ATROSAN DEVIL'S CLAW TABLETS

THR 13668/0012

UKPAR

TABLE OF CONTENTS

ATROSAN DEVIL'S CLAW TABLETS

THR 13668/0012

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Bioforce (UK) Limited a Traditional Herbal Registration certificate for the traditional herbal medicinal product Atrosan Devil's Claw tablets (Traditional Herbal Registration number: THR 13668/0012). This product is available without prescription and can be bought from pharmacies and other outlets.

The active ingredient of Atrosan Devil's Claw tablets comes from the roots of the plant *Harpagophytum procumbens* DE CANDOLLE, also known as Devil's claw. Devil's claw is a traditional herbal medicine used for the relief of backache, rheumatic or muscular pain, and general aches and pains in the muscles and joints. 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 the 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.

ATROSAN DEVIL'S CLAW TABLETS

THR 13668/0012

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal remedy Atrosan Devil's Claw tablets (Traditional Herbal Registration number: THR 13668/0012) to Bioforce (UK) Limited on 11 January 2008. This product is on the general sales list (GSL).

This application was submitted as a standard application according to Article 16.c of Directive 2001/83 EC, as amended, as part of the Traditional Herbal Medicines Registration Scheme.

The data supplied by the Applicant demonstrate 30 years of traditional use of Devil's Claw root products in the European Community. A satisfactory review of the available safety data on Devil's Claw has also been provided, together with an Expert Report supporting the proposed product.

PHARMACEUTICAL ASSESSMENT

HERBAL SUBSTANCE: DEVIL'S CLAW ROOT

General information

Scientific name of the plant:	*Harpagophytum procumbens* DE CANDOLLE *Harpagophytum zeyheri* L.
Family:	Pedaliaceae
Synonyms of the herbal substance:	Devil's Claw root
Parts of the plant used:	Dried tuberous secondary roots
Name of the herbal substance:	Devil's Claw root

General information

The therapeutically active constituents within the root have not been identified. Therefore, the genuine extract, that is the extract of the Devil's claw root, is considered to be the active principle in this product.

The plant is a tender trailing perennial with tubers, and many round- to oval-shaped stems. The leaves have white, hairy undersides. The plant has solitary, trumpet-shaped red to purple flowers that appear in spring, followed by the characteristic large, hooked and claw-like fruit.

Manufacture

The secondary roots are wild collected or harvested from controlled crops. The documentation confirms that the herbal substance is produced in accordance with the principles of Good Agricultural and Collection Practice (GACP). It is stated that no pesticides or fumigant treatments are used in the cultivation of this plant.

The dossier indicates that wild collection is only undertaken in rare cases when cultivated crops are not sufficient and, should it be necessary to employ material from wild collection, this will be sourced according to GACP and with the permission of the competent authority (Nature Conservation, Department of Agriculture of South Africa). During collection from the wild "nature conservation" is stated to be used, which ensures that over-collecting does not occur.

The tubers are washed with clean water, cut into slices and dried. The natural air drying occurs indoors in a secure and protected place.

Control of Herbal Substance

An appropriate specification based on the Ph Eur monograph for Devil's Claw root is used and is acceptable.

Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications. The specification is supported by the batch data provided.

Stability

Stability data for the herbal substance are not available. However, the manufacturer tests and releases the herbal substance according to the specifications. If unfavourable

storage conditions had a negative effect on the quality of the drug, this would be evident from the analytical results.

HERBAL PREPARATION: DEVIL'S CLAW ROOT ETHANOLIC EXTRACT

General information

Nomenclature

Name: Devil's Claw root ethanolic extract
Part of plant: Root
Drug to Extract Ratio (DER native): 1.5-3: 1 (defined with reference to dried mass)
Extractant (Extraction solvent): Ethanol 60% m/m.
Excipients: lactose monohydrate; silica, precipitated

Manufacture

A description and flow-chart of the manufacturing method has been provided.

