelling for this product is medically satisfactory.

RECOMMENDATIONS
A Traditional Herbal Registration may be granted.
OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY
The quality data submitted with this application are satisfactory.

NON-CLINICAL
No new non-clinical data were submitted with this application. However, assurance was provided that the results of genotoxicity testing will be provided before renewal of this registration. This is satisfactory.

EFFICACY AND SAFETY
No clinical efficacy data are required for registration of Traditional Herbal Medicinal Products (THMP).

The published HMPC assessment report and Community Monograph for Devil’s Claw adopted by the HMPC adequately covers the evidence for traditional use of the extract in the product under assessment for at least 30 years and the non-clinical and clinical safety issues associated with Devil’s Claw.

The SmPC, PIL and labelling are satisfactory.

RISK ASSESSMENT
The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The risk: benefit balance is acceptable and a Traditional Herbal Registration may be granted.
HOLLAND & BARRETT DEVIL’S CLAW CAPSULES
GNC LIVE WELL DEVIL’S CLAW CAPSULES
LIFECYCLE DEVIL’S CLAW CAPSULES
NATURE’S GARDEN DEVIL’S CLAW CAPSULES

THR 21710/0005

**STEPS TAKEN FOR ASSESSMENT**

1. The MHRA received the Traditional Herbal Registration application on 5 February 2010.
2. Following standard checks and communication with the applicant the MHRA considered the application valid on 24 February 2010.
3. Following assessment of the application the MHRA requested further information relating to the clinical dossier on 20 September 2010 and the quality dossier on 8 October 2010.
4. The applicant responded to the MHRA’s request, providing further information on the quality dossier on 30 November 2010 and the clinical dossier on 17 December 2010.
5. Following assessment of the response the MHRA requested further information relating to the quality dossier on 25 January 2011.
6. The applicant responded to the MHRA’s request, providing further information on the quality dossier on 21 February 2011.
7. A THR was granted on 25 February 2011.
1 NAME OF THE MEDICINAL PRODUCT
   • Holland & Barrett Devil’s Claw Capsules
   • GNC Live Well Devil’s Claw Capsules
   • Lifecycle Devil’s Claw Capsules
   • Nature’s Garden Devil’s Claw Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
   Each hard capsule contains 427mg of extract (as dry extract) from Devil’s Claw root (*Harpagophytum procumbens* D.C. and/or *H. zeyheri* L. Decne, radix) (Equivalent to 1493mg – 2133mg of Devil’s Claw root).
   Extraction solvent: Ethanol 60% v/v.

   For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
   Capsule, hard

   Two piece clear hard capsules with grey/brown powder fill.

4 CLINICAL PARTICULARS

   4.1 Therapeutic indications
   A traditional herbal medicinal product used for the relief of backache, rheumatic or muscular pain and general aches and pains in the muscles and joints. This is based on traditional use only.

   4.2 Posology and method of administration
   For oral use only

   **Adults and elderly**- Take 1 capsule 2 times daily. Swallow the whole capsule with water. Take one capsule in the morning and one in the evening

   Not for use in children or adolescents under 18 years (see section 4.4 ‘Special Warnings and Precautions for use’).

   **Duration of use:**
   If symptoms worsen or do not improve after 4 weeks, a doctor or a qualified healthcare practitioner should be consulted.

   4.3 Contraindications
   Hypersensitivity to the Devil’s claw or any of the excipients
4.4 Special warnings and precautions for use
• Not recommended for children and adolescents under 18 years of age because data are not sufficient and medical advice should be sought.
• Articular pain accompanied by swelling of joints, redness or fever should be examined by a doctor.
• As a general precaution, patients with gastric or duodenal ulcer should not use Devil’s Claw root preparations.
• Caution should be taken when Devil’s Claw is administered to patients affected by cardiovascular disorders.
• If symptoms worsen or not improve after 4 weeks consult a doctor or qualified Healthcare practitioner.
• Do not exceed the stated dose.

