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Lay Summary

The Medicines and Healthcare products Regulatory Agency (MHRA) granted The Herbal Research Company Limited a Traditional Herbal Registration Certificate for the traditional herbal medicinal products HRI Milk Thistle Tablets, Asda Milk Thistle Tablets, Power Health milk thistle tablets and Principle Healthcare digestive relief tablets (Traditional Herbal Registration number: THR 02231/0004) on 11 August 2011. These products 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. This product is available without prescription and can be bought from pharmacies and other outlets.

Milk Thistle Tablets 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. The active ingredient of Milk Thistle Tablets comes from the fruit of the Milk thistle plant (*Silybum marianum* (L.) Gaertner).

This registration is 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 this application and it was, therefore, decided that a Traditional Herbal Registration Certificate could be granted.
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 02231/0004) to The Herbal Research Company Limited on 11 August 2011. This product is on the general sales list (GSL).

This application was submitted according to Article 16.c of Directive 2001/83 EC, as amended, as part of the Traditional Herbal Medicines Registration Scheme. The product is used 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 product.
PHARMACEUTICAL ASSESSMENT

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

As the herbal preparation is supported by an EDQM Certificate of Suitability, assessment of the herbal substance, which is a precursor of the herbal preparation, is not needed.

HERBAL PREPARATION:  MILK THISTLE FRUIT DRY EXTRACT

Ratio of the herbal substance to the herbal preparation (based on unpressed fruit):  24-27:1
Extraction solvent:  Acetone 95% (v/v)

All aspects of the manufacture and control of the herbal preparation are supported by an EDQM Certificate of Suitability. This certificate is accepted as confirmation of the suitability of this herbal preparation for inclusion in this medicinal product.

HERBAL PRODUCT:  MILK THISTLE TABLETS

Description and Composition of the Herbal Product
Milk Thistle Tablets are pale purple, oval shaped, biconvex film coated tablets. Each tablet contains 300 mg of dry extract from Milk thistle fruit. The rest of the tablet core is composed of calcium carbonate, pregelatinised starch, sodium croscarmellose, silicon dioxide, magnesium stearate and stearic acid. The tablets are coated in hypromellose (4.8-7.2 mPas), purified talc and Spectracoat Purple (containing anthocyanin (E163), titanium dioxide (E171), hypromellose and citric acid).

The compatibility of the herbal preparation with the excipients is demonstrated by the stability testing results. The excipients are controlled in line with their respective Ph Eur monograph, with the exception of silicon dioxide and Spectracoat Purple, which are controlled in line with the USNF and a suitable in-house specification, respectively. In the absence of a Ph Eur monograph for these excipients this is acceptable. The magnesium stearate used in the product is confirmed to be of vegetable origin.

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

In-process controls are appropriate considering the nature of the product and the method of manufacture. Currently, process validation has not been carried out on...
commercial batches, however, as the manufacturer has committed to carry out process validation on commercial batches following an appropriate process validation protocol, this is acceptable.

**Control of Herbal Product**
The finished product specification is satisfactory. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where appropriate, safety. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification.

**Container Closure System**
The tablets are sealed into PVC/PVDC aluminium foil blister strips of 15 tablets that are inserted into a carton. Each carton contains 30, 60 or 90 tablets.

Suitable specifications have been provided by the packaging suppliers and it has been confirmed that all primary packaging materials comply with Directive 2008/39/EC 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 2 years is appropriate when the storage precautions ‘Do not store above 25° C’ and ‘Store in the original package’ are applied.

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

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

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

**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 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 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

PROPOSED INDICATION
The applicant has proposed the following therapeutic indication:

‘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
The applicant has proposed the following posology:

‘For oral administration
 Adult and the elderly: the recommended dosage is 1 or 2 tablets daily.

This product is not recommended for children or adolescents under 18 years of age (See Section 4.4 special warnings and precautions for use)
 If symptoms worsen during the use of the product or persist a doctor or a qualified healthcare practitioner should be consulted.’

This is acceptable.

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

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

The 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 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 BENEFIT: RISK ASSESSMENT

QUALITY
The quality data submitted with this application are satisfactory.

NON-CLINICAL
No new non-clinical data were submitted with this application. The results of genotoxicity testing will be provided before the Traditional Herbal Registration is renewed.

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 milk thistle fruit within the EU for a period exceeding 30 years.