The procedure is a standard extraction/maceration procedure and is suitable for this type of herbal preparation.

Control of Materials

Extraction solvent

The ethanol used for extraction complies with the Ph Eur monograph. The water used for extraction is potable; a typical Certificate of Analysis has been provided and tests applied are acceptable.

Excipients

Silica precipitated complies with the appropriate test. Lactose monohydrate complies with the Ph Eur monograph. Representative Certificates of Analysis have been provided for the extract excipients. A statement on the TSE status of lactose monohydrate confirms that it complies with TSE Directive 2001/83/EC and EMEA/410/01 rev 2.

Controls of Critical Steps and Intermediates

Satisfactory in-process controls are performed during manufacture of the herbal preparation.

Process Validation and/or Evaluation

Process validation has been carried out using production-scale batches of extract. The validation studies support the manufacturing process.

Characterisation

Suitable tests are performed to elucidate the structure and other characteristics of the herbal preparation.

Control of Herbal Preparation

Specification

A satisfactory specification, with appropriate tests and limits has been provided for the herbal preparation

Analytical Procedures/ Validation of Analytical Procedures

Analytical methods are either those of the Ph Eur or have been fully validated.

Batch Analyses
Batch analysis data are provided and these comply with the proposed specification.

Justification of Specification
In general the proposed specification has been justified satisfactorily.

Reference Standards or Materials
Suitable details have been provided for the reference standard. A satisfactory certificate of analysis has been provided.

Container Closure System
The herbal preparation is stored in a suitable container closure system. A description of the container closure system and its specifications are provided. The stability data provided show no incompatibilities between the herbal preparation and the container. Confirmation is provided that the components of the containers comply with Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs.

Stability
Batches were packed in the final container closure system and stored under ICH real time, intermediate and accelerated conditions. The data support the storage conditions and shelf life.

HERBAL PRODUCT

Description and Composition of the Herbal Product
Atrosan Devil's Claw tablets are white oval film-coated tablets, with a length of 18.6±0.2mm, a width of 9.2±0.2 mm and a height 6.5±0.3 mm. The tablets are odourless and have a bitter taste.

As well as the herbal preparation, the finished product contains lactose monohydrate, maize starch, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate (vegetable source) and precipitated silica. In addition, the film coating contains talc, titanium dioxide, macrogol and hypromellose. The formulation has been in production for some time and the excipients used are conventional pharmacopoeial substances.

Manufacture
A flow diagram summarising the manufacturing process and in-process controls has been provided.

Control of Critical Steps and Intermediates
A number of in-process control tests are performed during the manufacturing process. All are considered adequate.

Process Validation and/or Evaluation

Process validation results for production scale batches show that the production process provides a reproducible product of satisfactory quality and consistency. All results were within the release specification.

Control of Excipients
All of the excipients comply with their respective current European Pharmacopoeial monograph. Assurance has been provided that the magnesium stearate is of plant origin.

Documentation has been provided from the supplier of the lactose monohydrate confirming that the lactose monohydrate is sourced from milk in the same condition as milk collected for human consumption.

Control of Herbal Product
Specification
The finished product specifications at release and end of shelf life are detailed and the tests and limits used were found to be satisfactory for a product of this nature.

Analytical Procedures
Satisfactory details have been provided on all analytical procedures and these analytical procedures are valid.

Batch Analyses
Satisfactory batch data have been provided to support the specifications.

Justification of Specification(s)
The proposed release and shelf-life specifications have, in general been adequately justified with respect to the parameters controlled and the limits applied.

Reference Standards or Materials
Suitable details have been provided for the reference standard. A satisfactory certificate of analysis has been provided.

Container Closure System
The tablets are packed in amber glass bottles (type III, conforming to Ph Eur standards) with coated aluminium foil sealing and an aluminium pilfer proof screw cap fitted with a polyethylene liner. These bottles may hold 30, 50, 60 or 120 tablets.