4.5 Interaction with other medicinal products and other forms of interaction
Not known.

4.6 Pregnancy and lactation
Safety during pregnancy and lactation has not been established. Due to the lack of data, use during pregnancy and lactation is not recommended.

4.7 Effects on ability to drive and use machines
No studies on the effect on the ability to drive and use machines have been performed. However some patients have experienced dizziness and somnolence while taking Devil’s claw, which may affect the ability to drive and use machines.

4.8 Undesirable effects
• Gastrointestinal disorders such as, diarrhoea, nausea, vomiting and abdominal pain.
• Central Nervous system disorders such as headache and dizziness.
• Skin disorders such as allergic skin reactions (rash and itching).
The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or qualified health care practitioner should be consulted.

4.9 Overdose
No case of overdose has been reported.
Symptomatic and supportive measures should be taken as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Not required as per Article 16c(1)(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
Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Calcium Hydrogen phosphate dihydrate
Microcrystalline cellulose
Magnesium stearate
Silica colloidal hydrated

Excipients in the extract:
Maltodextrin
Silica colloidal anhydrous

Capsule shell:
Hypermellose

6.2 Incompatibilities
Not applicable

6.3 Shelf life
2 years

6.4 Special precautions for storage
Do not store above 25ºC.
Store in the original packaging

6.5 Nature and contents of container
Green Polyethylene terephthalate (PET) bottles with a chiffon green hinge cap (Polypropylene), with an inner seal liner designed to lift ‘n’ peel. The inner seal acts as a tamper evident seal under the cap. The Inner seal liner is made up of polyester film, polymer adhesive layer, polyester tab, polyolefin foam, aluminium foil and sealable polyester film

Pack size: 50 capsules and 100 capsules

6.6 Special precautions for disposal
No special requirements

7 MARKETING AUTHORISATION HOLDER
NBTY Europe Limited
Samuel Ryder House
Barling Way
Nuneaton
Warwickshire
CV10 7RH, United Kingdom

8  MARKETING AUTHORISATION NUMBER(S)
   THR 21710/0005

9  DATE OF FIRST AUTHORISATION/RENEWAL OF THE
    AUTHORIZATION
   25/02/2011

10 DATE OF REVISION OF THE TEXT
    25/02/2011
Consult a Doctor or a qualified Healthcare Practitioner if you have:
- Heart problems and want to take Devil's Claw Capsules
- Joint pain accompanied by swelling of the joint, redness or fever

3 - How to take this product

For oral use only
Adults and elderly:
Take 1 capsule 2 times daily.
Swallow the whole capsule with water. Take one capsule in the morning and one in the evening.
Do not exceed the stated dose.

If you take too much of the product (overdose): speak to a Doctor or a qualified Healthcare Practitioner immediately and take this leaflet and bottle with you.

If you forget to take this product: Do not take a double dose to make up for the missed dose(s). Continue to take your usual dose at the usual time. It does not matter if you have missed a dose.

Duration of use: If symptoms worsen or do not improve after 4 weeks, a Doctor or a qualified Healthcare Practitioner should be consulted.

4 - Possible side effects

Like all medicines, this product can have side effects. Possible side effects are:
- Gastrointestinal effects such as nausea (feeling sick), abdominal pain, diarrhoea and vomiting
- Central nervous system effects such as headache and dizziness
- Skin effects such as allergic skin reactions such as itching and/or rash

If any of the above side effects become serious or if you experience any other side effects not listed above, consult your Doctor, Pharmacist or a qualified Healthcare Practitioner.

