Gerard House Max Strength Milk Thistle Tablets

(TM 20894/0071)

Gerard House Milk Thistle Tablets
HERBALSTORE Milk Thistle Tablets
Wilko Milk Thistle Tablets

(TM 20894/0072)

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TABLE OF CONTENTS

Lay summary .......................................................... Page 2
Scientific discussion ............................................. Page 3
Steps taken for assessment ................................ Page 12
Summaries of Product Characteristics ................ Page 13
Product Information Leaflets .............................. Page 21
Labelling ................................................................. Page 25
LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Brunel Healthcare Manufacturing Limited Traditional Herbal Registration Certificates for the traditional herbal medicinal products Gerard House Max Strength Milk Thistle Tablets (Traditional Herbal Registration number: THR 20894/0071) and Gerard House Milk Thistle Tablets, HERBALSTORE Milk Thistle Tablets and Wilko Milk Thistle Tablets (Traditional Herbal Registration number: THR 20894/0072) on 14 March 2012. Gerard House Max Strength Milk Thistle Tablets will be referred to as Max Strength Milk Thistle Tablets in the remainder of this report. Gerard House Milk Thistle Tablets, HERBALSTORE Milk Thistle Tablets and Wilko Milk Thistle Tablets are identical to each other apart from the difference in product names and will be collectively referred to as Milk Thistle Tablets in the remainder of this report. These products are available without prescription and can be bought from pharmacies and other outlets.

Max Strength Milk Thistle Tablets and Milk Thistle Tablets are traditional herbal medicinal products used to relieve the symptoms associated with occasional overindulgence of food and drink such as indigestion and upset stomach, based on traditional use only. The active ingredient of Max Strength Milk Thistle Tablets and Milk Thistle Tablets comes from the fruit of the Milk thistle plant (*Silybum marianum* (L.) Gaertner).

These registrations are based exclusively upon the longstanding use of Milk thistle fruit 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 these applications and it was, therefore, decided that Traditional Herbal Registration Certificates could be granted.
GERARD HOUSE MAX STRENGTH MILK THISTLE TABLETS  
(THR 20894/0071)  
GERARD HOUSE MILK THISTLE TABLETS  
HERBALSTORE MILK THISTLE TABLETS  
WILKO MILK THISTLE TABLETS  
(THR 20894/0072)  

SCIENTIFIC DISCUSSION  

TABLE OF CONTENTS  

Introduction  
Page 4  

Pharmaceutical assessment  
Page 5  

Non clinical assessment  
Page 8  

Clinical assessment  
Page 9  

Overall conclusions and risk assessment  
Page 11
INTRODUCTION

The MHRA granted Traditional Herbal Registration Certificates for the traditional herbal medicinal products Max Strength Milk Thistle Tablets (THR 20894/0071) and Milk Thistle Tablets (THR 20894/0072) to Brunel Healthcare Manufacturing Limited on 14 March 2012. These products are on the general sales list (GSL).

These applications were submitted according to Article 16.c of Directive 2001/83 EC, as amended, as part of the Traditional Herbal Medicines Registration Scheme. The products are used to relieve the symptoms associated with occasional over indulgence of food and drink, such as indigestion and upset stomach, based on traditional use only.

The data supplied by the applicant demonstrate 30 years of traditional use of Milk thistle fruit in the EU. A satisfactory review of the available safety data on Milk thistle fruit has also been provided, together with an Expert Safety Report supporting the proposed products.
## PHARMACEUTICAL ASSESSMENT

**HERBAL SUBSTANCE:** MILK THISTLE FRUIT  
**Latin name of plant:** *Silybum marianum* (L.) Gaertner  
**Common name of plant:** Milk thistle  
**Plant family:** Asteraceae

The Milk thistle fruit used in this product are grown in Europe and are harvested during July and August.

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 during growing or storage.

### Control of Herbal Substance
An appropriate specification based on the Ph Eur monograph 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 current legislation relating to plastic materials and articles intended to come into contact with foodstuffs.

### Stability
Satisfactory stability studies have been carried out on the Milk thistle fruit.

## HERBAL PREPARATION: MILK THISTLE FRUIT DRY EXTRACT

**Drug extract ratio:** 20-40:1  
**Extraction solvent:** Ethyl acetate 100 % v/v

### Manufacture
A satisfactory description of the manufacturing process of the herbal preparation and flow diagram have 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 current legislation 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 Milk thistle fruit dry extract is acceptable.

