

A.Vogel Milk Thistle Complex tablets

Digestisan Milk Thistle tablets

THR 13668/0028

UKPAR

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A.VOGEL MILK THISTLE COMPLEX TABLETS

DIGESTISAN MILK THISTLE TABLETS

THR 13668/0028

LAY SUMMARY

The Medicines and Healthcare Products Regulatory Agency (MHRA) granted Bioforce (UK) Ltd a Traditional Herbal Registration Certificate for the traditional herbal medicinal products A.Vogel Milk Thistle Complex tablets and Digestisan Milk Thistle tablets (Traditional Herbal Registration number: THR 13668/0028) on 25 February 2013. These products are identical to each other apart from the difference in product name and will be collectively referred to as Milk Thistle tablets in the remainder of this report. Milk Thistle tablets are available without prescription and can be bought from pharmacies and other outlets.

The active ingredients in Milk Thistle tablets come from the leaves of the Artichoke plant (*Cynara scolymus* L.), the fruit of the Milk Thistle plant (*Silybum marianum* (L.) Gaertner), the root and herb of the Dandelion plant (*Taraxacum officinalis* WEB.) and the leaves of the Boldo plant (*Peumus boldus* MOLINA.)

Milk Thistle tablets is a traditional herbal medicinal product used for indigestion, sensation of fullness and flatulence associated with over-indulgence of food or drink, or both.

This registration is based exclusively upon the longstanding use of Artichoke leaves, Milk Thistle fruit, Dandelion root and herb and Boldo leaves as traditional herbal medicines 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.

A.VOGEL MILK THISTLE COMPLEX TABLETS

DIGESTISAN MILK THISTLE TABLETS

THR 13668/0028

SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Milk Thistle tablets (THR 13668/0028) to Bioforce (UK) Ltd on 25 February 2013. 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. Milk Thistle tablets is a traditional herbal medicinal product used for indigestion, sensation of fullness and flatulence associated with over-indulgence of food or drink, or both, based on traditional use only.

There is sufficient evidence to demonstrate use of Artichoke leaves, Milk Thistle fruit, Dandelion root and herb and Boldo leaves for at least 30 years, of which at least 15 years have been in an EU Member State. A satisfactory review of the available safety data on these herbal substances has also been provided, together with an Expert Safety Report supporting the proposed product.

PHARMACEUTICAL ASSESSMENT

HERBAL SUBSTANCE: **ARTICHOKE LEAVES**

Scientific name of the plant: *Cynara scolymus* L.

Plant family: Asteraceae

Manufacture of Herbal Substance

The herbal substance is cultivated in Switzerland under organic conditions (according to EC Directive 2092/91). Harvest takes place from June to autumn, during the rosette or bud periods.

The supplier of the Artichoke leaves has provided confirmation that the herbal substance is produced in accordance with the principles of Good Agricultural and Collection Practice (GACP) (EMA/HMPC/246816/20050) and that the plant material is not treated with ethylene oxide or irradiation following harvesting.

Control of Herbal Substance

The specification for the herbal substance complies with the Ph Eur monograph and is satisfactory.

Container Closure System

No information has been provided and none is necessary.

Stability of Herbal Substance

No stability data is provided. This is acceptable as the leaves are processed within 24 hours after harvest.

HERBAL PREPARATION: **ARTICHOKE LEAVES DRY EXTRACT**

Extract solvent: Ethanol 65% V/V

Drug extract ratio (native): 1:30-31

Manufacture of Herbal Preparation

A satisfactory description of the manufacturing process of the herbal preparation and flow diagram has been provided. The in-process controls are satisfactorily detailed. 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 specifications.

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 current legislation relating to plastic materials and articles intended to come into contact with foodstuffs.

Stability of Herbal Preparation

Stability studies have been carried out under ICH conditions. The results support the proposed retest period of the herbal preparation.