If you experience any allergic reactions, stop taking this product and consult your Doctor:

More information on back panel
5 - How to store this product
- Keep the capsules in the bottle until it is time to take them
- Do not take the capsules after the expiry date (see outer label). The expiry date refers to the last day of the month.
- Do not store above 25°C
- Store in the original packaging
- Keep the bottle tightly closed
- Keep the capsules out of sight and reach of children

6 - Further information
Each hard capsule contains 427mg of extract (as dry extract) from Devil’s Claw root (*Harpagophytum procumbens* D.C. and/or *H. zeyheri* L. Deone, radix) (equivalent to 1493mg-2133mg of Devil’s Claw root).
Extraction solvent: Ethanol 60% v/v.
This product also contains the following inactive (excipient) ingredients: Calcium hydrogen phosphate dihydrate, Microcrystalline cellulose, Magnesium stearate, Silica colloidal hydrated.
Excipients in the extract: Maltodextrin, Silica colloidal anhydrous.
Capsule shell: Hypromellose.
Each bottle contains 50 or 100 clear, hard, two piece capsules with grey/brown powder.

After taking this product: You must speak to a Doctor or a qualified Healthcare Practitioner if:
- Your symptoms get worse
- Your symptoms do not improve after 4 weeks
- Side effects not listed in this leaflet occur

Traditional Registration Holder:
THR 21710/0005

NBTY Europe Ltd
Samuel Ryder House
Barling Way
Nuneaton
Warwickshire, CV10 7RH
United Kingdom

Manufacturer of this product:
Vita Health Products Inc
150 Beignon Avenue
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Manitoba, R2J 3W2
Canada

For: NBTY Europe Ltd
Samuel Ryder House
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Nuneaton
Warwickshire, CV10 7RH
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If you would like further information about this product, please contact:

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Is this leaflet hard to see or read?
Contact us on:
Telephone: +44 (0) 2476 215 400
Fax: +44 (0) 2476 215 452
Email: customerservices@NBTYeurope.com

You can help to make medicines safer by reporting any side effects to the Yellow Card Scheme at: www.yellowcard.gov.uk
Alternatively you can get a paper Yellow Card form from your GP’s surgery or pharmacy, or call freephone 0808 100 3352
Consult a Doctor or a qualified Healthcare Practitioner if you have:
- Heart problems and want to take Devil’s Claw Capsules
- Joint pain accompanied by swelling of the joint, redness or fever

3 - How to take this product

For oral use only
Adults and elderly:
Take 1 capsule 2 times daily.
Swallow the whole capsule with water. Take one capsule in the morning and one in the evening.
Do not exceed the stated dose.

If you take too much of the product (overdose): speak to a Doctor or a qualified Healthcare Practitioner immediately and take this leaflet and bottle with you.

If you forget to take this product: Do not take a double dose to make up for the missed dose(s).
Continue to take your usual dose at the usual time. It does not matter if you have missed a dose.

Duration of use: If symptoms worsen or do not improve after 4 weeks, a Doctor or a qualified Healthcare Practitioner should be consulted.

4 - Possible side effects

Like all medicines, this product can have side effects. Possible side effects are:
- Gastrointestinal effects such as nausea (feeling sick), abdominal pain, diarrhoea and vomiting
- Central nervous system effects such as headache and dizziness
- Skin effects such as allergic skin reactions such as itching and/or rash

If any of the above side effects become serious or if you experience any other side effects not listed above, consult your Doctor, Pharmacist or a qualified Healthcare Practitioner.

If you experience any allergic reactions, stop taking this product and consult your doctor.

More information on back panel
5 - How to store this product

- Keep the capsules in the bottle until it is time to take them.
- Do not take the capsules after the expiry date (see outer label). The expiry date refers to the last day of the month.
- Do not store above 25°C.
- Store in the original packaging.
- Keep the bottle tightly closed.
- Keep the capsules out of sight and reach of children.

6 - Further information

Each hard capsule contains 427 mg of extract (as dry extract) from Devil’s Claw root (*Harpagophytum procumbens* D.C. and/or *H. zeyheri* L. Decne, radix) (equivalent to 1493 mg: 2133 mg of Devil’s Claw root).

Extraction solvent: Ethanol 60% v/v.

*This product also contains the following inactive (excipient) ingredients:* Calcium hydrogen phosphate dihydrate, Microcrystalline cellulose, Magnesium stearate, Silica colloidal hydrated.