**HERBAL PRODUCTS: MAX STRENGTH MILK THISTLE TABLETS**

**MILK THISTLE TABLETS**

**Description and Composition of the Herbal Products**
Max Strength Milk Thistle Tablets are pale yellow caplet shaped film coated tablets and Milk Thistle Tablets are yellow circular biconvex film coated tablets. Max Strength Milk Thistle Tablets contain 500 mg of standardised dry extract from Milk thistle fruit and Milk Thistle Tablets contain 125 mg of standardised dry extract from Milk thistle fruit. The tablet cores of these tablets are composed of calcium carbonate, maltodextrin, croscarmellose sodium, microcrystalline cellulose, colloidal anhydrous silica and magnesium stearate. The tablets are coated in hypromellose and purified talc.

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. The magnesium stearate used in the products is confirmed to be of vegetable origin. Certificates of Analysis have been provided for all excipients.

**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 products and the method of manufacture. Currently, process validation has not been carried out on commercial batches, however, as the manufacturer has committed to carry out process validation on commercial batches following an appropriate process validation protocol, this is acceptable.

**Control of Herbal Products**
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 Systems
The tablets are sealed into PVC/PVDC aluminium foil blisters that are inserted into a carton. Each carton contains 30, 60 or 120 tablets.

Suitable specifications have been provided by the packaging suppliers and it has been confirmed that all primary packaging materials comply with current legislation relating to plastic materials and articles intended to come into contact with foodstuffs.

Stability
Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a product shelf-life of 24 months 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 suitably experienced expert.

Summaries of Product Characteristics, Labels and Patient Information Leaflets
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 Traditional Herbal Registration Certificates from a quality point of view.
NON-CLINICAL ASSESSMENT

NON-CLINICAL OVERVIEW
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.

Due to a shortage of published data on Milk thistle fruit it is not possible to assess if the safety package for the phytochemical constituents of Milk thistle fruit 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.

Assurance has been given that the results of genotoxicity testing will be provided before the renewal date of the Traditional Herbal Registrations.

The overview submitted in support of this application is satisfactory.

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The SmPCs for these products are 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 Certificates from a non-clinical point of view.
CLINICAL ASSESSMENT

INDICATION
The applicant has proposed the following therapeutic indication for both products:

‘A traditional herbal medicinal product used to relieve the symptoms associated with occasional over indulgence of food and drink such as indigestion and upset stomach based on traditional use only.’

The indication is acceptable.

POSOLOGY AND METHOD OF ADMINISTRATION
For the Max Strength Milk Thistle Tablets the applicant has proposed the following:

“For oral use only.
Swallow the tablets whole with water. Do not chew.

Adults and the elderly: The recommended dosage is 1 tablet daily, before a meal.
Children and adolescents under 18 years old: This medicine is not recommended for children and adolescents under 18 years of age (see Section 4.4 Special warnings and precautions for use).”

For the Milk Thistle Tablets the applicant has proposed the following:

“For oral use only.
Swallow the tablets whole with water. Do not chew.

Adults and the elderly: The recommended dosage is 1 - 2 tablets twice daily, before a meal.
Children and adolescents under 18 years old: This medicine is not recommended for children and adolescents under 18 years of age (see Section 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 EU.

The applicant has provided a bibliographic review as evidence of the use of Milk thistle fruit within the EU for a period exceeding 30 years.
The information provided is considered to satisfy the requirement to demonstrate use for at least 30 years, of which at least 15 years have been in an EU Member State. The requirements of the Directive are, therefore, addressed for this aspect.

**SAFETY REVIEW**
Article 16 c 1 (d) requires the applicant to provide a bibliography of the safety data together with an Expert Safety Report.

A safety review has been provided as well as an Expert Safety Report written by a suitably qualified professional. These are satisfactory.

**PRODUCT LITERATURE**
The SmPCs, PILs and labelling for these products are medically satisfactory.

**CONCLUSION**
There are no objections to granting of Traditional Herbal Registration Certificates from a clinical point of view.
OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY
The quality data submitted with these applications are satisfactory.

NON-CLINICAL
No new non-clinical data were submitted with these applications. The results of genotoxicity testing will be provided before the Traditional Herbal Registrations are renewed.