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

The SmPC, PIL and labelling are satisfactory.

BENEFIT: 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.
HRI MILK THISTLE TABLETS
ASDA MILK THISTLE TABLETS
POWER HEALTH MILK THISTLE TABLETS
PRINCIPLE HEALTHCARE DIGESTIVE RELIEF TABLETS

THR 02231/0004

STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the Traditional Herbal Registration application on 17 December 2010
2. Following standard checks and communication with the applicant the MHRA considered the application valid on 1 February 2011
3. Following assessment of the application the MHRA requested further information relating to the clinical dossier on 17 March 2011 and the quality dossier on 6 April 2011
4. The applicant responded to the MHRA’s requests, providing further information on the clinical and quality dossiers on 2 June 2011
5. Following assessment of the response the MHRA requested further information relating to the clinical and the quality dossiers on 8 June 2011
6. The applicant responded to the MHRA’s requests, providing further information on the clinical and quality dossiers on 30 June 2011
7. Following assessment of the response the MHRA requested further information relating to the quality dossier on 5 July 2011
8. The applicant responded to the MHRA’s requests, providing further information on the quality dossier on 11 July 2011
9. Following assessment of the response the MHRA requested further information relating to the quality dossier on 18 July 2011
10. The applicant responded to the MHRA’s requests, providing further information on the quality dossier on 22 July 2011
11. Following assessment of the response the MHRA requested further information relating to the quality dossier on 22 July 2011
12. The applicant responded to the MHRA’s requests, providing further information on the quality dossier on 22 July 2011
13. A THR was granted on 11 August 2011
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
- HRI Milk Thistle Tablets
- Asda Milk Thistle Tablets
- Power Health milk thistle tablets
- Principle Healthcare digestive relief tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each film-coated tablet contains 300 mg of standardised extract (as dry extract) from Milk Thistle fruits (*Silybum marianum* (L.) Gaertner) (equivalent to 7200mg – 8100mg of Milk Thistle fruits) corresponding to 174 mg of silymarin, calculated as silibinin
Extraction solvent: Acetone 95% v/v

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Film-coated tablet
Pale purple oval shaped biconvex film coated 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 administration
Adult and the elderly: the recommended dosage is 1 or 2 tablets daily.

This product is not recommended for children or adolescents under 18 years of age (See Section 4.4 special warnings and precautions for use)
If symptoms worsen during the use of the product or persist a doctor or a qualified healthcare practitioner should be consulted.

4.3 Contraindications
Hypersensitivity to Milk Thistle or plants of the daisy (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’)

If the symptoms worsen during the use of the product or if symptoms persist, consult a doctor or qualified healthcare practitioner.

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

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 Pregnancy and lactation

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

Tests 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, pruritus, anaphylaxis)

The frequency is not known

If other adverse reactions not mentioned above occur, a doctor 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 carcinogenicity have not been performed.

6 **PHARMACEUTICAL PARTICULARS**

6.1 **List of excipients**  
**Tablet Core**  
Calcium Carbonate  
Pregelatinised Starch  
Sodium Croscarmellose  
Silicon Dioxide  
Magnesium Stearate  
Stearic Acid

**Tablet Coating**  
Hypermellose 4.8-7.2 mPas  
Purified Talc  
Spectracoat Purple containing:  
Anthocyanin (E163)  
Titanium Dioxide (E171),

Hypermellose  
Citric Acid

6.2 **Incompatibilities**  
Not Applicable

6.3 **Shelf life**  
2 years

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

6.5 **Nature and contents of container**  
Tablets are packed into PVC/PVDC blister strips of 15 tablets in the following pack sizes; 30, 60, 90 Tablets and packed into a Carton.  
Not all pack sizes may be marketed

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

7 **MARKETING AUTHORISATION HOLDER**  
The Herbal Research Company Limited
(Trading as Jessup Marketing)
27 Old Gloucester Street
LONDON
WC1N 3XX

8 MARKETING AUTHORISATION NUMBER(S)
THR 02231/0004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORIZATION
11/08/2011

10 DATE OF REVISION OF THE TEXT
11/08/2011
Please read this information carefully before you start taking these tablets. It contains some important information about this product. Keep this leaflet with the tablets. You may want to read it again or show it to your doctor, pharmacist or qualified healthcare practitioner.