Alternatively, COC blister packages with PP/COC/PP triple layer wells and aluminium foil sealing may be used to store 50 or 120 tablets.

Confirmation is provided that all components of the blister pack comply with Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs.

Stability
Stability studies have been conducted under ICH conditions (long term, accelerated) on production scale batches in the container proposed for marketing. The tablets were tested in accordance with the finished product specification using the same test methods.

The results support the proposed shelf life of 36 months and no special storage precautions are required.

ASSESSOR'S COMMENTS ON THE SUMMARY OF PRODUCT CHARACTERISTICS, LABEL AND PATIENT INFORMATION LEAFLET

All product literature is satisfactory.

ASSESSOR'S OVERALL CONCLUSIONS ON QUALITY

A Traditional Herbal Registration can be granted.

NONCLINICAL ASSESSMENT

Nonclinical aspects

The Expert Safety Report submitted by the applicant lists relevant references to published work studying the toxicology of Devil's Claw root.

Nonclincial overview

The applicant has submitted a good literature review with this application. An Expert Safety Report was also provided, which included reviews of some non-clinical data. The Expert Safety Report was written by a medical doctor with expertise in herbal treatments and is dated June 2006.

The overview contains a review of some non-clinical data for *Harpagophyti extractum* (aka Devils Claw root). Some of the studies in the literature review were conducted and published before GLP was a regulatory requirement. Moreover, it is not possible to ascertain if the data assessed in the review would comply with today's regulatory safety testing requirements with regards to design, conduct and analysis.

Due to a shortage of published data on Devils Claw root, it is not possible to assess if the safety package for the phytochemical constituents of Devils Claw root 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 may be acceptable and in compliance with guideline EMEA/HMPC/32116/05.

Summary of product characteristics

The Summary of Product Characteristics for this product is satisfactory.

Environmental risk assessment

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

Conclusion

The information supplied demonstrating traditional use of Devils Claw root is acceptable. An adequate literature review of Devils Claw root has been carried out by the applicant and no new nonclinical data were submitted for assessment with this application. Granting of a THR is acceptable.

CLINICAL ASSESSMENT

LEGAL STATUS

The Herbal Medicines Advisory Committee (HMAC) considered Devil's Claw acceptable for the General Sales List for internal use.

PROPOSED INDICATION

The applicant has proposed the following:

'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.'

Assessor's comment

This is acceptable

EVIDENCE OF LONG-STANDING 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 Community.

The Applicant has provided evidence for the use of Devil's Claw within the EU for a period exceeding 30 years. Bioforce have marketed a product containing Devil's Claw since 1985 in the UK. Other solid dosage forms containing Devil's Claw have been available in the EU since 1976.

Assessor's comment:

The information provided to demonstrate that Devil's Claw root has been in use for at least 30 years, of which at least 15 years have been in an EU Member State, is satisfactory.

SAFETY REVIEW

Article 16 c 1 (D) requires the Applicant to provide a bibliographic review of safety data together with an expert report. These have been provided and are satisfactory.

PRECLINICAL REVIEW OF SAFETY

See Preclinical Assessment report.

Assessor's comment:

The safety review is acceptable and includes most major studies.

From the data available the applicant has concluded that side effects resulting from the use of Devil's Claw are uncommon and that clinical studies found the most commonly reported ADRs to be mild gastrointestinal disturbances such as nausea, abdominal pain and diarrhoea. All studies reviewed found Devil's Claw to be well tolerated and no serious ADRs were found. Similar findings were reported in the clinical study on Atrosan Devil's Claw tablets.

In the absence of sufficient data the use during pregnancy and lactation is not recommended.

PRODUCT LITERATURE
All product literature is satisfactory.

The 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.

DISCUSSION
The data supplied by the Applicant are sufficient to demonstrate 30 years of traditional use within the European Community for required for registration under the Traditional Herbal Medicines Product Directive. A review of the available safety data relating to Devil's Claw has been provided, together with an expert report supporting the registration of the product.