*Excipients in the extract:* Maltodextrin, Silica colloidal anhydrous.

*Capsule shell:* Hypromellose.

Each bottle contains 50 or 100 clear, hard, two piece capsules with grey/brown powder.

*After taking this product:* You must speak to a Doctor or a qualified Healthcare Practitioner if:
- Your symptoms get worse.
- Your symptoms do not improve after 4 weeks.
- Side effects not listed in this leaflet occur.

Traditional Registration Holder:
THR 21710/0005

**NBTY Europe Ltd**
Samuel Ryder House
Barling Way
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Manufacturer of this product:
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Is this leaflet hard to see or read?
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**Fax:** +44 (0) 2476 215 452
**Email:** customerservices@NBTYeurope.com

You can help to make medicines safer by reporting any side effects to the Yellow Card Scheme at: [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk)
Alternatively you can get a paper Yellow Card form from your GP’s surgery or pharmacy, or call freephone 0808 100 3352

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MHRA PAR; DEVIL’S CLAW CAPSULES, THR 21710/0005
PATIENT INFORMATION LEAFLET

Devil’s Claw Capsules
Devil’s Claw Root Extract 427mg

Important notes

- Please read this leaflet carefully before you use this product because it contains important information
- Keep this leaflet; you may need to read it again
- Seek professional advice if you need more information
- Please tell a Doctor or a qualified Healthcare Practitioner if your symptoms worsen or do not improve after 4 weeks of taking this product
- Please tell a Doctor or a qualified Healthcare Practitioner if you suffer from side effects not listed in this leaflet and/or if any of the side effects become serious

3 - How to take this product

For oral use only

Adults and elderly:
Take 1 capsule 2 times daily.
Swallow the whole capsule with water. Take one capsule in the morning and one in the evening.
Do not exceed the stated dose.

If you take too much of the product (overdose):
speak to a Doctor or a qualified Healthcare Practitioner immediately and take this leaflet and bottle with you.

If you forget to take this product: Do not take a double dose to make up for the missed dose(s).
Continue to take your usual dose at the usual time. It does not matter if you have missed a dose.

Duration of use: If symptoms worsen or do not improve after 4 weeks, a Doctor or a qualified Healthcare Practitioner should be consulted.

In this leaflet

1. What this product is and what it is used for
2. Before you take this product
3. How to take this product
4. Possible side effects
5. How to store this product
6. Further information

1 - What this product is and what it is used for

This product contains Devil’s Claw root extract. It is a traditional herbal medicinal product used for the relief of backache, rheumatic or muscular pain and general aches and pains in the muscles and joints. This is based on traditional use only.

2 - Before you take this product

Do not take this product if you are:
- Under 18 years of age
- Pregnant or breastfeeding
- Allergic to Devil’s Claw or any of the ingredients listed in section 6 of this leaflet
- Suffering from or have had duodenal or stomach ulcers

Effects on ability to drive and use machines:
Some patients may experience dizziness or drowsiness while taking Devil’s claw root products, which may affect the ability to drive and use machines. If affected, do not drive or use machines.

Consult a Doctor or a qualified Healthcare Practitioner if you have:
- Heart problems and want to take Devil’s Claw Capsules
- Joint pain accompanied by swelling of the joint, redness or fever

4 - Possible side effects

Like all medicines, this product can have side effects. Possible side effects are:
- Gastrointestinal effects such as nausea (feeling sick), abdominal pain, diarrhoea and vomiting
- Central nervous system effects such as headache and dizziness
- Skin effects such as allergic skin reactions such as itching and/or rash

If any of the above side effects become serious or if you experience any other side effects not listed above, consult your Doctor, Pharmacist or a qualified Healthcare Practitioner:

If you experience any allergic reactions, stop taking this product and consult your Doctor.