What is in this leaflet?
1. What HRI Milk Thistle is and what it is used for
2. Before you take HRI Milk Thistle
3. How to take HRI Milk Thistle
4. Possible Side Effects
5. How to store HRI Milk Thistle
6. Further Information

1. What HRI Milk Thistle is and what it is used for

What HRI Milk Thistle is
This product is a traditional herbal medicinal product containing Milk Thistle standardised fruit extract.

Each film-coated tablet contains 300 mg of standardised extract (as dry extract) from Milk Thistle fruits (Silybum marianum (L.) Gaertn.) (equivalent to 720 mg - 8100 mg of Milk Thistle fruits) corresponding to 174 mg of silymarin, calculated as silybin. Extraction solvent: Acetone 95% v/v.

What HRI Milk Thistle is used for
HRI Milk Thistle 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 HRI Milk Thistle

Do not take if you:
• are under the age of 18 years
• are pregnant or breastfeeding
• are allergic to Milk Thistle or plants of the Asteraceae/Compositae family such as daisies, marigolds or artichokes or any other of the ingredients (see section 6)

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

Taking other medicines
Tell your doctor or pharmacist before using any other medicines, including those obtained without prescription.

3. How to take HRI Milk Thistle

Adults and the elderly
The recommended dosage is 1 or 2 tablets daily. The tablets must be swallowed whole with a little water. Do not chew the tablets. Do not exceed the stated dose.

This product is not recommended for children or adolescents under 18 years of age.

If you take too much of this product (overdose)
If you take more than the recommended dose, speak to a doctor, pharmacist or qualified healthcare practitioner and take this leaflet with you.

If you forget to take this product
Continue to take your usual dose at the usual time. It does not matter if you have missed a dose.

If your condition worsens or if symptoms persist one week after taking this product or if side effects become serious or if side effects not mentioned in the patient information leaflet occur, consult a doctor or a qualified healthcare practitioner. If you have any questions, or are unsure about anything, please ask your doctor, pharmacist or qualified healthcare practitioner.

4. Possible Side Effects

Like all medicines, this product can have side effects although the frequency is not known. These are listed below:
• Nausea (feeling sick)
• Upset stomach
• Diarrhoea
• Headache
• MILD allergic reactions such as itching and or skin rash, urticaria, anaphylaxis, hives, pruritus. If you experience an allergic reaction, stop taking this product and consult your doctor.

If side effects become serious or if you notice any side effects not mentioned above after taking this medicine, a doctor or qualified healthcare practitioner should be consulted.
5. How to Store HRI Milk Thistle

- Do not use your tablets after the expiry date. Medicines should not be disposed of via wastewater or household waste.
- Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.
- The expiry date is printed on the box and blister pack. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original packaging.
- Keep the tablets out of the reach and sight of children.
- Keep your tablets in the blister pack until it is time to take them.

6. Further Information

Active Ingredients: Each film-coated tablet contains 300 mg of standardised extract (as dry extract) from Milk Thistle fruits (Silybum marianum (L.) Gaertner) (equivalent to 7200mg - 8100mg of Milk Thistle fruits) corresponding to 174mg of silymarin, calculated as silybin. Extraction solvent: Acetone 95% v/v.

This product also contains the following ingredients:
- Tablet core: Calcium Carbonate, Pre-gelatinised Starch, Sodium Croscarmellose, Silicon Dioxide, Magnesium Stearate, Stearic Acid.
- Tablet coating: Hypromellose, Purified Talc, Spectracol Purple (Anthocyanin (E163), Titanium Dioxide (E171), Hypromellose, Citic Acid).

What these tablets look like
- HRI Milk Thistle Tablets are pale purple oval biconvex film coated tablets. This product is available in 30, 60, 90 pack sizes. Not all pack sizes may be marketed.

Traditional Herbal Registration Number: THR 02231/0004

Registration holder for this product:
- The Herbal Research Company Limited (trading as Jessup Marketing), 27 Old Gloucester Street, London WC1N 3XX
- Manufacturer of this product: Honeywood Ltd, Edmonds Close, Danington Industrial Estate, Wellingborough, Northants, NN8 2QY

If you would like further information about this product please contact: Jessup Marketing
- Email: info@jessup.co.uk
- 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 from your GP’s surgery or pharmacy, or call free phone 0808 100 3352 (available 10am - 2pm Monday to Friday).