EFFICACY AND SAFETY
No clinical efficacy data are required for registration of Traditional Herbal Medicinal Products. The applicant has provided a bibliographic review which shows ample evidence for the use of Milk thistle fruit within the EU for a period exceeding 30 years.

A satisfactory review of the safety data has also been provided.

The SmPCs, PILs and labelling are satisfactory.

RISK ASSESSMENT
The quality of the products is acceptable and no new non-clinical or clinical safety concerns have been identified. The benefit: risk balance is acceptable and Traditional Herbal Registration Certificates may be granted.
GERARD HOUSE MAX STRENGTH MILK THISTLE TABLETS  
(THR 20894/0071) 

GERARD HOUSE MILK THISTLE TABLETS  
HERBALSTORE MILK THISTLE TABLETS  
WILKO MILK THISTLE TABLETS  
(THR 20894/0072)  

STEPS TAKEN FOR ASSESSMENT

1 The MHRA received the Traditional Herbal Registration applications on 1 April 2011
2 Following standard checks and communication with the applicant the MHRA considered the applications valid on 9 May 2011
3 Following assessment of the applications the MHRA requested further information relating to the quality dossiers on 8 August 2011 and the clinical dossiers on 25 August 2011
4 The applicant responded to the MHRA’s requests, providing further information on the clinical dossiers on 4 October 2011 and the quality dossiers on 19 October 2011
5 Following assessment of the response the MHRA requested further information relating to the quality dossiers on 26 October 2011
6 The applicant responded to the MHRA’s request, providing further information on the quality dossiers on 7 November 2011
7 Following assessment of the response the MHRA requested further information relating to the quality dossiers on 17 November 2011
8 The applicant responded to the MHRA’s request, providing further information on the quality dossier on 8 March 2012
9 THRs were granted on 14 March 2012
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Gerard House Max Strength Milk Thistle Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each film coated tablet contains 500 mg of standardised extract (as dry extract) from Milk Thistle fruits (Silybum marianum (L.) Gaertner) (equivalent to 10.0 – 20.0 g of Milk Thistle fruits) corresponding to 250 – 300 mg of silymarin calculated as silibinin.

Extract solvent: Ethyl acetate 100 % v/v

For full list of excipients, see 6.1

3 PHARMACEUTICAL FORM
Film coated tablet.
Pale yellow caplet shaped tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
A traditional herbal medicinal product used to relieve the symptoms associated with occasional over indulgence of food and drink such as indigestion and upset stomach based on traditional use only.

4.2 Posology and method of administration
For oral use only.
Swallow the tablets whole with water. Do not chew.

Adults and the elderly: The recommended dosage is 1 tablet daily, before a meal.
Children and adolescents under 18 years old: This medicine is not recommended for children and adolescents under 18 years of age (see Section 4.4 Special warnings and precautions for use).

4.3 Contraindications
Hypersensitivity to Milk Thistle or to plants of the Asteraceae/Compositae family or to any of the excipients.

4.4 Special warnings and precautions for use
Do not exceed the stated dose.

Patients suffering from active liver disease should consult their doctor before taking this product.
Milk Thistle may alter the way that certain drugs are broken down by the liver (see Section 4.5 Interaction with other medicinal products and other forms of interaction).

The use in children and adolescents under 18 years of age is not recommended as there is no relevant indication.

If symptoms worsen or persist during the use of the product a doctor or qualified healthcare practitioner should be consulted.

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Fertility, pregnancy and lactation

The safety of this product during pregnancy and lactation has not been established. In the absence of sufficient data the use in pregnancy and lactation is not recommended.

Studies on the effects on fertility have not been performed.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Gastrointestinal reactions (nausea, upset stomach, diarrhoea), headache, allergic reactions (urticaria, skin rash, puritis anaphylaxis). The frequency is not known.

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

4.9 Overdose

No case of overdose has been reported. Supportive and symptomatic treatment should be provided 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
Tests on reproductive toxicity, genotoxicity and on carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Tablet core:
Calcium Carbonate
Maltodextrin
Crocarmellose Sodium
Microcrystalline Cellulose
Colloidal Anhydrous Silica
Magnesium Stearate

Film Coating:
Hypermellose
Purified Talc

6.2 Incompatibilities
None applicable.

6.3 Shelf life
24 months

6.4 Special precautions for storage
Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container
30, 60 or 120 tablets in a PVC/PVDC blister pack with aluminium foil with cardboard outer.