HERBAL SUBSTANCE: MILK THISTLE FRUIT

Scientific name of the plant: *Silybum marianum* (L.) Gaertner
Plant family: Asteraceae

Manufacture of Herbal Substance

The herbal substance is cultivated in Europe. The fruit is harvested mechanically when fully ripe.

The supplier of the Milk Thistle fruit has provided confirmation that the herbal substance is produced in accordance with the principles of Good Agricultural and Collection Practice (GACP) (EMEA/HMPC/246816/20050) and that the plant material is not treated with ethylene oxide or irradiation following harvesting.

Control of Herbal Substance

The specification for the herbal substance complies with the Ph Eur monograph for Milk Thistle fruit and is satisfactory.

Container Closure System

No information has been provided and none is necessary.

Stability of Herbal Substance

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 necessary 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: MILK THISTLE FRUIT DRY EXTRACT

Extract solvent: Ethanol 58% V/V
Drug extract ratio (native): 1:2.0-2.1

Manufacture of Herbal Preparation

A satisfactory description of the manufacturing process of the herbal preparation and

flow diagram has been provided. The in-process controls are satisfactorily detailed. 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 specifications.

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 current legislation relating to plastic materials and articles intended to come into contact with foodstuffs.

Stability of Herbal Preparation

Stability studies have been carried out under ICH conditions. The results support the proposed retest period of the herbal preparation.

HERBAL SUBSTANCE: DANDELION ROOT AND HERB

Scientific name of the plant: *Taraxacum officinalis* WEB

Plant family: Asteraceae

Manufacture of Herbal Substance

The herbal substance is cultivated in Switzerland and Germany under organic conditions (according to EC Directive 2092/91). Harvest takes place in April just before the flowering period. Following harvest the roots and herbs are washed and processed.

The supplier of the Dandelion root and herb has provided confirmation that the herbal substance is produced in accordance with the principles of Good Agricultural and Collection Practice (GACP) (EMEA/HMPC/246816/20050) and that the plant material is not treated with ethylene oxide or irradiation following harvesting.

Control of Herbal Substance

The herbal substance is controlled by a suitable in-house specification; as there is no Ph Eur monograph for Dandelion root and herb this is satisfactory.

Container Closure System

No information has been provided and none is necessary.

Stability of Herbal Substance

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 necessary 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: DANDELION ROOT AND HERB

Extract solvent: Ethanol 51% V/V

Drug extract ratio (native): 1:17-18

Manufacture of Herbal Preparation

A satisfactory description of the manufacturing process of the herbal preparation and flow diagram has been provided. The in-process controls are satisfactorily detailed. 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 specifications.

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 current legislation relating to plastic materials and articles intended to come into contact with foodstuffs.

Stability of Herbal Preparation

Stability studies have been carried out under ICH conditions. The results support the proposed retest period of the herbal preparation.

HERBAL SUBSTANCE: BOLDO LEAVES

Scientific name of the plant: *Peumus boldus* MOLINA

Plant family: Monimiaceae

Manufacture of Herbal Substance

The herbal substance is hand collected in Chile. The leaves are then dried, packed in bags and stored in a cool place protected from light and humidity.

The supplier of the Boldo leaves has provided confirmation that the herbal substance is produced in accordance with the principles of Good Agricultural and Collection

HERBAL PRODUCT:

MILK THISTLE TABLETS

Description and Composition of Herbal Product

Milk Thistle tablets are beige-coloured, round, biconvex tablets. Each tablet contains 4.6 mg of dry extract from fresh Artichoke leaves, 3.2 mg of dry extract from Milk Thistle fruit, 1.2 mg of dry extract from fresh Dandelion root and herb and 0.7 mg of dry extract from Boldo leaves and the excipients microcrystalline cellulose and hydrogenated cottonseed oil.

The compatibility of the herbal preparations 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.

Manufacture of Herbal Product

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 products and the method of manufacture. Process validation has been carried out on commercial batches and the results are satisfactory.