More information on back panel
5 - How to store this product

- Keep the capsules in the bottle until it is time to take them
- Do not take the capsules after the expiry date (see outer label). The expiry date refers to the last day of the month.
- Do not store above 25°C
- Store in the original packaging
- Keep the bottle tightly closed
- Keep the capsules out of sight and reach of children

6 - Further information

Each hard capsule contains 427mg of extract (as dry extract) from Devil’s Claw root (*Harpagophytum procumbens* D.C. and/or *H. zeyheri* L. Decne, radix) (equivalent to 1493mg-2133mg of Devil’s Claw root).

Extraction solvent: Ethanol 60% v/v.

This product also contains the following inactive (excipient) ingredients: Calcium hydrogen phosphate dihydrate, Microcrystalline cellulose, Magnesium stearate, Silica colloidal hydrated.

Excipients in the extract: Maltodextrin, Silica colloidal anhydrous.

Capsule shell: Hypromellose.

Each bottle contains 50 or 100 clear, hard, two piece capsules with grey/brown powder.

After taking this product: You must speak to a Doctor or a qualified Healthcare Practitioner if:

- Your symptoms get worse
- Your symptoms do not improve after 4 weeks
- Side effects not listed in this leaflet occur

Traditional Registration Holder:
THR 21710/0005

NBTY Europe Ltd
Samuel Ryder House
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Warwickshire, CV10 7RH
United Kingdom

Manufacturer of this product:
Vita Health Products Inc
150 Beghin Avenue
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Canada

For: NBTY Europe Ltd
Samuel Ryder House
Barling Way
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Warwickshire, CV10 7RH
United Kingdom

If you would like further information about this product, please contact:

NBTY Europe Limited
Regulatory Services
Samuel Ryder House
Barling Way
Nuneaton
Warwickshire, CV10 7RH
United Kingdom

Is this leaflet hard to see or read?
Contact us on:
Telephone: +44 (0) 2476 215 400
Fax: +44 (0) 2476 215 452
Email: customerservices@NBTYeurope.com

You can help to make medicines safer by reporting any side effects to the Yellow Card Scheme at: www.yellowcard.gov.uk
Alternatively you can get a paper Yellow Card form from your GP’s surgery or pharmacy, or call freephone 0808 100 3352

BM510-000  00A  T38134-000
CERTIFICATION MARK
Consult a Doctor or a qualified Healthcare Practitioner if you have:
- Heart problems and want to take Devil’s Claw Capsules
- Joint pain accompanied by swelling of the joint, redness or fever

3 - How to take this product
For oral use only
Adults and elderly:
Take 1 capsule 2 times daily.
Swallow the whole capsule with water. Take one capsule in the morning and one in the evening.
Do not exceed the stated dose.

If you take too much of the product (overdose): speak to a Doctor or a qualified Healthcare Practitioner immediately and take this leaflet and bottle with you.

If you forget to take this product: Do not take a double dose to make up for the missed dose(s).
Continue to take your usual dose at the usual time.
It does not matter if you have missed a dose.

Duration of use: If symptoms worsen or do not improve after 4 weeks, a Doctor or a qualified Healthcare Practitioner should be consulted.

4 - Possible side effects
Like all medicines, this product can have side effects. Possible side effects are:
- Gastrointestinal effects such as nausea (feeling sick), abdominal pain, diarrhoea and vomiting
- Central nervous system effects such as headache and dizziness
- Skin effects such as allergic skin reactions such as itching and/or rash

If any of the above side effects become serious or if you experience any other side effects not listed above, consult your Doctor, Pharmacist or a qualified Healthcare Practitioner.

More information on back panel

MHRA PAR; DEVIL’S CLAW CAPSULES, THR 21710/0005
5 - How to store this product

- Keep the capsules in the bottle until it is time to take them.
- Do not take the capsules after the expiry date (see outer label). The expiry date refers to the last day of the month.
- Do not store above 25°C.
- Store in the original packaging.
- Keep the bottle tightly closed.
- Keep the capsules out of sight and reach of children.

6 - Further information

Each hard capsule contains 427mg of extract (as dry extract) from Devil's Claw root (*Harpagophytum procumbens* D.C. and/or *H. zeyheri* L. Decne, radix) (equivalent to 1.493mg-2.133mg of Devil's Claw root).