RECOMMENDATIONS
A Traditional Registration may be granted.

OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY
Bioforce AG has over 30 years of experience in manufacturing herbal medicinal products. The quality data submitted with this application are satisfactory.

PRECLINICAL
No preclinical data were submitted and none are required for an application of this type.

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

The Applicant has provided a bibliographic review which shows ample evidence for the use of Devil's claw root within the EU for a period exceeding 30 years.

The SPC, PIL and labelling are satisfactory.

RISK ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified.

ATROSAN DEVIL'S CLAW TABLETS

THR 13668/0012

STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the Traditional Herbal Registration application on 26 September 2006
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 2 January 2007
3	Following assessment of the application the MHRA requested further information relating to the dossier on 18 July 2007
4	The applicant responded to the MHRA's requests, providing further information on the dossier on 18 July 2007
5	Following assessment of the response the MHRA requested further information relating to the dossier on 19 July 2007
6	The applicant responded to the MHRA's requests, providing further information on the dossier on 11 January 2008
7	A THR was granted on 11 January 2008

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Atrosan Devil's Claw tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains 480mg of extract (as dry extract) from Devil's claw (*Harpagophytum procumbens* D.C. and/or *H. zeyheri* L. Decne.) root (1.5-3.0:1). Extraction solvent: Ethanol 60% V/V.
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.
It is an oval-shaped, white coated tablet.

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, based on traditional use only.

4.2 Posology and method of administration

Adults and the elderly: One tablet twice daily immediately after food.
The dose can be increased to two tablets twice daily if relief is not obtained after 3 to 5 days.
This product is not indicated in patients less than 18 years old.
For oral use only.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active substance or one of the excipients.
This product contains lactose. One film-coated tablet contains a maximum of 105 mg lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
Patients under 18 years of age.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.
If the condition worsens or symptoms persist for more than eight weeks, or if adverse effects not mentioned in the package leaflet occur, a doctor or a qualified health care practitioner should be consulted.
If articular pain accompanied by swelling of joint, redness or fever are present a doctor should be consulted.

The dosing and safety of Devil's claw have not been studied thoroughly in children and adolescents and safety is not established.
Some studies in animals have shown at high concentrations of Devil's claw possible calcium antagonistic effect similar to verapamil, caution should be taken when Devil's claw is administered to patients with cardiac disorders.
As a general precaution, patients with gastric or duodenal ulcer should not use Devil's claw preparations

4.5 Interaction with other medicinal products and other forms of interaction

There is no evidence, from limited interaction studies, that Devil's claw root extracts will interact with other medicinal products.

4.6 Pregnancy and lactation

The safety of the product during pregnancy and lactation has not been established. In the absence of sufficient data the 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. In rare cases some patients have experienced dizziness and somnolence while taking Devil's claw.

4.8 Undesirable effects

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

4.9 Overdose

There are no data on human overdose with Devil's claw. Symptomatic and supportive measures should be taken as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The active constituents of Devil's claw have not been definitely established. However, the iridoid glucoside constituents, such as harpagoside, are considered to play an important role in its activity. It is thought that Devil's claw root does not produce the biochemical effects on arachidonic acid metabolism characteristic of anti-arthritic drugs of the NSAIDs.

5.2 Pharmacokinetic properties

Non-clinical pharmacokinetic studies have not been conducted.

5.3 Preclinical safety data

The non-clinical toxicology data available for Devil's claw is limited. Non-clinical studies to investigate reproductive toxicity and carcinogenicity have not been performed.

Two *in vitro* studies have shown this Devil's claw extract to be non-mutagenic in the *Salmonella typhimurium* reverse mutation assay up to the dose of 5,000µg/plate, and non-clastogenic in the *in vitro* chromosome aberration test at concentrations up to 867.5µg/ml.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

For the tablet:
Lactose monohydrate
Maize starch
Cellulose, microcrystalline
Silica, colloidal anhydrous
Magnesium stearate (vegetable source)
Silica, precipitated

For the film coating:
Talc
Titanium dioxide
Macrogol
Hypromellose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.
Keep out of the reach and sight of children.

6.5 Nature and contents of container

Amber glass bottles (type III conforming to Ph.Eur. standards) with coated aluminium foil sealing and aluminium pilfer proof screw cap fitted with a polyethylene liner.

Pack sizes: 30 tablets
50 tablets
60 tablets
120 tablets

COC Blister packages with PP/COC/PP triple layer wells and aluminium foil sealing.

Pack sizes: 50 and 120 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Bioforce (UK) Ltd,
2 Brewster Place,
Irvine
KA11 5DD, UK
Telephone: 01294 277344
enquiries@avogel.co.uk

8 MARKETING AUTHORISATION NUMBER(S)

THR 13668/0012

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11/01/2008

10 DATE OF REVISION OF THE TEXT

11/01/2008

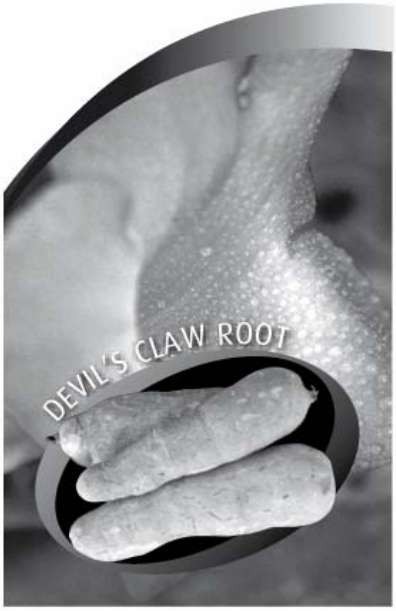
PATIENT INFORMATION LEAFLET

Package Leaflet:
Information for the User

A.Vogel

Atrosan®

Devil's Claw tablets



Information

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Atrosan carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- If you need more information or advice ask your doctor, pharmacist or other healthcare practitioner.
- Contact a doctor if your symptoms worsen or do not improve within 8 weeks.
- If any of the side effects become serious, or if you notice any side effect not listed in this leaflet, please speak to your doctor, pharmacist or healthcare practitioner.

In this leaflet:

Do's and Don'ts for using Atrosan

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

Atrosan is a traditional herbal medicinal product used for the relief of:

- Rheumatic or muscular pain
- General aches and pains in the muscles and joints
- Backache

This is based on traditional use only.

2. Before you take this product

Do not take this product if:

- You are allergic to Devil's claw (also known as Harpagophytum). This product contains Devil's claw root.
- You are allergic to any of the other ingredients in this product (see Section 6 Further Information).
- You have an ulcer (either a gastric and/or duodenal ulcer). Atrosan is not suitable for you.
- You are under 18 years old.

Tell your doctor if:

- Your symptoms worsen.
- You do not feel any benefit from Atrosan within 8 weeks.
- Your joint pain is accompanied by swelling of the joint, redness or a fever.
- You have heart problems and want to take Atrosan.

Using other medicines

- You can use Atrosan with other medicines.

Using this product with food and drink

- This product is best taken immediately after food.
- You can eat and drink as normal.

Pregnancy and breast-feeding

- Do not use if you are pregnant or breast-feeding.

Driving and using machines

- In rare cases Atrosan may cause dizziness and drowsiness. If this happens to you, do not drive or use machines.

Important information about some of the ingredients of Atrosan

- Do not use this product if you have been told by your doctor that you have an intolerance to products containing lactose. Atrosan contains lactose.

Please turn over...

Using

3. How to take this product

Adults and the elderly: Take one tablet twice daily immediately after food. The dose can be increased to two tablets twice daily if relief is not obtained after 3 to 5 days.

Not for use in children or those under 18. For oral use only. Don't take more than the recommended dose.

If you take more of this product than you should

- If you take too much and feel ill, talk to your doctor. Taking too much is unlikely to be harmful.

If you forget to take this product

- Don't worry about the missed dose. Take the next tablet as usual.

If you stop taking this product

- You can stop taking Atrosan at any time.

If you feel this product isn't working

- See your doctor if your symptoms worsen or do not improve within 8 weeks.

There is additional information in Section 6 at the end of this leaflet.

Side effects

4. Possible side effects

Like all medicines, Atrosan can cause side effects, although not everybody gets them.

Minor side effects

The following minor side effects can occur when using this product.

Digestive symptoms

- Stomach discomfort
- Feeling sick
- Digestive upsets such as sickness or diarrhoea

Other side effects

- Rash
- Itching
- Headache
- Dizziness

Discontinue use if you find these symptoms are troubling you. Talk to a doctor, pharmacist or other healthcare practitioner if you are concerned.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Information

5. How to store this product

- Keep out of the reach and sight of children.
- Do not use Atrosan after the expiry date which is stated on the packaging. The expiry date refers to the last day of the month.
- Atrosan does not require any special storage conditions.
- Do not use Atrosan if you notice a change in colour. The tablets should be white.

6. Further Information

What Atrosan tablets contain

The active ingredient contained in Atrosan is the extract from Devil's claw root, also otherwise known as *Harpagophytum procumbens* root.

1 film-coated tablet contains 480mg of extract (as dry extract) from Devil's claw root *(Harpagophytum procumbens* D.C. and/or *H. zeyheri* L. Decne.) (1.5-3.0:1). Extraction solvent: Ethanol 60% V/V.

The other ingredients used for the tablet are lactose, maize starch, microcrystalline cellulose, precipitated silica, colloidal silica and magnesium stearate (vegetable source).

The tablet coating contains talc, titanium dioxide, macrogol and hypromellose.

What this product looks like and the contents of the pack

Atrosan tablets are oval-shaped, white tablets. They are available in packs of 30, 50, 60 or 120 tablets. Not all pack sizes may be marketed.

Traditional Herbal Registration Holder and Manufacturer

Traditional Herbal Registration Holder and Batch Release:
Bioforce (UK) Ltd,
2 Brewster Place,
Irvine KA11 5DD

Manufacturer:
Bioforce AG, CH-9325, Roggwil
Switzerland

THR No. 13668/0012

This leaflet was approved on 01/2008

What is Devil's claw?

Devil's claw is a plant which is native to southern Africa. It produces storage tubers (roots) and it is the extract of these tubers which is used to make Atrosan.

You should also know

Bioforce runs a helpline by phone and email which can provide you with further information.

Email: **enquiries@avogel.co.uk**

Phone: 0845 608 5858

You can get a larger print or audio version of this leaflet.
Call this number:
0845 608 5858.

LABELLING

Labels:

Atrosan is a traditional herbal medicinal product used for the relief of rheumatic and muscular pains, general aches in joints and muscles and backache. This is based on traditional use only.

Directions for use: For oral use only. Read leaflet before use.
Adults and the elderly: Take one tablet twice daily immediately after food. The dose can be increased to two tablets twice daily if relief is not obtained after 3 to 5 days. Not for use in children or those under 18. Do not use if you are allergic to Devil's claw or any of the other ingredients; contains lactose.
Keep out of the reach and sight of children.

Traditional Herbal Registration Holder:
Bioforce (UK) Ltd, Irvine, UK, KA11 5DD
THR No. 13668/0012

60 tablets

A.Vogel

Atrosan®

Devil's claw tablets

Ingredients: 1 film-coated tablet contains 480 mg of extract (as dry extract) from Devil's claw root (*Harpagophytum procumbens* D.C. and/or *H. zeyheri* L. Decne.) (1.5-3.0:1). Extraction solvent: Ethanol 60% V/V. The other ingredients used for the tablet are lactose, maize starch, microcrystalline cellulose, precipitated silica, colloidal silica and magnesium stearate (vegetable source). The tablet coating contains talc, titanium dioxide, macrogol and hypromellose.

Batch:

EXP:

305261

Cartons:


A.Vogel
Atrosan®
Devil's claw tablets
30 tablets
Atrosan is a traditional herbal medicinal product used for the relief of:
• Rheumatic or muscular pain
• General aches and pains in the muscles and joints
• Backache
This is based on traditional use only.
Ingredients:
1 film-coated tablet contains 480 mg of extract (as dry extract) from Devil's claw root (Harpagophytum procumbens D.C. and/or H. zeyheri L. Decne.) (1.5-3.0:1). Extraction solvent: Ethanol 60% (V/V).
The other ingredients used for the tablet are lactose, maize starch, microcrystalline cellulose, precipitated silica, colloidal silica and magnesium stearate (vegetable source). The tablet coating contains talc, titanium dioxide, macrogol and hypromellose.
Traditional Herbal Registration Holder:
Bioforce (UK) Ltd.
Irvine, Ayrshire, UK, KA11 5DD
Telephone: 01294 277344
enquiries@avogel.co.uk
THR No. 13668/0012
Made in Switzerland
30 tablets
Directions for use:
Adults and the elderly: Take one tablet twice daily immediately after food. The dose can be increased to two tablets twice daily if relief is not obtained after 3 to 5 days.
Not for use in children or those under 18.
For oral use only. Read leaflet before use.
Do not use if you are allergic to Devil's claw or any of the other ingredients. This product contains lactose.
Keep out of the reach and sight of children.
Tablet Size
DEVIL'S CLAW ROOT
Traditional herbal medicinal product used for the relief of RHEUMATIC or MUSCULAR PAIN & BACKACHE
7 610313 303557
BATCH xxxxx
EXP xx.xxxx
Safety Sealed
Container. If seal
is broken or
missing, do not
use!
KSP5084-003, 2007-05-30

A.Vogel
Atrosan®
Devil's claw tablets
60 tablets
Atrosan is a traditional herbal medicinal product used for the relief of:
• Rheumatic or muscular pain
• General aches and pains in the muscles and joints
• Backache
This is based on traditional use only.
Ingredients:
1 film-coated tablet contains 480 mg of extract (as dry extract) from Devil's claw root (Harpagophytum procumbens D.C. and/or H. zeyheri L. Decne.) (1.5-3.0:1). Extraction solvent: Ethanol 60% V/V.
The other ingredients used for the tablet are lactose, maize starch, microcrystalline cellulose, precipitated silica, colloidal silica and magnesium stearate (vegetable source). The tablet coating contains talc, titanium dioxide, macrogol and hypromellose.
Traditional Herbal Registration Holder:
Bioforce (UK) Ltd.
Irvine, Ayrshire, UK, KA11 5DD
Telephone: 01294 277344
enquiries@avogel.co.uk
THR No. 13668/0012
Made in Switzerland
60 tablets
Directions for use:
Adults and the elderly: Take one tablet twice daily immediately after food. The dose can be increased to two tablets twice daily if relief is not obtained after 3 to 5 days.
Not for use in children or those under 18.
For oral use only. Read leaflet before use.
Do not use if you are allergic to devil's claw or any of the other ingredients. This product contains lactose.
Keep out of the reach and sight of children.
Traditional herbal medicinal product used for the relief of RHEUMATIC or MUSCULAR PAIN & BACKACHE
DEVIL'S CLAW ROOT
Tablet Size
7 610313 303557
BATCH xxxxx
EXP xx.xxxx
60 tablets
Safety Sealed Container. If seal is broken or missing, do not use!
KSP5084-003, 2007-05-30