Not all pack sizes may be marketed

6.6 Special precautions for disposal
No special requirements.

7 MARKETING AUTHORISATION HOLDER
Brunel Healthcare Manufacturing Limited
William Nadin Way
Swadlincote
Derbyshire
DE11 0BB

8 MARKETING AUTHORISATION NUMBER(S)
THR 20894/0071
9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
14/03/2012

10 DATE OF REVISION OF THE TEXT
14/03/2012
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Gerard House Milk Thistle Tablets
HERBALSTORE Milk Thistle Tablets
Wilko Milk Thistle Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each film coated tablet contains: 125 mg of standardised extract (as dry extract) from Milk Thistle fruits (Silybum marianum (L.) Gaertner) (equivalent to 2.5 – 5.0 g of Milk Thistle fruits) corresponding to 62.5 – 75 mg of silymarin, calculated as silibinin.

Extract solvent: Ethyl acetate 100 % v/v

For full list of excipients, see 6.1

3 PHARMACEUTICAL FORM
Film coated tablet.
Yellow circular biconvex

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
A traditional herbal medicinal product used to relieve the symptoms associated with occasional over indulgence of food and drink such as indigestion and upset stomach based on traditional use only.

4.2 Posology and method of administration
For oral use only.
Swallow the tablets whole with water. Do not chew.

Adults and the elderly: The recommended dosage is 1 - 2 tablets twice daily, before a meal.
Children and adolescents under 18 years old: This medicine is not recommended for children and adolescents under 18 years of age (see Section 4.4 Special warnings and precautions for use).

4.3 Contraindications
Hypersensitivity to Milk Thistle or to plants of the Asteraceae/Compositae family or to any of the excipients.

4.4 Special warnings and precautions for use
Do not exceed the stated dose.
Patients suffering from active liver disease should consult their doctor before taking this product.

Milk Thistle may alter the way that certain drugs are broken down by the liver (see Section 4.5 Interaction with other medicinal products and other forms of interaction).

The use in children and adolescents under 18 years of age is not recommended as there is no relevant indication.

If symptoms worsen or persist during the use of the product a doctor or qualified healthcare practitioner should be consulted.

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No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

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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 on carcinogenicity have not been performed.

6 **PHARMACEUTICAL PARTICULARS**

6.1 **List of excipients**
**Tablet core:**
Calcium Carbonate
Maltodextrin
Croscarmellose Sodium
Microcrystalline Cellulose
Colloidal Anhydrous Silica
Magnesium Stearate

**Film Coating:**
Hypermellose
Purified Talc

6.2 **Incompatibilities**
None applicable.

6.3 **Shelf life**
24 months.

6.4 **Special precautions for storage**
Do not store above 25°C. Store in the original package.

6.5 **Nature and contents of container**
30, 60 or 120 tablets in a PVC/PVDC blister pack with aluminium foil with cardboard outer.

Not all pack sizes may be marketed

6.6 **Special precautions for disposal**
No special requirements.

7 **MARKETING AUTHORISATION HOLDER**
Brunel Healthcare Manufacturing Limited
William Nadin Way
Swadlincote
Derbyshire
DE11 0BB
8 MARKETING AUTHORISATION NUMBER(S)
THR 20894/0072

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
14/03/2012

10 DATE OF REVISION OF THE TEXT
14/03/2012
Patient Information Leaflet

Max Strength Milk Thistle Tablets
Milk thistle standardised fruit extract 500 mg

Read all of this leaflet carefully before you take this product because it contains important information you need to know.

This product is available without prescription; however, you still need to use this product carefully to get the best results from it.

Keep this leaflet as you may need to read it again. Ask your doctor, pharmacist or qualified healthcare practitioner if you need more information or advice.

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:
• Milk thistle standardised fruit extract

This product is a traditional herbal medicinal product used to relieve the symptoms associated with occasional over indulgence of food and drink such as indigestion and upset stomach based on traditional use only.

2. Before you take this product

Do not take this product if you are:
• allergic to Milk Thistle or to plants of the same plant family: (Asteraceae/Compositae) such as daisies, marigolds or artichokes
• allergic to any of the ingredients of this product (see section 6)
• are under 18 years old.

Tell your doctor before you take this product if you are currently suffering from active liver disease.

Taking other medicines
Tell your doctor or pharmacist before taking this product if you are taking any other medicines, including those obtained without a prescription.

