

TANDAR[®] 4% LOTION

PL 00240/0344

THORNTON & ROSS HEADLICE 4% LOTION

PL 00240/0345

UKPAR

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TANDAR[®] 4% LOTION

PL 00240/0344

THORNTON & ROSS HEADLICE 4% LOTION

PL 00240/0345

LAY SUMMARY

The MHRA granted Thornton & Ross Limited Marketing Authorisations (licences) for the medicinal products Tandar[®] 4% Lotion and Thornton & Ross Headlice 4% Lotion (PL 00240/0344-5). These are pharmacy only medicines (P) used for eradication of headlice.

They contain the active substance Dimeticone 4%w/w. Dimeticone is not a chemical poison. It works by a physical process which effectively covers and drowns the louse. The other ingredient Cyclomethicone 5 is a carrier ingredient which evaporates after application leaving the active ingredient to kill the lice.

No new or unexpected safety concerns arose from these applications and it was therefore judged that the benefits of using Tandar[®] 4% Lotion and Thornton & Ross Headlice 4% Lotion outweigh the risks, hence marketing authorisations have been granted.

TANDAR[®] 4% LOTION

PL 00240/0344

THORNTON & ROSS HEADLICE 4% LOTION

PL 00240/0345

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted marketing authorisations for the medicinal products Tandar[®] 4% Lotion and Thornton & Ross Headlice 4% Lotion (PL 00240/0344-5) to Thornton & Ross Limited on 7th March 2008. These are Pharmacy only medicines (P) indicated for the eradication of headlice infestations.

These applications were submitted under Article 10(c) of Directive 2001/83/EC, claiming to possess the same qualitative and quantitative composition in terms of the active substance and the same pharmaceutical form of an already authorised product. The relevant product in the UK is Hedrin cutaneous solution 4% w/w (PL 00240/0137) held by Thornton & Ross Limited, which was granted on 23rd November 2005.

The solution contains dimeticone, which is used in many pharmaceutical and cosmetic preparations. A 4% concentration has been found to affect the physico-physiological activity of lice. It is less effective in its ovicidal activity and therefore two applications 7 days apart are required.

Tandar[®] 4% Lotion and Thornton & Ross Headlice Lotion contain no neurotoxic organophosphate insecticides and therefore do not work by acting on specific enzymes within the louse. They act on the lice by a physical process to cover the lice and disrupt the ability of the lice to manage its water balance so that treated insects fail to excrete surplus water. Tandar[®] 4% Lotion and Thornton & Ross Headlice Lotion activity is not diminished in insecticide resistant head lice.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 00240/0344-5

PROPRIETARY NAME: Tandar[®] 4% Lotion and Thornton & Ross Headlice 4% Lotion

COMPANY NAME: Thornton & Ross Limited

E.C. ARTICLE: Article 10 (c) of Directive 2001/83/EC

LEGAL STATUS: P

1 INTRODUCTION

These national simple abridged applications are for Tandar[®] 4% Lotion and Thornton & Ross Headlice 4% Lotion. The products are indicated for eradication of headlice infestations.

These applications were submitted under Article 10(c) of Directive 2001/83/EC, claiming to possess the same qualitative and quantitative composition in terms of the active substance and the same pharmaceutical form of an already authorised product. The relevant product in the UK is Hedrin Cutaneous solution 4%w/w (PL 00240/0137) currently authorised to Thornton & Ross Limited.

2 MARKETING AUTHORISATION APPLICATION (MAA)

2.1 Name(s)

The proposed names of the products are Tandar[®] 4% Lotion and Thornton & Ross Headlice 4% Lotion. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

The product contains the active ingredient Dimeticone. It will be packaged into HDPE dropper container. The packagings are identical to the packaging used for the reference product.

The respective SPC have indicated that Tandar[®] 4% Lotion and Thornton & Ross Headlice 4% Lotion are packed in pack sizes of 50ml, 100ml, 150ml and 200ml. The same pack sizes are stated in the reference product. The proposed shelf life is 3 years which is identical to the reference product. The proposed storage condition is also consistent with the details registered for the cross-reference product.