For a large print, Braille or audio version of this leaflet call 01932 854825.
- This leaflet was last revised in August 2011.
PATIENT INFORMATION LEAFLET

ASDA Milk Thistle™ Tablets
Milk Thistle standardised fruit extract 300 mg

Please read this information carefully before you start taking these tablets. It contains some important information about this product. Keep this leaflet with the tablets. You may want to read it again or show it to your doctor, pharmacist or qualified healthcare practitioner.

What is in this leaflet?
1. What ASDA Milk Thistle is and what it is used for
2. Before you take ASDA Milk Thistle
3. How to take ASDA Milk Thistle
4. Possible Side Effects
5. How to store ASDA Milk Thistle
6. Further Information

1. What ASDA Milk Thistle is and what it is used for

What ASDA Milk Thistle is
This product is a traditional herbal medicinal product containing Milk Thistle standardised fruit extract.

Each film-coated tablet contains 300 mg of standardised extract (as dry extract) from Milk Thistle fruits (Silybum marianum (L.) Gaerth) (equivalent to 7200mg - 8100mg of Milk Thistle fruits) corresponding to 174mg of silymarin, calculated as silybin. Extraction solvent: Acetone 95% v/v.

What ASDA Milk Thistle is used for
ASDA Milk Thistle 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 ASDA Milk Thistle

Do not take if you:
• are under the age of 18 years
• are pregnant or breastfeeding
• are allergic to Milk Thistle or plants of the Asteraceae/Compositae family such as daisies, marigolds or artichokes or any other of the ingredients (see section 6)

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

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

3. How to take ASDA Milk Thistle

Adults and the elderly
The recommended dosage is 1 or 2 tablets daily. The tablets must be swallowed whole with a little water. Do not chew the tablets. Do not exceed the stated dose. This product is not recommended for children or adolescents under 18 years of age.

If you take too much of this product (overdose)
If you take more than the recommended dose, speak to a doctor, pharmacist or qualified healthcare practitioner and take this leaflet with you.

If you forget to take this product
Continue to take your usual dose at the usual time, it does not matter if you have missed a dose.

If your condition worsens or if symptoms persist one week after taking this product or if side effects become serious or if side effects not mentioned in the patient information leaflet occur, consult a doctor or a qualified healthcare practitioner. If you have any questions, or are unsure about anything, please ask your doctor, pharmacist or qualified healthcare practitioner.

4. Possible Side Effects

Like all medicines, this product can have side effects although the frequency is not known. These are listed below:
• Nausea (feeling sick)
• Upset stomach
• Diarrhoea
• Headache
• Mild allergic reactions such as itching and or skin rash, urticaria, anaphylaxis, hives, pruritus. If you experience an allergic reaction, stop taking this product and consult your doctor.

If side effects become serious or if you notice any side effects not mentioned above after taking this medicine, a doctor or qualified healthcare practitioner should be consulted.
5. How to Store ASDA Milk Thistle

- Do not use your tablets after the expiry date. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.
- The expiry date is printed on the box and the blister pack. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original packaging.
- Keep the tablets out of the reach and sight of children.
- Keep your tablets in the blister pack until it is time to take them.

6. Further Information

Active Ingredients: Each film-coated tablet contains 300 mg of standardised extract (as dry extract) from Milk Thistle fruits (Silybum marianum (L.) Gaertn) (equivalent to 7200mg - 8100mg of Milk Thistle fruits) corresponding to 174mg of silymarin, calculated as silybinin. Extraction solvent: Acetone 95% v/v.

This product also contains the following ingredients:
- Tablet core: Calcium Carbonate, Pre-gelatinised Starch, Sodium Croscarmellose, Silicon Dioxide, Magnesium Stearate, Stearic Acid.
- Tablet coating: Hypromellose, Purified Talc, Spectracoat Purple (Anthocyanin (E163), Titanium Dioxide (E171), Hypromellose, Citric Acid).

What these tablets look like
- ASDA Milk Thistle Tablets are pale purple oval biconvex film coated tablets. This product is available in 30, 60, 90 pack sizes.
- Not all pack sizes may be marketed.

