¹ Variation 0011 MHRA Approved Artwo**W**HRA Approval 8th July 2014

6: Further information

Each hard capsule of this product contains 193 mg – 261 mg of standardised extract (as dry extract) from Milk Thistle fruits (*Silybum marianum* (L.) Gaertn.) (equivalent to 3.725 g – 10.818 g of Milk Thistle fruits). This amount of standardised extract corresponds to 108 mg of silymarin, calculated as silibinin. Extraction solvent: Acetone 95% v/v.

This product also contains the following ingredients: Extract excipients: mannitol

Capsule contents: mannitol, cellulose microcrystalline, croscarmellose sodium, silica colloidal anhydrous, magnesium stearate.

Capsule shell: gelatin, purified water, titanium dioxide E171, sodium lauryl sulphate, iron (III)-oxide E172 (= red iron oxide), iron oxide hydrate E172 (= yellow iron oxide).

Each pack contains 21, 28, 30, 56, 60 or 90 hard capsules. Not all pack sizes may be marketed.

Registration holder for this product

Schwabe Pharma (UK) Ltd Alexander House, Mere Park, Dedmere Road, Marlow, Bucks SL7 1FX

Manufacturer of this product

Wiewelhove GmbH, Dörnebrink19, 49479 Ibbenbüren, Germany

Traditional herbal registration number: THR 23056/0010



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

Schwabe Pharma (UK) Ltd Alexander House, Mere Park, Dedmere Road, Marlow, Bucks, SL7 1FX Telephone: 01628 401980 Email: info@schwabepharma.co.uk

This leaflet was revised in 05/2014

For large print, Braille or audio version of this leaflet, please call 01628 401980

Patient Information Leaflet

Thisilyn[®] Maximum Strength Milk Thistle capsules

standardised fruit extract

Please read this leaflet carefully before you start taking these capsules. It contains some important information about Thisilyn[®] Maximum Strength Milk Thistle.

Keep this leaflet with the capsules.

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 this product is and what it is used for	.page 1
2: Before you take this product	.page 2
3: How to take this product	.page 2
4: Possible side-effects	.page 3
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1: What this product is and what it is used for

This product is a traditional herbal medicinal product containing Milk Thistle standardised fruit extract. Each capsule of this product contains 193 mg – 261 mg of standardised extract (as dry extract) from Milk Thistle fruits (*Silybum marianum* (L.) Gaertn.) (equivalent to 3.725 g - 10.818 g of Milk Thistle fruits). This amount of standardised extract corresponds to 108 mg of silymarin, calculated as silibinin. Extraction solvent: Acetone 95% v/v.

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

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2: Before you take this product

DO NOT TAKE this product if you are:

- under 18 years of age
- pregnant or breast-feeding
- allergic to any of the ingredients or to plants of the Asteraceae/Compositae family such as daisies, marigolds or artichokes (see section 6)

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

3: How to take this product

Adults and the elderly

Take 1 capsule up to twice daily. Swallow the capsules whole with some water or other liquid. Do not chew the capsules.

Do not exceed the stated dose.

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

If you take too much of this product (overdose)

If you take more than the recommended dose, speak to your doctor, pharmacist or gualified 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 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.

Side-effects

- If these persist for more than a few nausea or feeling sick diarrhoea upset stomach
- headache
- mild allergic skin reactions itching and/or skin rash, urticaria, hives, pruritis itching, anaphylaxis.

days, or become troublesome, stop taking this product. These side-effects are often only temporary.

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

Side-effects

Tell your doctor or pharmacist if you notice any other side-effect not mentioned in this leaflet.

You must speak to a gualified healthcare practitioner if your symptoms worsen, if they do not improve after one week, or if side-effects not mentioned in this leaflet occur.

You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.vellowcard.gov.uk. 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).

5: How to store this product

Do not use your capsules after the expiry date.

Return any out-of-date capsules to your pharmacist who will dispose of them for you. The expiry date is printed on the box and the blister pack.

Store the capsules in a cool dry place below 25° C.

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

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