Extraction solvent: Ethanol 60% v/v.

This product also contains the following inactive (excipient) ingredients: Calcium hydrogen phosphate dihydrate, Microcrystalline cellulose, Magnesium stearate, Silica colloidal hydrated.

Excipients in the extract: Maltodextrin, Silica colloidal anhydrous.

Capsule shell: Hypromellose.

Each bottle contains 50 or 100 clear, hard, two-piece capsules with grey/brown powder.

After taking this product: You must speak to a Doctor or a qualified Healthcare Practitioner if:

- Your symptoms get worse.
- Your symptoms do not improve after 4 weeks.
- Side effects not listed in this leaflet occur.

Traditional Registration Holder:
THR 21710/0005

NBTY Europe Ltd
Samuel Ryder House
Barling Way
Nuneaton
Warwickshire, CV10 7RH
United Kingdom

Manufacturer of this product:
Vita Health Products Inc
150 Beghin Avenue
Winnipeg
Manitoba, R2J 3V2
Canada

For: NBTY Europe Ltd
Samuel Ryder House
Barling Way
Nuneaton
Warwickshire, CV10 7RH
United Kingdom

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BMS10.000 00A 138209.000 CERTIFICATION MARK
LABELLING

Holland & Barrett Devil’s Claw Capsules

Labels:
GNC Live Well Devil’s Claw Capsules

Labels:

Active Ingredients: Each hard capsule contains 427mg of extract (as dry extract) from Devil’s Claw root (Harpagophyllum procumbens D.C. and/or H. jaylelii D. Decne, radix) (equivalent to 1490mg–2155mg of Devil’s Claw root). Extraction solvent: Ethanol 60% v/v.

Dosage: For oral use only.
- Adults and elderly: Take 1 capsule 2 times daily.
- Swallow the whole capsule with water. Take one capsule in the morning and one in the evening.

Duration of use: If symptoms worsen or do not improve after 4 weeks, a Doctor or a qualified Healthcare Practitioner should be consulted.

Warnings:
- DO NOT EXCEED THE STATED DOSE
- Do not take this product if you are:
  - Under 18 years of age
  - Pregnant or breastfeeding
  - Allergic to Devil’s Claw or any of the ingredients in this product
  - Suffering from or have had duodenal or stomach ulcers

Consult a Doctor or a qualified Healthcare Practitioner if you have:
- Heart problems and want to take this product
- Joint pain accompanied by swelling of the joint, redness or fever

Storage: Do not store above 25°C. Keep in the original container. Keep the bottle tightly closed. Keep out of sight and reach of children.

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Active Ingredients: Each hard capsule contains 427mg of extract (as dry extract) from Devil’s Claw root (Harpagophyllum procumbens D.C. and/or H. jaylelii D. Decne, radix) (equivalent to 1490mg–2155mg of Devil’s Claw root). Extraction solvent: Ethanol 60% v/v.

Dosage: For oral use only.
- Adults and elderly: Take 1 capsule 2 times daily.
- Swallow the whole capsule with water. Take one capsule in the morning and one in the evening.

Duration of use: If symptoms worsen or do not improve after 4 weeks, a Doctor or a qualified Healthcare Practitioner should be consulted.

Warnings:
- DO NOT EXCEED THE STATED DOSE
- Do not take this product if you are:
  - Under 18 years of age
  - Pregnant or breastfeeding
  - Allergic to Devil’s Claw or any of the ingredients in this product
  - Suffering from or have had duodenal or stomach ulcers

Consult a Doctor or a qualified Healthcare Practitioner if you have:
- Heart problems and want to take this product
- Joint pain accompanied by swelling of the joint, redness or fever

Storage: Do not store above 25°C. Keep in the original container. Keep the bottle tightly closed. Keep out of sight and reach of children.
Cartons:


Expiry Date - see base

Warnings:
- Do not exceed the stated dose.
- Do not take this product if you are:
  - Under 16 years of age
  - Pregnant or breastfeeding
  - Allergic to Devil’s Claw or any of the ingredients in this product
  - Suffering from ulcer of the duodenum or stomach ulcer

Consult a Healthcare Professional if you:
- Have a heart condition
- Are taking any medication
- Have any medical problems
- Are pregnant or breastfeeding

Active ingredients: Each hard capsule contains 457mg of extract of devil’s claw root (Heracleum froggatum DC), and/or (H. sphondylium DC) (equivalent to 1.45g of Devil’s Claw root).