Traditional Herbal Registration Number: THR 02231/0004
Registration holder for this product:
The Herbal Research Company Limited, 27 Old Gloucester Street, London WC1N 3XX
Manufacturer of this product:
Honeywood Ltd, Edmonds Close, Denington Industrial Estate, Wellingborough, Northants, NN8 2QY

If you would like further information about this product please contact: Asda Stores Limited, Leeds, LS11 5AD.

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 free phone 0808 100 3352 (available 10am - 2pm Monday to Friday).

For a large print, Braille or audio version of this leaflet call 01932 854825.

This leaflet was last revised in August 2011.
PATIENT INFORMATION LEAFLET
powerhealth milk thistle™ tablets
Milk Thistle standardised fruit extract 300 mg

Please read this information carefully before you start taking these tablets. It contains some important information about this product. Keep this leaflet with the tablets. You may want to read it again or show it to your doctor, pharmacist or qualified healthcare practitioner.

What is in this leaflet?
1. What Power Health milk thistle is and what it is used for
2. Before you take Power Health milk thistle
3. How to take Power Health milk thistle
4. Possible Side Effects
5. How to store Power Health milk thistle
6. Further Information

1. What Power Health milk thistle is and what it is used for

What Power Health milk thistle is
This product is a traditional herbal medicinal product containing Milk Thistle standardised fruit extract.

Each film-coated tablet contains 300 mg of standardised extract (as dry extract) from Milk Thistle fruits (Silybum marianum (L.) Gaertner) (equivalent to 7200 mg - 8100 mg of Milk Thistle fruits) corresponding to 174 mg of silymarin, calculated as silibinin. Extraction solvent: Acetone 95% v/v.

What Power Health milk thistle is used for
Power Health milk thistle is 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.

2. Before you take Power Health milk thistle

Do not take if you:
- are under the age of 18 years
- are pregnant or breastfeeding
- are allergic to Milk Thistle or plants of the Asteraceae/Compositae family such as daisies, marigolds or artichokes or any other of the ingredients (see section 6)

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

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

3. How to take Power Health milk thistle

Adults and the elderly
The recommended dosage is 1 or 2 tablets daily. The tablets must be swallowed whole with a little water. Do not chew the tablets. Do not exceed the stated dose.

This product is not recommended for children or adolescents under 18 years of age.

If you take too much of this product (overdose)
If you take more than the recommended dose, speak to a doctor, pharmacist or qualified healthcare practitioner and take this leaflet with you.

If you forget to take this product
Continue to take your usual dose at the usual time, it does not matter if you have missed a dose.

If your condition worsens or if symptoms persist one week after taking this product or if side effects become serious or if side effects not mentioned in the patient information leaflet occur, consult a doctor or a qualified healthcare practitioner. If you have any questions, or are unsure about anything, please ask your doctor, pharmacist or qualified healthcare practitioner.

4. Possible Side Effects

Like all medicines, this product can have side effects although the frequency is not known. These are listed below.
- Nausea (feeling sick)
- Upset stomach
- Diarrhoea
- Headache
- Mild allergic reactions such as itching and or skin rash, urticaria, anaphylaxis, hives, pruritus. If you experience an allergic reaction, stop taking this product and consult your doctor.

If side effects become serious or if you notice any side effects not mentioned above after taking this medicine, a doctor or qualified healthcare practitioner should be consulted.
5. How to Store Power Health milk thistle

Do not use your tablets after the expiry date. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

The expiry date is printed on the box and the blister pack. The expiry date refers to the last day of that month.

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

Keep the tablets out of the reach and sight of children.

Keep your tablets in the blister pack until it is time to take them.

6. Further Information

Active Ingredients: Each film-coated tablet contains 300 mg of standardised extract (as dry extract) from Milk Thistle fruits (Silybum marianum (L.) Gaertner) (equivalent to 7200mg - 8100mg of Milk Thistle fruits) corresponding to 174mg of silymarin, calculated as silibinin. Extraction solvent: Acetone 95% v/v.

This product also contains the following ingredients:

Tablet core: Calcium Carbonate, Pregelatinised Starch, Sodium Croscarmellose, Silicon Dioxide, Magnesium Stearate, Stearic Acid.

Tablet coating: Hypromellose, Purified Talc, Spectracote Purple (Anthocyanin (E163), Titanium Dioxide (E171), Hypromellose, Citric Acid).

What these tablets look like

Power Health milk thistle tablets are pale purple oval biconvex film coated tablets. This product is available in 30, 60, 90 pack sizes.