Control of Herbal Product

The finished product specifications are 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 tablets are stored in type III glass, amber bottles enclosed by a coated aluminium sealing foil and aluminium pilfer proof cap fitted with a polyethylene liner. The product is available in packs 60 tablets.

Suitable specifications have been provided by the packaging suppliers and it has been confirmed that all primary packaging materials comply with Directive 2002/72/EC.

Stability of Herbal Product

Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a product shelf-life of 1 year is appropriate.

Pharmaceutical Expert

The Quality Overall Summary has been written by an expert with suitable experience.

Product Literature

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.

CONCLUSION

There are no objections to granting of a Traditional Herbal Registration from a quality point of view.

NON-CLINICAL ASSESSMENT

NON-CLINICAL OVERVIEW

An Expert Safety Report was provided, which includes reviews of some non-clinical data. The Expert Safety Report was written by a suitably qualified professional. In addition, the Committee on Herbal Medicinal Products (HMPC) Community Monograph and assessment report for Dandelion root and herb, Boldo leaves and Milk Thistle fruit adequately cover the non-clinical safety issues for these herbal preparations.

Due to a shortage of published data on Artichoke leaves, Dandelion root and herb, Boldo leaves and Milk Thistle fruit, it is not possible to assess if the safety package for the phytochemical constituents of this active ingredient 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.

The overview submitted in support of this application is satisfactory.

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

INDICATIONS

The submitted the following therapeutic indications:

“A traditional herbal medicinal product used for indigestion, sensation of fullness and flatulence associated with over-indulgence of food or drink, or both, based on traditional use only.”

These indications are acceptable.

POSOLOGY AND METHOD OF ADMINISTRATION

The applicant has submitted the following:

“For oral use only.

Adults and the elderly (18 years and over): Take 1 tablet twice a day.

If symptoms worsen or do not improve after 2 weeks a doctor or qualified healthcare practitioner should be consulted.

Not for children or adolescents under 18 years (see also 4.4 Special warnings and precautions for use).”

This is acceptable.

EFFICACY

No clinical efficacy data is required for registration of Traditional Herbal Medicinal Products.

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 European Community.

Evidence has been presented to demonstrate that a product similar to Milk Thistle tablets based on 10 ingredients has been available in Switzerland since 1974. The formulation was modified to a five ingredient formulation in 1978 and made available Germany. The proposed indication for Milk Thistle tablets is in line with the traditional indications for all four drug substances and the HMPC monographs for Dandelion root with herb and Boldo leaf and the draft monograph for Artichoke leaf. In addition, a number of THRs have already been granted for products containing Milk Thistle fruit.

The requirements of the Directive are, therefore, 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 Reports for Dandelion root and herb and Boldo leaves cover the bibliographic data available and the safety of Dandelion root and herb and Boldo leaves has been demonstrated. Satisfactory safety data are also provided for Artichoke leaves and Milk Thistle fruit in this application.

PRODUCT LITERATURE

The SmPC, PIL and labelling for this product are medically satisfactory.

CONCLUSION

There are no objections to granting of a Traditional Herbal Registration from a clinical point of view.

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, the published HMPC assessment report and Community Monograph for Dandelion root and herb and Boldo leaves adopted by the HMPC adequately cover the non-clinical safety issues associated with these herbal preparations. Adequate references are provided for Artichoke leaves and Milk Thistle fruit.

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 Dandelion root and herb and Boldo leaves adopted by the HMPC adequately cover the evidence for traditional use of the extract in the product under assessment for at least 30 years and the clinical safety issues associated with these herbal preparations. Satisfactory safety data are also provided for Artichoke leaves and Milk Thistle fruit.

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 benefit: risk balance is acceptable and a Traditional Herbal Registration may be granted.