Extraction solvent: Ethanol 60% v/v.

Dosage: For oral use only.
- Adults and elderly:
  - Take 1 capsule 2 times daily.
  - Swallow the whole capsule with water.

Duration of use: If symptoms are not improved after 4 weeks, a Doctor or a qualified Healthcare Professional should be consulted.

A traditional herbal medicinal product used for the relief of headache, rheumatic or muscular pain and general aches and pains in the muscles and joints. This is based on traditional use only.

50 Capsules
 Lifecycle Devil’s Claw Capsules

Labels

Active Ingredients: Each hard capsule contains 427mg of extract (as dry extract) from Devil’s Claw root (Harpephyllum cour蟠cunum D.C. and/or Zeyheria L. Deacon, radix) (equivalent to 140mg-215mg of Devil’s Claw root).

Dosage: For oral use only.

Adults and elderly: Take 1 capsule 2 times daily.

Duration of use: If symptoms worsen or do not improve after 4 weeks, a doctor or a qualified healthcare practitioner should be consulted.

Warnings: DO NOT EXCEED THE STATED DOSE
Do not take this product if you are:
- Under 18 years of age
- Pregnant or breastfeeding
- Allergic to Devil’s Claw or any of the ingredients in this product
- Suffering from or have had duodenal or stomach ulcers

Consult a doctor or a qualified healthcare practitioner if you have:
- Heart problems and want to take this product
- Joint pain accompanied by swelling of the joint, redness or fever

Storage: Do not store above 25°C. Keep in the original container. Keep the bottle tightly closed. Keep out of sight and reach of children.

Lifecycle Devil’s Claw Capsules

Active Ingredients: Each hard capsule contains 427mg of extract (as dry extract) from Devil’s Claw root (Harpephyllum cour蟠cunum D.C. and/or Zeyheria L. Deacon, radix) (equivalent to 140mg-215mg of Devil’s Claw root).

Dosage: For oral use only.

Adults and elderly: Take 1 capsule 2 times daily.

Duration of use: If symptoms worsen or do not improve after 4 weeks, a doctor or a qualified healthcare practitioner should be consulted.

Warnings: DO NOT EXCEED THE STATED DOSE
Do not take this product if you are:
- Under 18 years of age
- Pregnant or breastfeeding
- Allergic to Devil’s Claw or any of the ingredients in this product
- Suffering from or have had duodenal or stomach ulcers

Consult a doctor or a qualified healthcare practitioner if you have:
- Heart problems and want to take this product
- Joint pain accompanied by swelling of the joint, redness or fever

Storage: Do not store above 25°C. Keep in the original container. Keep the bottle tightly closed. Keep out of sight and reach of children.
Cartons:

Storage: Do not store above 25°C. Keep in the original container. Keep out of the reach of children.

Expiry Date - see base

Warnings:
- Do not exceed the stated dose
- Do not take this product if you are:
  - Under 18 years of age
  - Pregnant or breastfeeding
  - Allergic to Devil’s Claw or any of the ingredients in this product
  - Suffering from a cold, cough or cold symptoms or other nasal or sinus conditions

Consult your Healthcare Practitioner if you have:
- Headache or persistent or frequent headaches
- Joint pain accompanied by swelling of the joints
- Fever

You must read the enclosed leaflet carefully before using this product.