Not all pack sizes may be marketed.

Traditional Herbal Registration Number: THR 02231/0004

Registration holder for this product:

The Herbal Research Company Limited, 27 Old Gloucester Street, London WC1N 3XX

Manufacturer of this product:

Honeywood Ltd, Edmonds Close, Denington Industrial Estate, Wellingborough, Northants, NN8 2QY

If you would like further information about this product please contact: Power Health Products Ltd., Poolekington, York Y042 1NR. Email: enquiries@power-health.co.uk. Tel: 01759 302595.

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 free phone 0808 100 3352 (available 10am - 2pm Monday to Friday).

For a large print, Braille or audio version of this leaflet call 01759 302595.

This leaflet was last revised in August 2011.
Please read this information carefully before you start taking these tablets. It contains some important information about this product. Keep this leaflet with the tablets. You may want to read it again or show it to your doctor, pharmacist or qualified healthcare practitioner.

What is in this leaflet?
1. What Principle Healthcare digestive relief is and what it is used for
2. Before you take Principle Healthcare digestive relief
3. How to take Principle Healthcare digestive relief
4. Possible Side Effects
5. How to store Principle Healthcare digestive relief
6. Further Information

1. What Principle Healthcare digestive relief is and what it is used for
What Principle Healthcare digestive relief is
This product is a traditional herbal medicinal product containing Milk Thistle standardised fruit extract.
Each film-coated tablet contains 300 mg of standardised extract (as dry extract) from Milk Thistle fruits (Silybum marianum (L.) Gaertner) equivalent to 7200mg - 8100mg of Milk Thistle fruits) corresponding to 174mg of silymarin, calculated as silybin. Extraction solvent: Acetone 95% v/v.

What Principle Healthcare digestive relief is used for
Principle Healthcare digestive relief is a traditional herbal medicinal product used to relieve the symptoms associated with occasional indigestion and upset stomach such as indigestion and upset stomach based on traditional use only.

2. Before you take Principle Healthcare digestive relief
Do not take if you:
• are under the age of 18 years
• are pregnant or breastfeeding
• are allergic to Milk Thistle or plants of the Astersaeae/Compositae family such as daisies, marigolds or artichokes or any other of the ingredients (see section 6)

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

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

3. How to take Principle Healthcare digestive relief
Adults and the elderly
The recommended dosage is 1 or 2 tablets daily. The tablets must be swallowed whole with a little water. Do not chew the tablets. Do not exceed the stated dose.
This product is not recommended for children or adolescents under 18 years of age.

If you take too much of this product (overdose)
If you take more than the recommended dose, speak to a doctor, pharmacist or qualified healthcare practitioner and take this leaflet with you.

If you forget to take this product
Continue to take your usual dose at the usual time, it does not matter if you have missed a dose.

If your condition worsens or if symptoms persist one week after taking this product or if side effects become serious or if side effects not mentioned in the patient information leaflet occur, consult a doctor or a qualified healthcare practitioner. If you have any questions, or are unsure about anything, please ask your doctor, pharmacist or qualified healthcare practitioner.

4. Possible Side Effects
Like all medicines, this product can have side effects although the frequency is not known. These are listed below.
• Nausea (feeling sick)
• Upset stomach
• Diarrhoea
• Headache
• Mild allergic reactions such as itching and or skin rash, urticaria, itching, hives, pruritus. If you experience an allergic reaction, stop taking this product and consult your doctor.
If side effects become serious or if you notice any side effects not mentioned above after taking this medicine, a doctor or qualified healthcare practitioner should be consulted.
5. How to Store Principle Healthcare digestive relief

- Do not use your tablets after the expiry date. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment. The expiry date is printed on the box and the blister pack. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original packaging.
- Keep the tablets out of the reach and sight of children.
- Keep your tablets in the blister pack until it is time to take them.

6. Further Information

**Active Ingredients:** Each film-coated tablet contains 300 mg of standardised extract (as dry extract) from Milk Thistle fruits (Silybum marianum (L.) Gaertner) (equivalent to 7200mg - 8100mg of Milk Thistle fruits corresponding to 174mg of silymarin, calculated as silybinin. Extraction solvent: Acetone 95% v/v.