A.VOGEL MILK THISTLE COMPLEX TABLETS

DIGESTISAN MILK THISTLE TABLETS

THR 13668/0028

STEPS TAKEN FOR ASSESSMENT

- 1 The MHRA received the Traditional Herbal Registration application on 2 June 2011
- 2 Following standard checks and communication with the applicant the MHRA considered the application valid on 16 June 2011
- 3 Following assessment of the application the MHRA requested further information relating to the clinical dossier on 8 December 2011 and the quality dossier on 9 January 2012
- 4 The applicant responded to the MHRA's request, providing further information on the clinical and quality dossiers on 11 July 2012
- 5 Following assessment of the response the MHRA requested further information relating to the quality dossier on 3 August 2012
- 6 The applicant responded to the MHRA's request, providing further information on the quality dossier on 9 January 2013
- 7 A THR was granted on 25 February 2013

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

A.Vogel Milk Thistle Complex tablets
Digestisan Milk Thistle tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet contains:

- 4.6 mg of extract (as dry extract) from fresh Artichoke leaves (*Cynara scolymus* L., folium) (1:30-31). Extraction solvent: Ethanol 65% V/V.
- 3.2 mg of extract (as dry extract) from Milk Thistle fruit (*Silybum marianum* (L.) Gaertn., fructus) (1:2.0-2.1). Extraction solvent: Ethanol 58% V/V
- 1.2 mg of extract (as dry extract) from fresh Dandelion root and herb (*Taraxacum officinalis* WEB., radix cum herba) (1:17-18. Extraction solvent: Ethanol 51% V/V.
- 0.7 mg of extract (as dry extract) from Boldo leaves (*Peumus boldus* MOLINA., folium) (1:10-11). Extraction solvent: Ethanol 70% V/V

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablets
Beige-coloured, round, biconvex tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used for indigestion, sensation of fullness and flatulence associated with over-indulgence of food or drink, or both, based on traditional use only.

4.2 Posology and method of administration

For oral use only.

Adults and the elderly (18 years and over): Take 1 tablet twice a day.

If symptoms worsen or do not improve after 2 weeks a doctor or qualified healthcare practitioner should be consulted.

Not for children or adolescents under 18 years (see also 4.4 Special warnings and precautions for use).

4.3 Contraindications

Hypersensitivity to any of the active substances or to plants of the Asteraceae (Compositae) family or to any of the excipients.

Patients with:

- obstruction of the bile duct or intestinal tract,
- cholangitis,
- liver disease including hepatitis,
- gallstones, active peptic ulcer and any other biliary disorders

4.4 Special warnings and precautions for use

Do not exceed stated dose.

Patients with renal failure and/or diabetes, and/or heart failure should avoid taking the product because of possible complications due to hyperkalaemia.

Patients suffering from active liver disease should consult their doctor before taking the product.

If the condition worsens or does not improve after two weeks, consult a doctor or a qualified healthcare practitioner.

Use in children and adolescents under 18 years of age is not recommended because data are insufficient and medical advice should be sought.

4.5 Interaction with other medicinal products and other forms of interaction

None reported.

In vitro Milk Thistle extract resulted in inhibition of CYP isoenzymes. However, the clinical relevance of these findings is not known.

4.6 Fertility, pregnancy and lactation

The safety of this product during pregnancy and lactation has not been established.

In view of the pre-clinical safety data (see section 5.3) the use of this product during pregnancy and lactation is not recommended.

Studies on fertility have not been performed.

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.

4.8 Undesirable effects

Hypersensitivity and allergic reactions have been reported including reports of anaphylaxis with products containing Boldo.

Mild gastrointestinal symptoms such as nausea, diarrhoea with abdominal spasm, abdominal pain, hyperacidity and heartburn, headache and allergic reactions (urticaria, skin rash, pruritis, anaphylaxis) may occur.

The frequency is not known.

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

4.9 Overdose

No case of overdose has been reported.

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

Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed with the product.