Pregnancy and breast feeding
Do not take this product if you are pregnant or breast feeding, because there is no evidence that it is safe to do so.

3. How to take this product

Swallow the tablets whole with water.
Do not chew.

Adults and the elderly:
Take 1 tablet daily, before a meal.

Do not give to children or adolescents under 18 years old.

Do not exceed the stated dose.
If you take too many tablets by mistake, contact your doctor or pharmacist straight away and take this leaflet with you.
If your symptoms worsen or persist for more than one week, consult a doctor or qualified healthcare practitioner. If you have any questions or are not sure about anything, ask your doctor, pharmacist or qualified healthcare practitioner for advice.

4. Possible side effects
Like all medicines, this product can cause side effects, although not everybody gets them.

The frequency of the side effects is not known. The following side effects have been reported:

- nausea or feeling sick
- diarrhoea
- upset stomach
- headache

Mild allergic skin reactions such as itching or skin rash, urticaria, hives, pruritis and anaphylaxis may occur.

Stop taking this product immediately if you experience any allergic skin reactions.

If you are concerned about any side effect, if a side effect becomes serious or if you notice a side effect not listed in this leaflet, please tell your doctor or qualified healthcare practitioner.

5. How to store this product
Keep out of the reach and sight of children.

Do not use these tablets after the expiry date printed on the pack.

Do not store above 25°C.

Store in the original packaging.

6. Further information
Each film coated tablet contains 500 mg of standardised extract (as dry extract) from Milk Thistle fruits (Silybum marianum (L.) Gaertn.) (equivalent to 10.0 - 20.0 g of Milk Thistle fruits) corresponding to 250 - 300 mg of silymarin calculated as silibinin.

Extraction solvent: Ethyl acetate 100% v/v

Also contains:

- Tablet core: calcium carbonate, maltodextrin, croscarmellose sodium microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate.
- Film coating: hypromellose and purified talc.

This product is available in pack sizes of 30, 60 or 120 tablets.

Not all pack sizes are marketed.

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 GP's surgery or pharmacy or call freephone 0808 100 3352 (available 10am - 2pm Monday - Friday)

To request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name:
Max Strength Milk Thistle Tablets

Reference number: THR 20894/0071

THR holder and manufacturer is:

Text revised: October 2011

THR 20894/0071
Patient Information Leaflet

Milk Thistle Tablets
Milk thistle standardised fruit extract 125 mg

Read all of this leaflet carefully before you take this product because it contains important information you need to know.

This product is available without prescription; however, you still need to use this product carefully to get the best results from it.

Keep this leaflet as you may need to read it again. Ask your doctor, pharmacist or qualified healthcare practitioner if you need more information or advice.

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:
- Milk thistle standardised fruit extract

This product is a traditional herbal medicinal product used to relieve the symptoms associated with occasional over indulgence of food and drink such as indigestion and upset stomach based on traditional use only.

2. Before you take this product

Do not take this product if you are:
- allergic to Milk Thistle or to plants of the same plant family: (Asteraceae/Compositae) such as daisies, marigolds or artichokes
- allergic to any of the ingredients of this product (see section 6)
- are under 18 years old.

Tell your doctor before you take this product if you are currently suffering from active liver disease.

Taking other medicines
Tell your doctor or pharmacist before taking this product if you are taking any other medicines, including those obtained without a prescription.

Pregnancy and breast feeding
Do not take this product if you are pregnant or breast feeding, because there is no evidence that it is safe to do so.

3. How to take this product

Swallow the tablets whole with water.
Do not chew.

Adults and the elderly:
Take 1 - 2 tablets twice daily, before a meal.

Do not give to children or adolescents under 18 years old.

Do not exceed the stated dose.
If you take too many tablets by mistake, contact your doctor or pharmacist straight away and take this leaflet with you.
If your symptoms worsen or persist for more than one week, consult a doctor or qualified healthcare practitioner. If you have any questions or are not sure about anything, ask your doctor, pharmacist or qualified healthcare practitioner for advice.

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The frequency of the side effects is not known. The following side effects have been reported:

- nausea or feeling sick
- diarrhoea
- upset stomach
- headache

Mild allergic skin reactions such as itching or skin rash, urticaria, hives, pruritis and anaphylaxis may occur.

Stop taking this product immediately if you experience any allergic skin reactions.

If you are concerned about any side effect, if a side effect becomes serious or if you notice a side effect not listed in this leaflet, please tell your doctor or qualified healthcare practitioner.