This product also contains the following ingredients:

- Tablet core: Calcium Carbonate, Pre gelatinised Starch, Sodium Croscarmellose, Silicon Dioxide, Magnesium Stearate, Stearic Acid.
- Tablet coating: Hyromellose, Purified Talc, Spectracoat Purple (Anthoecyanin (E163), Titanium Dioxide (E171), Hyromellose, Citric Acid).

**What these tablets look like**

Principle Healthcare digestive relief tablets are pale purple oval biconvex film coated tablets. This product is available in 30, 60, 90 pack sizes. Not all pack sizes may be marketed.

Traditional Herbal Registration Number: THR 02231/0004

Registration holder for this product:

**The Herbal Research Company Limited, 27 Old Gloucester Street, London WC1N 3XX**

Manufacturer of this product:

Honeywood Ltd, Edmunds Close, Denington Industrial Estate, Wellingborough, Northants, NN8 2QY

If you would like further information about this product please contact: Principle Healthcare Ltd., Millennium Road, Airedale Business Centre, Skipton, North Yorkshire BD23 2JZ,

Email: enquiries@principlesharecare.com. Tel.: +44 (0) 1756 792600.

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 free phone 0808 100 3352 (available 10am - 2pm Monday to Friday).

For a large print, Braille or audio version of this leaflet call 01756 792600.

This leaflet was last revised in August 2011.
HRI Milk Thistle Tablets

Blister:
MHRA PAR; HRI MILK THISTLE TABLETS, ASDA MILK THISTLE TABLETS, POWER HEALTH MILK THISTLE TABLETS AND PRINCIPLE HEALTHCARE DIGESTIVE RELIEF TABLETS, THR 02231/0004
Asda Milk Thistle Tablets

Blister:
Asda Milk Thistle Tablets is a traditional herbal medicinal product used to relieve the symptoms associated with occasional indigestion and upset stomach based on traditional use only.

**ACTIVE INGREDIENTS**
Each film-coated tablet contains 300mg of standardised extract (dry weight) from Milk Thistle from C. vulgare macrocarpum (C.G.S. 10761) equivalent to 750mg – 1500mg of Milk Thistle fruit corresponding to 75mg of silymarin (a mixture of silibinin, silychristin and silyvirpin 95% v/v).

**DOSEAGE**
Adults and the elderly: The recommended dosage is 1 tablet daily. The tablets must be swallowed whole with a little water. This product is not recommended for children or adolescents under 18 years of age.

**WARNINGS**
Do not exceed the stated dose. If symptoms worsen during the use of the product or persist a doctor or a qualified healthcare practitioner should be consulted.
Do not use if:
• Under 18 years.
• Pregnant or breast-feeding.
• Allergic to Milk Thistle or any of its excipients.

You must read the enclosed leaflet before taking this product. Keep out of reach of children. Store in a cool, dry place not exceeding 25°C, Store in the original packaging. Expiry date see below. Do not use after this date.

MHRA PAR; HRI MILK THISTLE TABLETS, ASDA MILK THISTLE TABLETS, POWER HEALTH MILK THISTLE TABLETS AND PRINCIPLE HEALTHCARE DIGESTIVE RELIEF TABLETS, THR 02231/0004
Power Health milk thistle tablets

Blister:
Principle Healthcare digestive relief tablets

Blister:
**Carton:**

**digestive relief tablets**

**milk thistle**

standardised fruit extract 300mg

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.

**ACTIVE INGREDIENTS:**

Each film-coated tablet contains 300mg of standardised extract (as dry extract) from Milk Thistle (Silybum marianum (L.) Gaertn) (equivalent to 7200mg of 4:1 extract of Milk Thistle fruit) corresponding to 17mg of silymarin, calculated as silymarin.

**Dosage:**

Adults and the elderly: the recommended dosage is 1 or 2 tablets daily. The tablets must be swallowed whole with a little water. This product is not recommended for children or adolescents under 16 years of age.

**WARNINGS:**

- Do not exceed the stated dose.
- If symptoms worsen or do not improve within 7 days, or if new symptoms develop, discontinue use and consult a health care professional.
- Keep out of the reach of children.
- Do not use if有效期（Expire）is expired.
- For use only as directed.
- Store in a cool, dry place.

**Manufactured by:**

Principle Healthcare Limited

3200 Brothers Rd, Alpharetta, GA 30004, USA

Tel: 678-208-3300

email: info@principlehealthcare.com

**Product Code:**

THR 02231/0004