Tests on reproductive toxicity have been performed with a dry ethanolic extract of boldo leaf and boldine administered orally to pregnant rats. Results showed anatomical alterations in the fetus and a few cases of abortion at high rates.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Hydrogenated cottonseed oil

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

1 year unopened

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

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

Pack sizes: 60 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, Ayrshire
KA11 5DD, United Kingdom
Tel: 01294 277344
enquiries@avogel.co.uk

8 MARKETING AUTHORISATION NUMBER(S)

THR 13668/0028

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25/02/2013

10 DATE OF REVISION OF THE TEXT

25/02/2013

PATIENT INFORMATION LEAFLETS



Patient Information Leaflet

A.Vogel

Milk Thistle
Complex tablets



Information

Important things you need to know

- This product is for relieving indigestion and feelings of fullness and flatulence associated with over-indulgence of food or drink or both.
- This product is suitable for adults over 18 years.
- **Don't take** this product if you are allergic to any of the ingredients: see section 6.
- **Before you take this product:** read section 2.
- **Dosage instructions:** see section 3.
- **Talk to your doctor** if your symptoms worsen or you do not feel any benefit from this product within 2 weeks.
- Side effects are minor: see section 4.

Now read the rest of this leaflet carefully. Keep this leaflet. You may need to read it again.

1. What this product is for

Milk Thistle Complex is a traditional herbal medicinal product used for the relief of:

- Indigestion
- Feelings of fullness and flatulence associated with over-indulgence of food or drink or both

This is based on traditional use only.

Do's & Don'ts

2. Before you use this product

Do not take this product:

- If you are under 18 years of age.
- If you are **allergic** to:
 - Any of the ingredients in this product (see section 6)
 - Plants of the daisy (Asteraceae/Compositae) family. Artichoke, Dandelion and Milk Thistle are members of the daisy family.
- If you **suffer** from:
 - Blockage of the bile duct
 - Blockage of the intestine
 - Inflammation of the bile duct (cholangitis)
 - Gallstones
 - Biliary disorders
 - Peptic ulcer
 - Liver disease including hepatitis
 - Kidney failure
 - Diabetes
 - Heart failure
- If you are pregnant or breast-feeding.

Using

3. How to use this product

Adults and the elderly: Take one tablet twice daily.

For oral use only. Don't take more than the recommended dose.

Not for use in children or those under 18.

If you take too much

- 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 dose as usual.

If you feel this product isn't working

- See your doctor if your symptoms worsen or do not improve within 2 weeks.

Please turn over...



Side effects

4. Possible side effects

Like all medicines, this product 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

- Feeling sick (nausea)
- Diarrhoea accompanied by stomach cramps
- Abdominal pain
- Increase in stomach acid
- Heartburn

Other

- Headache

These are often short-lived and should go away by themselves. However if they are troubling you, talk to your doctor or pharmacist.

Allergic reactions

- Red, itchy spots (urticaria)
- Rash
- Itching (pruritis)

Stop taking the product if these occur.

- Difficulty breathing or dizziness (anaphylaxis)

Stop taking the product immediately if this occurs. Seek medical advice and take this leaflet with you.



If you are concerned about any side effect 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 this product after the expiry date on the packaging. The expiry date refers to the last day of that month.
- This product does not require any special storage conditions.
- Do not use this product if you notice a change in colour. The tablets should be beige in colour.

6. Further Information

What this product contains

1 tablet contains the extracts (as dry extract) of:

Fresh Artichoke leaves 4.6 mg
(*Cynara scolymus* L.) (1:30-31)
Extraction solvent: ethanol 65% V/V

Milk Thistle fruit 3.2 mg
(*Silybum marianum* L. Gaertn.) (1:2.0-2.1)
Extraction solvent: ethanol 58% V/V

Fresh Dandelion root & herb 1.2 mg
(*Taraxacum officinalis* WEB.) (1:17-18)
Extraction solvent: ethanol 51% V/V

Boldo leaves 0.7 mg
(*Peumus boldus* MOLINA) (1:10-11)
Extraction solvent: ethanol 70% V/V

The other ingredients used for the tablets are microcrystalline cellulose and hydrogenated cottonseed oil.