5. How to store this product

Keep out of the reach and sight of children.

Do not use these tablets after the expiry date printed on the pack.

Do not store above 25°C.

Store in the original packaging.

6. Further information

Each film coated tablet contains 125 mg of standardised extract (as dry extract) from Milk Thistle fruits (Silybum marianum (L.) Gaertner) (equivalent to 2.5 - 5.0 g of Milk Thistle fruits) corresponding to 62.5 - 75 mg of silymarin calculated as silibinin.

Extraction solvent: Ethyl acetate 100% v/v

Also contains:

- Tablet core: calcium carbonate, maltodextrin, croscarmellose sodium microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate.
- Film coating: hypromellose and purified talc.

This product is available in pack sizes of 30, 60 or 120 tablets.

Not all pack sizes are marketed.

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 GP's surgery or pharmacy or call freephone 0808 100 3352 (available 10am - 2pm Monday - Friday).

To request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)

Please be ready to give the following information:

- Product name: Milk Thistle Tablets
- Reference number: THR 20894/0072
- THR holder and manufacturer is: Brunel Healthcare Manufacturing Ltd, William Nadin Way, Swadlincote, Derbyshire, DE11 0BB, U.K.

Text revised: October 2011

THR 20894/0072
# LABELLING

**Gerard House Max Strength Milk Thistle Tablets**

**Blister:**

<table>
<thead>
<tr>
<th>Gerard House Max Strength Milk Thistle Tablets</th>
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MHRA PAR: GERARD HOUSE MAX STRENGTH MILK THISTLE TABLETS (THR 20894/0071) AND GERARD HOUSE MILK THISTLE TABLETS, HERBALSTORE MILK THISTLE TABLETS AND WILKO MILK THISTLE TABLETS (THR 20894/0072)
## Gerard House Milk Thistle Tablets

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Gerard House Milk Thistle Tablets

Standardised fruit extract 125 mg

A traditional herbal medicinal product used to relieve the symptoms associated with occasional Over Indulgence of Food and Drink such as Indigestion and Upset Stomach based on traditional use only.

Please read the enclosed leaflet carefully before use.

Do not exceed the stated dose.

DO NOT EXCEED THE STATED DOSE. This product is not suitable if you are under 18 years, pregnant, breast feeding or trying to become pregnant. Do not use if you are allergic to Milk Thistle or to plants of the Compositae/Composites family or any of the ingredients.

If symptoms worsen or persist for more than one week or if you are pregnant, consult your doctor or pharmacist. Do not use these tablets after the expiry date stated on the base of pack. Do not store above 25°C. Store in the original container. KEEP OUT OF THE REACH & SIGHT OF CHILDREN.

Active ingredients:

Each film coated tablet contains 125 mg of standardised extract (as dry extract) from Milk Thistle Fruit (Silybum marianum (L.) Gaertner), (equivalent to 2.3 - 3.0 g of Milk Thistle Starch) corresponding to 62 - 73 mg of silymarin, calculated as silymarin. Excipients: Ethyl acetate 100% w/w.

THR Holder: Brent Healthcare Manufacturing Ltd, William Neale Way, Swindon, Wiltshire, SN5 6EY, UK. THR 20894/0071

MHRA PAR: GERARD HOUSE MAX STRENGTH MILK THISTLE TABLETS (THR 20894/0071) AND GERARD HOUSE MILK THISTLE TABLETS, HERBALSTORE MILK THISTLE TABLETS AND WILKO MILK THISTLE TABLETS (THR 20894/0072)
HERBALSTORE Milk Thistle Tablets

Blister:
HERBALSTORE milk Thistle Tablets
A traditional herbal medicinal product used to relieve the symptoms associated with occasional OVER INDULGENCE of FOOD and DRINK such as INDIGESTION and UPSET STOMACH based on traditional use only.

Please read the enclosed leaflet carefully before use.

DIRECTIONS FOR USE: For oral use. Swallow the tablets whole with water. Do not chew.

DOSAGE: Adults and the elderly:
Take 1-2 tablets twice daily, before a meal.

DO NOT EXCEED THE STATED DOSE.

This product is not suitable if you are under 18 years of age, pregnant, breast feeding or trying to become pregnant.

Do not use if you are allergic to Milk Thistle or to plants of the daisy (Asteraceae/Compositae) family or any of the ingredients.