Active Ingredients: Each hard capsule contains 420mg of extract (as dry extract) from Devil’s Claw root (Harpagophytum procumbens (DC.) andror H. Steynr L., Devils, root) (equivalent to 140mg-213mg of Devil’s Claw root). Extraction solvent: Ethanol 60% w/v

Dosage: For oral use only.

Adults and elderly:
Take 1 capsule 2 times daily. Swallow the whole capsule with water. Take one capsule in the morning and one in the evening.

Duration of use: If symptoms worsen or do not improve after 4 weeks, a Doctor or a qualified Healthcare Practitioner should be consulted.
Nature’s Garden Devil’s Claw Capsules

**Labels:**

**Active Ingredients:** Each hard capsule contains 427mg of extract (as dry extract) from Devil’s Claw root (*Harpagophytum procumbens* D.C. and/or *H. zeyheri* L. Deeke, radix) (equivalent to 1490mg-2135mg of Devil’s Claw root).

**Dosage:** For oral use only.
- Adults and elderly: Take 1 capsule 2 times daily. Swallow the whole capsule with water. Take one capsule in the morning and one in the evening.
- Duration of use: If symptoms worsen or do not improve after 4 weeks, a Doctor or a qualified Healthcare Practitioner should be consulted.

**Warnings:**
- DO NOT EXCEED THE STATED DOSE
- Do not take this product if you are:
  - Under 18 years of age
  - Pregnant or breastfeeding
  - Allergic to Devil’s Claw or any of the ingredients in this product
  - Suffering from or have had duodenal or stomach ulcers
- Consult a Doctor or a qualified Healthcare Practitioner if you have:
  - Heart problems and want to take this product
  - Joint pain accompanied by swelling of the joint, redness or fever

**Storage:** Do not store above 25°C. Keep in the original container. Keep out of sight and reach of children.
Cartons:

**NATURE'S GARDEN**

**DEVIL'S CLAW Capsules**

Devil's Claw Root Extract 427mg

**Warnings:**
- DO NOT EXCEED THE STATED DOSE
- Do not take this product if you are:
  - Under 18 years of age
  - Pregnant or breastfeeding
  - Allergic to Devil's Claw or any of the ingredients in this product
  - Suffering from or have had gallstones or stomach ulcer

Consult a Doctor or a qualified Healthcare Professional before use.

Active ingredients: Each hard capsule contains 427mg of extract (as dry extract from Devil's Claw root (Harpagophytum procumbens D.C. and/or H. longifolium)).

Storage: Store in a cool, dry place. Keep out of reach of children.

Expiration Date - see base.

Active ingredients: Each hard capsule contains 427mg of extract (as dry extract from Devil's Claw root (Harpagophytum procumbens D.C. and/or H. longifolium)).

Active ingredients: Each hard capsule contains 427mg of extract (as dry extract from Devil's Claw root (Harpagophytum procumbens D.C. and/or H. longifolium)).

Dosage: For oral use only.
- Adults and elderly: Take 1 capsule 3 times daily. Swallow the whole capsule with water. Take one capsule in the morning and one in the evening.
- Duration of use: If symptoms worsen or do not improve after 4 weeks, a Doctor or a qualified Healthcare Practitioner should be consulted.

A traditional herbal medicinal product used for the relief of backache, rheumatism or muscular pain and general aches and pains in the muscles and joints. This is based on traditional use only.

50 Capsules
MHRA PAR; DEVIL’S CLAW CAPSULES, THR 21710/0005

Active ingredients: Each hard capsule contains 457mg of extract (as dry extract) from Devil’s Claw root (Harpagophytum procumbens) D.C. and/or H. angustifolius Lam, (equiv. to 145mg (215mg) of Devil’s Claw root). Excipients: Gelatin, Ethanol 40% v/v.

Dosage: For oral use only. Adults and elderly: Take 1 capsule 2-3 times daily. Swallow the whole capsule with water. Take one capsule in the morning and one in the evening.

Duration of use: If symptoms worsen or do not improve after 4 weeks, a Doctor or a qualified Healthcare Practitioner should be consulted.