2.3 Legal status

The products are Pharmacy only medicines (P).

2.4 Marketing authorisation holder/Contact Persons/Company

The proposed Marketing Authorisation holder is Thornton & Ross Limited, Linthwaite, Huddersfield, West Yorkshire, HD7 5QH, UK.

The QP responsible for pharmacovigilance is stated and a CV is included.

2.5 Manufacturers

The proposed manufacturing sites are consistent with that registered for the cross-reference product and evidence of GMP compliance has been provided. A flow diagram showing the sequence and activities of the different sites involved in the manufacturing process has been provided.

2.6 Qualitative and quantitative composition

The proposed compositions are consistent with the details registered for the cross-reference products.

2.7 Manufacturing process

The proposed manufacturing process is consistent with the details registered for the cross-reference products and the maximum batch size is stated.

2.8 Finished product/shelf-life specification

The proposed finished product specification is in line with the details registered for the cross-reference products.

2.9 Drug substance specification

The proposed drug substance specification conformed to current Ph Eur monograph for dimeticone and was consistent with that of the reference product.

Current Ph Eur certificate of suitability for the drug substance manufacturer has been provided to support the sources of active substance. This manufacturer is in line with the reference product.

2.10 TSE Compliance

The active ingredient supplier has confirmed that no materials of human or animal origin have been used in the manufacture of dimeticone.

2.11 Bioequivalence / Bioavailability

No bioavailability and bioequivalence data are required to support this informed consent application as the proposed product is manufactured to the same formula utilising the same process. The finished product manufacturing site is also identical to that used by the reference product.

3 EXPERT REPORT

The applicant has included detailed expert reports of the application. Signed declarations and copies of the experts' CVs are enclosed for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the proposed product names. The appearances of the products are identical to the cross-reference products.

5. SUMMARY OF PRODUCT CHARACTERISTICS

The proposed SmPCs are consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET/BLISTER

PIL

The patient information leaflet has been prepared in-line with the details registered for the cross-reference products.

The result of user testing has been provided.

The proposed artwork complies with the relevant statutory requirements.

7. CONCLUSIONS

The data submitted with the applications is acceptable. Marketing Authorisation should be granted.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with these applications and none is required for an application of this type.

CLINICAL ASSESSMENT

No new preclinical data have been supplied with these applications and none is required for an application of this type.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for these applications are consistent with that previously assessed for the cross-reference product and as such has been judged to be satisfactory.

PRECLINICAL

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

EFFICACY

These applications are identical to previously granted application for Hedrin Cutaneous Solution 4% w/w.

Preclinical, pharmaceutical and clinical expert statements have been provided together with CVs showing the experts are appropriately qualified. The experts confirm that the product is identical in composition, manufacture and pharmaceutical characteristics to the respective reference product and that there are no toxicological or clinical issues.

No new or unexpected safety concerns arise from these applications.

The SPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. Extensive clinical experience with dimeticone is considered to have demonstrated the therapeutic value of the compound. The risk benefit is therefore considered to be positive.

TANDAR[®] 4% LOTION

PL 00240/0344

THORNTON & ROSS HEADLICE 4% LOTION

PL 00240/0345

STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation application on 29 th October 2006
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 30 th January 2007
3	Following assessment of the application the MHRA requested further information relating to the quality dossiers on 14 th September 2007 and 28 th February 2008
4	The applicant responded to the MHRA's request, providing further information for the quality section on 27 th November 2007 and 4 th March 2008.
5	The applications were determined on 7 th March 2008

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Tandar[®] 4% Lotion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Dimeticone 4% w/w

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution.

Tandar[®] 4% Lotion is a clear, colourless liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Tandar[®] 4% Lotion is indicated for the eradication of headlice infestations.

4.2 Posology and method of administration

Adults and children (aged six months and above)

For topical external use only.