If symptoms worsen or persist see your doctor or pharmacist.

Do not use these tablets after the expiry date stated on pack.

Do not store above 25°C. Store in the original package.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Active Ingredient:
Each film coated tablet contains: 125 mg of standardised extract (as dry extract) from Milk Thistle fruits (Silybum marianum L.) Gaertn. (equivalent to 2.5 – 5.0 g of Milk Thistle fruits) corresponding to 62.5 – 75 mg of silymarin, calculated as silybin.

Extraction solvent: Ethyl acetate 100% v/v

MHRA PAR: GERARD HOUSE MAX STRENGTH MILK THISTLE TABLETS (THR 20894/0071) AND GERARD HOUSE MILK THISTLE TABLETS, HERBALSTORE MILK THISTLE TABLETS AND WILKO MILK THISTLE TABLETS (THR 20894/0072)
HERBALSTORE Milk Thistle Tablets

A traditional herbal medicinal product used to relieve the symptoms associated with occasional overindulgence of food and drink such as indigestion and upset stomach based on traditional use only.

Please read the enclosed leaflet carefully before use.

DIRECTIONS FOR USE: For oral use. Swallow the tablets whole with water. Do not chew.

DOSEAGE: Adults and the elderly
Take 1-2 tablets twice daily, before a meal.

DO NOT EXCEED THE STATED DOSE.
This product is not suitable if you are under 18 years of age, pregnant, breast feeding or trying to become pregnant.

Do not use if you are allergic to Milk Thistle or to plants of the family (Asteraceae/Compositae) family or any of the ingredients.

If symptoms worsen or persist, see your doctor or pharmacist.
Do not use these tablets after the expiry date stated on pack.
Do not store above 25°C. Store in the original package.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Active ingredient:
Each film-coated tablet contains: 125 mg of standardised extract (as dry extract) from Milk Thistle fruits (Silybum marianum L. Gaertn) equivalent to 2.5–5.0 g of Milk Thistle fruits corresponding to 62.5–75 mg of silymarin, calculated as silybin.

Extraction solvent: Ethyl acetate 100%, v/v
HERBAL STORE

Milk Thistle Tablets
120 tablets

Standardised fluid extract 125 mg
A traditional herbal medicinal product used to relieve the symptoms associated with occasional over indulgence of food and drink such as indigestion and upset stomach based on traditional use only.

Directions for use: For oral use. Swallow the tablets whole with water. Do not chew.

Dosage: Adults and the elderly:
Take 1-2 tablets once daily, before a meal.

Do not exceed the stated dose.

This product is not suitable if you are under 18 years of age, pregnant, breastfeeding or trying to become pregnant.

Do not use if you are allergic to Milk Thistle or any plant of the family Asteraceae/Compositae family or any of the ingredients.

If symptoms worsen or persist ask your doctor or pharmacist.

Do not use these tablets after the expiry date stated on pack.
Do not store above 25°C. Store in the original packaging.
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Active ingredient:
Each film-coated tablet contains: 125 mg of standardised extract (dry extract from Milk Thistle fruits 0.95% minimum 8.5% of silymarin equivalent to 2.5 - 5.0 g of Milk Thistle fruits containing 0.63 - 1.25 mg of silymarin calculated as silybin.

Extraneous excipients: Ethyl acetate 100% w/w
## Wilko Milk Thistle Tablets

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Wilko Milko Thistle Tablets

Standardised fruit extract 125 mg

A traditional herbal medicinal product used to relieve the symptoms associated with occasional OVER INDULGENCE of FOOD and DRINK such as INDIGESTION and UPSET STOMACH based on traditional use only.

Ingredients:

Each film-coated tablet contains 125 mg of standardised extract (as dry extract) from Milk Thistle fruits (Silybum marianum (L.) Gaertn.) (equivalent to 52.5 – 75 mg of Silymarin, calculated as silymarin. Extraction solvent: EtOH) at least 10% w/w.

borough: Science Park, Unit 8, 25 Science Park Way, Cambridge, CB4 0DN.

MHRA PAR: GERARD HOUSE MAX STRENGTH MILK THISTLE TABLETS
(THR 20894/0071) AND GERARD HOUSE MILK THISTLE TABLETS, HERBALSTORE MILK THISTLE TABLETS AND WILKO MILK THISTLE TABLETS (THR 20894/0072)