What this product looks like and the contents of the pack

The tablets are round and beige in colour. Milk Thistle Complex is available in packs containing 60 tablets.

Traditional Herbal Registration Holder and Manufacturer

Traditional Herbal Registration Holder and Batch Release:

Bioforce (UK) Ltd,
2 Brewster Place,
Irvine, Ayrshire, UK
KA11 5DD

Manufacturer:

Bioforce AG, CH-9325, Roggwil
Switzerland

THR No. 13668/0028



Certification Mark

This leaflet was approved on 01/2013

About the ingredients of Milk Thistle Complex

- Artichoke and Dandelion are flowering plants which have been used as food throughout the world for many years.

- Milk Thistle is a flowering plant which is native to the Mediterranean. The extract of the fruits are used to make Milk Thistle Complex.
- Boldo is an evergreen shrub which is native to South America. The extract of the leaves is used to make Milk Thistle Complex.

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 help to make medicines safer by reporting any side effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. Alternatively you can get a paper Yellow Card form from your doctor's surgery or pharmacy, or call freephone 0800 100 3352 (available 10am-2pm Monday-Friday).

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



Patient Information Leaflet

A.Vogel

Digestisan

Milk Thistle tablets



Information

Important things you need to know

- This product is for relieving indigestion and feelings of fullness and flatulence associated with over-indulgence of food or drink or both.
- This product is suitable for adults over 18 years.
- **Don't take** this product if you are allergic to any of the ingredients: see section 6.
- **Before you take this product:** read section 2.
- **Dosage instructions:** see section 3.
- **Talk to your doctor** if your symptoms worsen or you do not feel any benefit from this product within 2 weeks.
- Side effects are minor: see section 4.

Now read the rest of this leaflet carefully. Keep this leaflet. You may need to read it again.

1. What this product is for

Digestisan Milk Thistle tablets are a traditional herbal medicinal product used for the relief of:

- Indigestion
- Feelings of fullness and flatulence associated with over-indulgence of food or drink or both

This is based on traditional use only.



Do's & Don'ts

2. Before you use this product

Do not take this product:

- If you are under 18 years of age.
- If you are **allergic** to:
 - Any of the ingredients in this product (see section 6)
 - Plants of the daisy (Asteraceae/Compositae) family. Artichoke, Dandelion and Milk Thistle are members of the daisy family.
- If you **suffer** from:
 - Blockage of the bile duct
 - Blockage of the intestine
 - Inflammation of the bile duct (cholangitis)
 - Gallstones
 - Biliary disorders
 - Peptic ulcer
 - Liver disease including hepatitis
 - Kidney failure
 - Diabetes
 - Heart failure
- If you are pregnant or breast-feeding.



Using

3. How to use this product

Adults and the elderly: Take one tablet twice daily.

For oral use only. Don't take more than the recommended dose.

Not for use in children or those under 18.

If you take too much

- 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 dose as usual.

If you feel this product isn't working

- See your doctor if your symptoms worsen or do not improve within 2 weeks.

Please turn over...

Side effects

4. Possible side effects

Like all medicines, this product 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

- Feeling sick (nausea)
- Diarrhoea accompanied by stomach cramps
- Abdominal pain
- Increase in stomach acid
- Heartburn

Other

- Headache

These are often short-lived and should go away by themselves. However if they are troubling you, talk to your doctor or pharmacist.

Allergic reactions

- Red, itchy spots (urticaria)
- Rash
- Itching (pruritis)

Stop taking the product if these occur.

- Difficulty breathing or dizziness (anaphylaxis)

Stop taking the product immediately if this occurs. Seek medical advice and take this leaflet with you.



If you are concerned about any side effect 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 this product after the expiry date on the packaging. The expiry date refers to the last day of that month.
- This product does not require any special storage conditions.
- Do not use this product if you notice a change in colour. The tablets should be beige in colour.