Apply sufficient lotion to cover dry hair from the base to the tip to ensure that no part of the scalp is left uncovered. Work into the hair spreading the liquid evenly from roots to tips. Allow hair to dry naturally. Tandar[®] 4% Lotion should be left on hair for a minimum of 8 hours or overnight. Wash out with normal shampoo, rinsing thoroughly with water. Repeat the treatment after seven days.

Children under the age of six months should only be treated under medical supervision.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Discontinue at the first appearance of a skin rash or any other signs of local or general hypersensitivity.

For external use only.

If accidentally introduced into the eyes, flush with water.

4.5 Interaction with other medicinal products and other forms of interaction

Dimeticone is not known to interact with other drugs.

4.6 Pregnancy and lactation

There is no data to suggest that Tandar[®] 4% Lotion may not be used in pregnancy.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Dimeticone is usually well tolerated. Minor adverse events include an itchy or flaky scalp and dripping/irritation around the eyes.

4.9 Overdose

There are no known recognised symptoms of overdose.

It is unlikely that Tandar® 4% Lotion will enter the bloodstream via scratched skin however if this does occur, available data suggests it will be rapidly eliminated unchanged. If the lotion were to be accidentally ingested, again, the available data suggests that there are no specific safety concerns.

No special procedures are likely to be needed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: PO3 AX Other entoparasiticides, incl Scabicides

The solution contains dimeticone, which is used in many pharmaceutical and cosmetic preparations. A 4% concentration has been found to affect the physico-physiological activity of lice. It is less effective in its ovicidal activity and therefore two applications 7 days apart are required.

Tandar® 4% Lotion contains no neurotoxic organophosphate insecticides and therefore does not work by acting on specific enzymes within the louse. Tandar® 4% Lotion acts on the lice by a physical process to cover the lice and disrupt the ability of the lice to manage its water balance so that treated insects fail to excrete surplus water. Tandar® 4% Lotion activity is not diminished in insecticide resistant head lice.

5.2 Pharmacokinetic properties

Tandar® 4% Lotion is applied topically to the affected area but there is little or no absorption of Tandar® 4% Lotion through the skin.

5.3 Preclinical safety data

There are no further relevant data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cyclomethicone 5.

6.2 Incompatibilities

None known.

6.3 Shelf life

Three years, when stored unopened.

6.4 Special precautions for storage

This product does not require any special storage conditions.

6.5 Nature and contents of container

HDPE dropper containers with screw caps; 50, 100, 150 and 200ml capacity.

6.6 Special precautions for disposal

Care should be taken as the product may cause a slip hazard if accidentally spilt onto smooth surfaces.

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Ltd
Linthwaite
Huddersfield
HD7 5QH
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00240/0344

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
07/03/2008

10 DATE OF REVISION OF THE TEXT
07/03/2008

1 NAME OF THE MEDICINAL PRODUCT

Thornton & Ross Headlice 4% Lotion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Dimeticone 4% w/w

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution.

Thornton & Ross Headlice Lotion is a clear, colourless liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Thornton & Ross Headlice Lotion is indicated for the eradication of headlice infestations

4.2 Posology and method of administration

Adults and children (aged six months and above)

For topical external use only.

Apply sufficient lotion to cover dry hair from the base to the tip to ensure that no part of the scalp is left uncovered. Work into the hair spreading the liquid evenly from roots to tips. Allow hair to dry naturally. Thornton & Ross Headlice Lotion should be left on hair for a minimum of 8 hours or overnight. Wash out with normal shampoo, rinsing thoroughly with water. Repeat the treatment after seven days.

Children under the age of six months should only be treated under medical supervision.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Discontinue at the first appearance of a skin rash or any other signs of local or general hypersensitivity.

For external use only.

If accidentally introduced into the eyes, flush with water.

4.5 Interaction with other medicinal products and other forms of interaction

Dimeticone is not known to interact with other drugs.

4.6 Pregnancy and lactation

There is no data to suggest that Thornton & Ross Headlice Lotion may not be used in pregnancy

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Dimeticone is usually well tolerated. Minor adverse events include an itchy or flaky scalp and dripping/irritation around the eyes.

4.9 Overdose

There are no known recognised symptoms of overdose.

It is unlikely that Thornton & Ross Headlice Lotion will enter the bloodstream via scratched skin however if this does occur, available data suggests it will be rapidly eliminated

unchanged. If the lotion were to be accidentally ingested, again, the available data suggests that there are no specific safety concerns.

No special procedures are likely to be needed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: PO3 AX Other entoparasiticides, incl Scabicides

The solution contains dimeticone, which is used in many pharmaceutical and cosmetic preparations. A 4% concentration has been found to affect the physico-physiological activity of lice. It is less effective in its ovicidal activity and therefore two applications 7 days apart are required.

Thornton & Ross Headlice Lotion contains no neurotoxic organophosphate insecticides and therefore does not work by acting on specific enzymes within the louse. Thornton & Ross Headlice Lotion acts on the lice by a physical process to cover the lice and disrupt the ability of the lice to manage its water balance so that treated insects fail to excrete surplus water. Thornton & Ross Headlice Lotion activity is not diminished in insecticide resistant head lice.

5.2 Pharmacokinetic properties

Thornton & Ross Headlice Lotion is applied topically to the affected area but there is little or no absorption of Thornton & Ross Headlice Lotion through the skin.

5.3 Preclinical safety data

There are no further relevant data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cyclomethicone 5.

6.2 Incompatibilities

None known.

6.3 Shelf life

Three years, when stored unopened.

6.4 Special precautions for storage

This product does not require any special storage conditions.

6.5 Nature and contents of container

HDPE dropper containers with screw caps; 50, 100, 150 and 200ml capacity.

6.6 Special precautions for disposal

Care should be taken as the product may cause a slip hazard if accidentally spilt onto smooth surfaces.

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Ltd
Linthwaite
Huddersfield
HD7 5QH
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00240/0345

- 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**
07/03/2008
- 10 DATE OF REVISION OF THE TEXT**
07/03/2008

PATIENT INFORMATION LEAFLET

Text for Non-Marketed Packs

Product: Leaflet: Tandar 4% Lotion 50ml, 100ml, 150ml, 200ml

Tandar® 4% Lotion
Dimeticone

Patient Information
T&R

P

A topical lotion for the eradication of head lice.

You can use this medicine to treat adults and children over 6 months old without seeing a doctor, but use it carefully to get the best results.

Read all this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you notice any side effects or any side effects not mentioned in this leaflet, talk to your doctor or pharmacist.

In this leaflet

- 1 What Tandar® Lotion and what does it do?
- 2 Before using Tandar®
- 3 How to use Tandar®
- 4 Possible side effects
- 5 Storing Tandar®
- 6 Further information

1 What is Tandar® Lotion and what does it do?

The name of your medicine is Tandar® 4% Lotion. It is a solution which is highly effective against head lice.

2 Before using Tandar®

Do not use Tandar®:

- If you are **allergic** to either of the ingredients listed.

Take special care with Tandar® Lotion:

- For external use only.
- Avoid contact of the lotion with your eyes. If it accidentally comes into contact with your eyes, flush with water.
- **Warning:** Hair should be kept away from naked flames, cigarettes, and other sources of ignition while treatment with Tandar® is underway. Tandar® is not water based and will not prevent hair from burning.

If you accidentally swallow some

If you accidentally swallow some of the solution, you should consult a doctor as soon as possible. Take the pack with you to show which medicine you have swallowed.

Use in pregnancy and breastfeeding:

Tandar® Lotion may be used during pregnancy and breastfeeding.

Use in infants under 6 months:

Children under 6 months should only be treated under medical supervision.

Driving and using machines:

Tandar® Lotion does not affect your ability to drive or operate machinery.

3 How to use Tandar®

Tandar® is suitable for adults and children aged 6 months and over.

Please note:

If a member of the family has live headlice, check the other family members and treat all other cases of live head lice which are discovered, at the same time.

Tandar® is for external use only.

Directions

- **Apply sufficient lotion evenly over DRY hair ensuring that the scalp is fully covered.**
- **Work into the hair spreading the liquid evenly from the roots to tips. Allow the hair to dry naturally.**
- **Leave on the hair for at least 8 hours or overnight.**
- **Wash the hair with normal shampoo, rinse thoroughly with water and dry.**

Duration of treatment

- It is important that Tandar® Lotion is applied again after **seven days** to deal with any lice which may hatch in that time. Failure to repeat the treatment may result in the return of a louse infestation.

4 Possible side effects

Important side effects

If you experience any of the following, stop using Tandar® immediately and talk to a doctor or pharmacist.

- Allergic reactions such as rash, swelling or weals on the skin.
- Breathing difficulties.

Other side effects

When using Tandar® on broken skin, slight irritation may occur. Sometimes application may cause flaking of the scalp, itching and irritation around the eyes.

If you notice any of these or other side effects, stop using the product and talk to a doctor or pharmacist.

5 Storing Tandar®

- Keep out of the reach and sight of children.
- This product does not require any other special storage conditions.
- Do not use the pack after the expiry date shown on the pack.
- Care should be taken if Tandar® is spilled as it may cause a slip hazard.

6 Further information

What Tandar® Lotion contains

The active substance is Dimeticone 4% w/w.

Dimeticone is not a chemical poison. It works by a physical process which effectively covers and drowns the louse.

The other ingredients are Cyclomethicone 5.

Cyclomethicone 5 is a carrier ingredient which evaporates after application leaving the active ingredient to kill the lice.

What Tandar® looks like

It is a clear colourless solution.

Tandar® is available in 50ml, 100ml, 150ml and 200ml although not all packs may be marketed.

Marketing Authorisation Holder and Manufacturer

Thornton & Ross Ltd., Huddersfield, HD7 5QH, UK.

Date of preparation of the package leaflet

This leaflet was prepared in January 2008

Tandar® is a registered Trade Mark of Thornton & Ross Ltd.

About head lice

- Head lice vary in size according to their age. They may be between 1/2mm and 3mm long (from the size of a printed full stop up to the size of a sesame seed). Head lice can be difficult to spot because they can match their colour to that of the environment.
- Lice live close to the scalp where they feed on blood and this can cause the scalp to itch.
- Head lice cannot jump, fly or swim and can only be acquired by direct head to head contact. This is why lice are commonly found on the heads of children and those in close contact with children and why it is important to check the heads of all the family members when head lice are found.
- Head lice only live on humans and have no preference for clean or dirty hair.

- The female louse will lay between 3 and 5 eggs per day and these hatch after 7 days. This is why it is important to repeat this treatment after 7 days to ensure that any lice which have hatched after the first treatment are killed.
- Once the louse has hatched, the empty case (known as a nit) will remain glued to the hair shaft. Nits are completely harmless and can be removed with the fingers of a fine toothed comb.

LABELLING

Text for Non-Marketed Packs

Product: Carton: Tandar 4% Lotion 50ml, 100ml, 150ml, 200ml

FRONT DESIGN PANEL

T&R
Clinically proven to kill headlice
A new way to eradicate head lice
Tandar® 4% Lotion
Dimeticone
Skin friendly
Odourless
Easy to apply
No organophosphates

P

BACKTEXT PANEL

IMPORTANT: Please read the enclosed information leaflet carefully before use.

Tandar® Lotion is for the treatment of head lice in adults and children aged 6 months and over.

HOW TO APPLY:

- Apply sufficient lotion evenly over DRY hair ensuring that the scalp is fully covered.
- Work into the hair spreading the liquid evenly from the roots to tips. Allow the hair to dry naturally.
- Leave on the hair for at least 8 hours or overnight.
- Wash the hair with normal shampoo, rinse thoroughly with water and dry.
- It is important that Tandar® Lotion is applied again after seven days to deal with any lice which may hatch in that time. Failure to repeat the treatment may result in the return of a louse infestation.

If accidentally introduced into the eyes, flush with water.

Do not continue using Tandar® if a skin rash or other signs of hypersensitivity occur.

FOR EXTERNAL USE ONLY

Tandar® solution is applied to the hair and scalp and is for external use only.

Do not use if you are sensitive to either of the ingredients in Tandar®.

Children under 6 months should only be treated under medical supervision.

Warning: Hair should be kept away from naked flames, cigarettes and other sources of ignition while treatment with Tandar® is underway. Tandar® is not water based and will not prevent hair from burning.

Take care if accidentally spilled as Tandar® may cause a slip hazard.

Active ingredient: Dimeticone 4% w/w.

Also contains Cyclomethicone 5.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Keep in original carton.

PL 00240/0344

Licence Holder: Thornton & Ross Ltd., Huddersfield, HD7 5QH, UK

Tandar® is a registered Trade Mark of Thornton & Ross Ltd.

Text for Non-Marketed Packs

Product: Label: Tandar 4% Lotion 50ml, 100ml, 150ml, 200ml

FRONT LABEL

T&R

Tandar® 4% Lotion

Dimeticone

A new way to eradicate head lice

Skin friendly

Odourless

Easy to apply

No organophosphates

P

BACK LABEL

Tandar® Lotion is for the treatment of head lice in adults and children aged 6 months and over.

IMPORTANT: Please read the enclosed information leaflet carefully before use.

Do not use if you are sensitive to either of the ingredients in Tandar®.

HOW TO APPLY:

- Apply sufficient lotion evenly over DRY hair ensuring that the scalp is fully covered.
- Work into the hair spreading the liquid evenly from the roots to tips. Allow the hair to dry naturally.
- Leave on the hair for at least 8 hours or overnight.
- Wash the hair with normal shampoo, rinse thoroughly with water and dry.
- It is important that Tandar® Lotion is applied again after seven days to deal with any lice which may hatch in that time. Failure to repeat the treatment may result in the return of a louse infestation.

Warning: Hair should be kept away from naked flames, cigarettes and other sources of ignition while treatment with Tandar® is underway. Tandar® is not water based and will not prevent hair from burning.

If accidentally introduced into the eyes, flush with water. Do not continue using Tandar® if a skin rash or other signs of hypersensitivity occur.

FOR EXTERNAL USE ONLY

ACTIVE INGREDIENT: Dimeticone 4% w/w.

Also contains Cyclomethicone 5.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Licence Holder: Thornton & Ross Ltd., Huddersfield, HD7 5QH, UK

PL 00240/0344

Text for Non-Marketed Packs

Product: Back Label: Tandar 4% Lotion 50ml

BACK LABEL

Tandar® Lotion is for the treatment of head lice in adults and children aged 6 months and over.

IMPORTANT: Peel and read reverse of label before use. Do not remove. Please also read the enclosed information leaflet carefully before use.

FOR EXTERNAL USE ONLY

ACTIVE INGREDIENT: Dimeticone 4% w/w.

Also contains Cyclomethicone 5.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Licence Holder: Thornton & Ross Ltd., Huddersfield, HD7 5QH, UK

PL 00240/0344

HOW TO APPLY:

- Apply sufficient lotion evenly over DRY hair ensuring that the scalp is fully covered.
- Work into the hair spreading the liquid evenly from the roots to tips. Allow the hair to dry naturally.
- Leave on the hair for at least 8 hours or overnight.
- Wash the hair with normal shampoo, rinse thoroughly with water and dry.
- It is important that Tandar® Lotion is applied again after seven days to deal with any lice which may hatch in that time. Failure to repeat the treatment may result in the return of a louse infestation.

IMPORTANT:

Warning: Hair should be kept away from naked flames, cigarettes and other sources of ignition while treatment with Tandar® is underway. Tandar® is not water based and will not prevent hair from burning.

If accidentally introduced into the eyes, flush with water.

Do not use if you are sensitive to either of the ingredients in Tandar®.

Children under 6 months should only be treated under medical supervision.

Do not continue using Tandar® if a skin rash or other signs of hypersensitivity occur.

Take care if accidentally spilled as Tandar® may cause a slip hazard.

Tandar® is a registered Trade Mark of Thornton & Ross Ltd.

PEEL BACK GREEN TAB