6. Further Information

What this product contains

1 tablet contains the extracts (as dry extract) of:

Fresh Artichoke leaves 4.6 mg
(*Cynara scolymus* L.) (1:30-31)
Extraction solvent: ethanol 65% V/V

Milk Thistle fruit 3.2 mg
(*Silybum marianum* L. Gaertn.) (1:2.0-2.1)
Extraction solvent: ethanol 58% V/V

Fresh Dandelion root & herb 1.2 mg
(*Taraxacum officinalis* WEB.) (1:17-18)
Extraction solvent: ethanol 51% V/V

Boldo leaves 0.7 mg
(*Peumus boldus* MOLINA) (1:10-11)
Extraction solvent: ethanol 70% V/V

The other ingredients used for the tablets are microcrystalline cellulose and hydrogenated cottonseed oil.

What this product looks like and the contents of the pack

The tablets are round and beige in colour. Digestisan Milk Thistle tablets are available in packs containing 60 tablets.

Traditional Herbal Registration Holder and Manufacturer

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

Manufacturer:
Bioforce AG, CH-9325, Roggwil
Switzerland

THR No. 13668/0028



Certification Mark

This leaflet was approved on 01/2013

About the ingredients of Digestisan Milk Thistle tablets

- Artichoke and Dandelion are flowering plants which have been used as food throughout the world for many years.

- Milk Thistle is a flowering plant which is native to the Mediterranean. The extract of the fruits are used to make Digestisan Milk Thistle tablets.

- Boldo is an evergreen shrub which is native to South America. The extract of the leaves is used to make Digestisan Milk Thistle tablets.

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 help to make medicines safer by reporting any side effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. Alternatively you can get a paper Yellow Card form from your doctor's surgery or pharmacy, or call freephone 0800 100 3352 (available 10am-2pm Monday-Friday).

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

LABELLING

A.Vogel Milk Thistle Complex tablets

Label:

Milk Thistle Complex is a traditional herbal medicinal product used for the relief of indigestion and feelings of fullness and flatulence associated with over-indulgence of food or drink or both. This is based on traditional use only.

Directions for use: Adults and the elderly: Take one tablet twice daily. Not for use in children or those under 18. For oral use only. Read leaflet before use.

Do not use if you are pregnant or breast-feeding.
Keep out of the reach and sight of children. This product does not require any special storage conditions.

Traditional Herbal Registration Holder:
Bioforce (UK) Ltd, Irvine, UK, KA11 5DU
THR No. 13668/0028

60 tablets

A.Vogel

Milk Thistle

Complex tablets

Ingredients: 1 tablet contains the extracts (as dry extract) of:

Fresh Artichoke leaves (<i>Cynara scolymus</i> L.)	4.6 mg
Milk Thistle fruit (<i>Silybum marianum</i> L. Gaertn.)	3.2 mg
Fresh Dandelion root & herb (<i>Taraxacum officinale</i> WEB.)	1.2 mg
Boldo leaves (<i>Peumus boldus</i> MOLINA)	0.7 mg

Safety Sealed Container. If ring at bottom of cap is missing or separated, do not use.

EXP:

Batch:

tech.data

0911 4476 / 7077 1160

137000X

Assumed / 06mm



Label:

Traditional Herbal Registration Holder:
Bioforce (UK) Ltd, Irvine, UK, KA11 5DD
THR No. 13668/0028

60 tablets



Ingredients: 1 tablet contains the extracts (as dry extract) of:

Fresh Artichoke leaves (<i>Cynara scolymus</i> L.)	4.6 mg
Milk Thistle fruit (<i>Silybum marianum</i> L. Gaertn.)	3.2 mg
Fresh Dandelion root & herb (<i>Taraxacum officinale</i> WEB.)	1.2 mg
Boldo leaves (<i>Peumus boldus</i> MOLINA)	0.7 mg

Safety Sealed Container. If ring at bottom of cap is missing or separated, do not use.

EXP:
Batch:

tech.data



09114400/dcmmy

Carton:

