

Public Assessment Report

TARODENT 0.2% MOUTHWASH

**CHLORHEXIDINE DIGLUCONATE 0.2% W/V
(AS CHLORHEXIDINE DIGLUCONATE SOLUTION)**

PL 15842/0009

TARODENT 0.2% MOUTHWASH
Chlorhexidine Digluconate 0.2% w/v
(as Chlorhexidine Digluconate Solution)

PL 15842/0009

UKPAR

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TARODENT 0.2% MOUTHWASH
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PL 15842/0009

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) has granted Taro Pharmaceuticals (UK) Limited a Marketing Authorisation (licence) for the medicinal product Tarodent 0.2% Mouthwash. Tarodent Mouthwash is indicated for:

The inhibition of the formation of dental plaque.

As an aid in the treatment and prevention of gingivitis and in the maintenance of oral hygiene, particularly in situations where toothbrushing cannot be adequately employed (e.g. following oral surgery, in mentally or physically handicapped patients).

Also for use in a post-peridontal surgery regimen to promote gingival healing.

It is useful in the management of aphthous ulceration and oral candidal infections (e.g. denture stomatitis and thrush).

Tarodent Mouthwash contains 0.2% w/v chlorhexidine digluconate which is an antimicrobial preparation for external use. It is effective against a wide range of Gram negative and Gram positive vegetative bacteria, yeast, dermatophyte fungi and lipophilic viruses. It is active against a wide range of many common dental conditions.

The data presented to the MHRA, before licensing, demonstrated that Tarodent Mouthwash is essentially similar or equivalent to the approved product, Corsodyl Mouthwash, PL 00079/0313, held by Beecham Group, granted in February 1994. Corsodyl Mouthwash was first licensed in Ireland in 1976 and in the UK in 1977 (as PL 00029/0124 held at the time by ICI). Consequently, Tarodent Mouthwash and Corsodyl Mouthwash can be used interchangeably.

No new or unexpected safety concerns arose from this application and it was decided that the benefits of using Tarodent Mouthwash outweigh the risks, hence a Marketing Authorisation has been granted.

TARODENT 0.2% MOUTHWASH
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(AS CHLORHEXIDINE DIGLUCONATE SOLUTION)

PL 15842/0009

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 Tarodent Mouthwash (PL 15842/0009) to Taro Pharmaceuticals (UK) Limited on 26th April 2006. The legal status of this product is General Public Medicine.

The application was submitted as an abridged application according to Article 10.1 [formerly Article 10.1(a)(iii)] of Directive 2001/83/EC as amended, claiming essential similarity to Corsodyl Mouthwash, PL 00079/0313, held by Beecham Group, granted in February 1994. Corsodyl Mouthwash was first licensed in Ireland in 1976 and in the UK in 1977 (as PL 00029/0124 held at the time by ICI).

The product contains the active ingredient chlorhexidine digluconate. Chlorhexidine digluconate is an antimicrobial preparation for external use. It is effective against a wide range of Gram negative and Gram positive vegetative bacteria, yeast, dermatophyte fungi and lipophilic viruses.

Because of its cationic nature, Chlorhexidine binds strongly to skin, mucosa and tissues and is thus very poorly absorbed. No detectable blood levels have been found following oral use.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 15842/0009

PROPRIETARY NAME: Tarodent 0.2% Mouthwash

ACTIVE(S): Chlorhexidine Digluconate

COMPANY NAME: Taro Pharmaceuticals (UK) Limited

E.C. ARTICLE: Article 10.1 [formerly Article 10.1(a)(iii) of Directive 2001/83/EC]

LEGAL STATUS: GSL

INTRODUCTION

1.1 Legal Basis

A standard abridged application for an oral aqueous mouthwash solution containing 0.2% v/v of Chlorhexidine Digluconate, as the active ingredient. The application has been presented under Article 10.1 and claims essential similarity with Corsodyl Mouthwash, PL 00079/0313, held by Beecham Group, granted in February 1994. Corsodyl Mouthwash was first licensed in Ireland in 1976 and in the UK in 1977 (as PL 00029/0124 held at the time by ICI).

Chlorhexidine has been used for many years as an antiseptic and disinfectant, effective against a wide range of Gram negative and Gram positive vegetative bacteria, yeast, dermatophyte fungi and lipophilic viruses. It is effective in the treatment of a wide range of many common dental conditions.

1.2 Use

Chlorhexidine has been used for many years as an antiseptic and disinfectant, and its activity against a wide range of both Gram-positive and Gram-negative bacteria is well documented.

1.3 Legal status

The legal status is GSL.

DRUG SUBSTANCE

A single source of active substance is proposed). Information on the drug substance has been provided by use of a Certificate of Suitability. The certificate certifies that the Ph. Eur monograph for chlorhexidine digluconate solution suitably controls the purity of the drug substance.

The specification proposed by the applicant complies with Ph. Eur requirements and is satisfactory. Certificates of Analysis have been provided for four batches of chlorhexidine digluconate solution from the active ingredient manufacturer. All batches comply with the Ph. Eur specification. Batch analytical data are also provided for the same batches retested by the finished product manufacturer and are satisfactory.

The drug substance is stored in metal drums with polyethylene liners. Satisfactory stability data is provided to support the proposed re test period of 3 years when stored at or below 25°C

DRUG PRODUCT

Composition

The composition is satisfactory and tabulated below.

Ingredients	Ref Standard
Chlorhexidine Digluconate Solution (20% solution)	Ph. Eur
Ethanol 96%	Ph. Eur
Polysorbate 80	Ph. Eur
Peppermint oil	Ph. Eur
Sorbitol 70% solution	Ph. Eur
Purified water	Ph. Eur

Note: Chlorhexidine Digluconate Solution (Ph. Eur) is a 20% solution.

PHARMACEUTICAL DEVELOPMENT

Drug Substance

The product is a simple solution of the drug substance in purified water with other excipients added. Chlorhexidine digluconate itself cannot be isolated as a solid and is manufactured as a 20% w/v aqueous solution for the manufacture of the mouthwash.

Excipients

The function of each added excipient has also been explained and justified.

Container Closure System

The mouthwash is packaged in amber polyethylene terephthalate bottles with polypropylene child resistant, tamper evident closures. Each bottle contains 300 ml and is supplied with a polypropylene measuring cup. Data are provided for the primary packaging to show compliance with EU food safety requirements

Microbiological Attributes

The finished product specification includes a Ph Eur test for microbial contamination, and complies with Category 3A requirements. Due to the inherent antimicrobial properties of chlorhexidine and certain formulation constituents and previous successful microbial testing the manufacturer intends to periodically test the finished product.

MANUFACTURE

GMP Statement and Manufacturing Chain

Suitable sites are named for manufacture, assembly, QC and EU batch release. A satisfactory GMP compliance statement and manufacturing licence issued by the Irish Medicines Board are provided for the named sites.

Description of the Manufacturing Process

A satisfactory formula and description of manufacture are provided. There are no re-processing data provided.

Critical phases of the manufacturing process have been satisfactorily identified and appropriate in-process controls are in place.

The analytical methods and limits are the same as those used in finished product testing and comply with current guidelines and are accepted.

No formal process validation data are provided but retrospective analytical data for several production batches manufactured at the proposed manufacturing site are provided. The results comply with in-process requirements and also demonstrate batch to batch consistency to a satisfactory standard.

CONTROL OF EXCIPIENTS

The list of excipients, complying with Ph. Eur requirements, is given under “Composition” above. Satisfactory Certificates of Analysis have been provided for each excipient and are accepted. The drug product manufacturer, following receipt from the suppliers, performs satisfactory routine tests.

CONTROL OF DRUG PRODUCT

Specifications

A satisfactory finished product specification (release and shelf-life) is provided and complies with BP requirements for Chlorhexidine Mouthwash. The specification proposed is supported by batch analytical and stability data.

Analytical Procedures

Satisfactory methodology and validation data are provided.

Batch data

Satisfactory data are provided for batches manufactured at the proposed site and are considered representative of the product to be marketed.

Characterisation of Impurities

This is satisfactory.

CONTAINER CLOSURE SYSTEM

Satisfactory details of supplier specification, product construction, standards and compliance statements are provided. Satisfactory routine tests performed by drug product manufacturer following receipt of packaging materials are provided.

STABILITY OF DRUG PRODUCT

Stability data has been provided on several batches stored under real-time and accelerated conditions. The data supports the product shelf-life of three years with the storage precautions: Do not store above 25°C. Store in original container. An in-use shelf life of 1 month after first opening Tarodent is proposed and is satisfactory.

TSE

The applicant has provided a declaration that no material of animal or human origin is used in manufacture of the finished product. Polysorbate 80 used is of plant origin.

ESSENTIAL SIMILARITY

The following data support essential similarity:

- a) Acceptable choice of test and reference products
- b) The impurity profile of the test product is comparable with that of the reference product and considered satisfactory.
- c) Bactericidal and bacteriostatic activity of test and reference products are similar
- d) The active substances conform to Ph. Eur. requirements and comply with the ICH guidelines.

QUALITY OVERALL SUMMARY

This is satisfactory.

PRODUCT PARTICULARS

Product Brand Name

The proposed name of the product is Tarodent 0.2% Mouthwash. The product has been named in line with current requirements and is considered satisfactory.

Summary of Product Characteristics

Satisfactory SPC provided.

Patient Information Leaflet

Satisfactory coloured mock-ups are provided. The applicant has until 1st July 2008 to amend the order in which the information appears in the leaflet and provide user testing data (both parts of Article 59, Directive 2004/27/EC must be complied with at the same time).

Labelling

Satisfactory. Braille labelling also provided.

Marketing Authorisation Application (MAA) Form

This is satisfactory. The Marketing Authorisation holder is Taro Pharmaceuticals (UK) Limited, First Floor, Prince of Wales House, Bluecoats Avenue, Hertford, Hertfordshire, SG14 1PB, United Kingdom. The Qualified Person responsible for pharmacovigilance is stated and their CV is included.

CONCLUSION

A product licence may be granted for this product.

PRECLINICAL ASSESSMENT

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

CLINICAL ASSESSMENT

1. INTRODUCTION AND BACKGROUND

This is a National Abridged application claiming essential similarity to the UK brand leader Corsodyl Mouthwash Original, PL 0079/0313, which has been licensed in the UK for more than 10 years. It was first licensed in the UK to ICI in 1977, and following change of ownership is now licensed to Beecham Group plc trading as GlaxoSmithKline Consumer Healthcare. Its legal status is GSL.

A number of similar generic products are already licensed in the UK.

Tarodent mouthwash contains 0.2% w/v Chlorhexidine Digluconate which is well characterised in the literature. It is an antimicrobial preparation for external use, effective against a wide range of Gram negative and Gram positive vegetative bacteria, yeast, dermatophyte fungi and lipophilic viruses. It is effective in the treatment of a wide range of many common dental conditions.

As the product is locally acting for external use (and is very poorly absorbed), the provisions of the CPMP note for guidance 239/95 for locally applied, locally acting products apply. In particular, therapeutic equivalence with regard to efficacy and safety must be demonstrated by means such as clinical trials, human pharmacodynamic studies or local availability studies. Non-clinical models must be adequately validated.

2. INDICATIONS

The applicant has submitted the following:

For inhibition of the formation of dental plaque.

As an aid in the treatment and prevention of gingivitis and in the maintenance of oral hygiene, particularly in situations where toothbrushing cannot be adequately employed (e.g. following oral surgery, in mentally or physically handicapped patients).

Also for use in a post-peridontal surgery regimen to promote gingival healing.

It is useful in the management of aphthous ulceration and oral candidal infections (e.g. denture stomatitis and thrush).

3. DOSE & DOSE SCHEDULE

The applicant has submitted the following:

Thoroughly rinse the mouth for about one minute with 10 ml, twice daily. In the dental surgery the patient should be instructed to rinse the mouth for one minute prior to treatment.

Tarodent is incompatible with anionic agents, which are usually present in conventional dentifrices. These should, therefore, be used before Tarodent (rinsing the mouth between treatments) or at a different time of the day.

For the treatment of gingivitis a course of about one month is advisable although some variation in response is to be expected. In the case of aphthous ulceration and oral candidal infections treatment should be continued for 48 hours after clinical resolution. For the treatment of dental stomatitis the dentures should be cleansed and soaked in Tarodent for 15 minutes, twice daily.

Children and the elderly: There are no special dosage recommendations for either elderly patients or children. The normal adult dose is appropriate unless otherwise recommended by the dentist or the physician.

Route of administration: External (oral) use. This product is not intended to be swallowed.

4. TOXICOLOGY

Extensive bibliographic toxicology documentation is provided.

5. CLINICAL PHARMACOLOGY

Tarodent mouthwash contains 0.2% w/v Chlorhexidine Digluconate which is an antimicrobial preparation for external use. It is effective against a wide range of Gram negative and Gram positive vegetative bacteria, yeast, dermatophyte fungi and lipophilic viruses.

Because of its cationic nature, Chlorhexidine binds strongly to skin, mucosa and tissues and is thus very poorly absorbed. No detectable blood levels have been found following oral use.

Chlorhexidine's activity in treating common dental conditions is based on its non specific interaction with bacterial cell membrane phospholipids. The clinical expert argues that efficacy may thus be demonstrated by validated microbiological methods. This assessor accepts the legitimacy of this approach. The solution formulation of the product is such that there is no reason to suspect that Tarodent and Corsodyl might differ in the active ingredient getting to the site of therapeutic action, i.e. the bacterial cell membrane.

MIC Testing (bacteriostatic activity)

MIC testing was performed for test and reference preparations on the major oral organisms including *Candida albicans*. In 10 of the 12 organisms tested activity was identical whilst in the remaining two there was a small difference only. This is satisfactory.

European Suspension Test (bactericidal activity)

The European Suspension Test was performed for test and reference preparations on five major oral bacteria plus *Candida albicans*. Results were recorded at the conventional 5 minute point and also at 1 minute, in order to reflect the way the product is used according to the SPC. The results at both time points were satisfactory for the demonstration that the two products should be therapeutically equivalent.

Assessor's Comment

The nature of these formulations is such that one would not expect that there might be any meaningful difference in efficacy between them. The results of the microbiological tests performed by the applicant are fully consistent with this expectation and are sufficient to demonstrate *in vitro* equivalence.

6. EFFICACY

No new clinical data are submitted. It is not considered that clinical trials are necessary in order to demonstrate therapeutic equivalence.

7. SAFETY

Standard literature references (e.g. Dollery) state that chlorhexidine does not have pharmacological activity on human tissues. The safety of this type of product has been established by long clinical experience and no new safety issues are identified in the dossier or in the expert reports.

8. EXPERT REPORT

An appropriately qualified pharmaceutical physician, provides a satisfactory clinical expert report. It includes a brief review of the published literature and discusses the work undertaken by the applicant in support of this application. The clinical expert successfully argues that therapeutic equivalence is adequately demonstrated by well established and validated *in vitro* bacteriological studies, and that clinical trials are not necessary.

9. SUMMARY OF PRODUCT CHARACTERISTICS

The SPCs are considered satisfactory and are consistent with the SPCs for the reference product.

10. PATIENT INFORMATION LEAFLET

The PILs are considered satisfactory and are consistent with the PILs for the reference product.

11. LABELLING

The labelling is considered satisfactory.

12. DISCUSSION

The requested indications are satisfactory and equivalence to the UK brand leader has been satisfactorily demonstrated by the *in vitro* bacteriological studies. The product literature is satisfactory.

12. CONCLUSIONS

Overall, there is no clinical objection to the grant of marketing authorisations for these applications. No new or unexpected safety concerns arise from these applications.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The quality characteristics of Tarodent Mouthwash are well defined and controlled. The specifications are satisfactory and supported by batch analytical data and stability data. The product has been found to be essentially similar to the reference product.

PRECLINICAL

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

EFFICACY

Tarodent mouthwash contains 0.2% w/v Chlorhexidine Digluconate which is well characterised antimicrobial in the literature, effective in the treatment of a wide range of many common dental conditions. No new or unexpected safety concerns arise from this application.

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 product is essentially similar to the reference product. Extensive clinical experience with Chlorhexidine Digluconate is considered to have demonstrated the therapeutic value of the compound. The risk benefit is therefore considered to be positive.

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CHLORHEXIDINE DIGLUCONATE 0.2% W/V
(AS CHLORHEXIDINE DIGLUCONATE SOLUTION)

PL 15842/0009

STEPS TAKEN FOR ASSESMENT

1	Application received 9 th May 2001
2	Assessment started 6 th July 2001
3	Further information requested 17 th September 2001
4	Replies outstanding 20 th June 2002
5	Response to questions received 23 rd September 2002
6	Replies outstanding 24 th September 2002
7	Response to questions received 16 th July 2003
8	Response to questions received 5 th September 2003
9	Further information requested 16 th October 2003
10	Response to questions received 26 th May 2004
11	Further information requested 19 th November 2004
12	Response to questions received 4 th May 2005, 22 nd June 2005, 19 th January 2006
13	The application was determined on 25 th April 2006.

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STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

TARODENT 0.2% MOUTHWASH
CHLORHEXIDINE DIGLUCONATE 0.2% W/V
(AS CHLORHEXIDINE DIGLUCONATE SOLUTION)

PL 15842/0009

SUMMARY OF PRODUCT CHARACTERISTICS

1. Trade Name of the Medicinal Product

Tarodent 0.2% Mouthwash

2. Qualitative and Quantitative Composition

Chlorhexidine Digluconate 0.2% w/v.(as Chlorhexidine Digluconate Solution).

For excipients see Section 6.1

3. Pharmaceutical Form

Mouthwash

A clear or slightly opalescent solution with peppermint odour

Clinical Particulars

4.1. Therapeutic Indications

For inhibition of the formation of dental plaque.

As an aid in the treatment and prevention of gingivitis and in the maintenance of oral hygiene, particularly in situations where toothbrushing cannot be adequately employed (e.g. following oral surgery, in mentally or physically handicapped patients).

Also for use in a post-peridontal surgery regimen to promote gingival healing.

It is useful in the management of aphthous ulceration and oral candidal infections (e.g. denture stomatitis and thrush).

4.2. Posology and Method of Administration

Thoroughly rinse the mouth for about one minute with 10 ml, twice daily. In the dental surgery the patient should be instructed to rinse the mouth for one minute prior to treatment.

Tarodent is incompatible with anionic agents which are usually present in conventional dentifrices. These should, therefore, be used before Tarodent (rinsing the mouth between treatments) or at a different time of the day.

For the treatment of gingivitis a course of about one month is advisable although some variation in response is to be expected. In the case of aphthous ulceration and oral candidal infections treatment should be continued for 48 hours after clinical resolution. For the treatment of dental stomatitis the dentures should be cleansed and soaked in Tarodent for 15 minutes, twice daily.

Children and the elderly: There are no special dosage recommendations for either elderly patients or children. The normal adult dose is appropriate unless otherwise recommended by the dentist or the physician.

Route of administration: External (oral) use. This product is not intended to be swallowed.

4.3. Contra-indications

Tarodent is contraindicated for patients who have previously shown a hypersensitivity reaction to chlorhexidine. Such reactions are rare.

4.4. Special Warnings and Precautions for Use

For oral (external) use only – keep out of the eyes and ears.

If the mouthwash comes into contact with the eyes, wash out immediately and thoroughly with water.

4.5. Interactions with other Medicaments and other forms of Interaction

Chlorhexidine Digluconate is incompatible with anionic agents.

4.6. Pregnancy and Lactation

There is no evidence of any adverse effects on the foetus arising from the use of chlorhexidine during pregnancy or lactation, therefore, no special precautions are recommended.

4.7. Effects on Ability to Drive and Use Machines

None reported.

4.8. Undesirable Effects

Discolouration

A superficial discolouration of the dorsum of the tongue may occur. This disappears after treatment is discontinued. Discolouration of the teeth and silicate or composite restorations may also occur. This stain is not permanent and can largely be prevented by brushing with a conventional toothpaste daily before using the mouthwash, or, in the case of dentures, cleaning with a conventional denture cleaner. However, in certain circumstances a professional prophylaxis (scaling and polishing) may be required to remove this stain completely. Stained anterior tooth-coloured restorations with poor margins or rough surfaces which are not adequately cleaned by professional prophylaxis may require replacing. Similarly, where normal toothbrushing is not possible, for example with intermaxillary fixation, or with extensive orthodontic appliances, scaling and polishing may also be required once the underlying condition has been resolved.

Taste

Transient disturbances of taste sensation and a burning sensation of the tongue may occur on initial use of the mouthwash. These effects usually diminish with continued use.

Oral Desquamation

In cases where oral desquamation occurs dilution of the mouthwash with an equal volume of tap water, freshly mixed, will often allow continued use of the mouthwash.

Parotid gland swelling

Very occasionally, swelling of the parotid glands during the use of chlorhexidine mouthrinses has been reported. In all cases spontaneous resolution has occurred on discontinuing treatment.

Irritative skin reactions

Irritative skin reactions to Chlorhexidine preparations can occasionally occur. Generalised allergic reactions to Chlorhexidine have also been reported but are extremely rare.

4.9. Overdose

This has not been reported.

Accidental ingestion: chlorhexidine taken orally is poorly absorbed. Systemic effects are unlikely even if large volumes are ingested. However, gastric lavage may be advisable using milk, raw egg, gelatin or mild soap. Employ supportive measures as appropriate.

Pharmacological Properties

5.1. Pharmacodynamic Properties

Tarodent mouthwash contains 0.2% w/v Chlorhexidine Digluconate which is an antimicrobial preparation for external use. It is effective against a wide range of Gram negative and Gram positive vegetative bacteria, yeast, dermatophyte fungi and lipophilic viruses. It is active against a wide range of many common dental conditions.

5.2. Pharmacokinetic Properties

Because of its cationic nature, Chlorhexidine binds strongly to skin, mucosa and tissues and is thus very poorly absorbed. No detectable blood levels have been found following oral use.

5.3. Preclinical Safety Data

No further information is included

Pharmaceutical Particulars

6.1. List of Excipients

Ethanol (96%), Polysorbate 80, sorbitol 70% solution, peppermint oil, purified water.

6.2. Incompatibilities

Hypochlorite bleaches may cause brown stains to develop in fabrics that have previously been in contact with preparations containing Chlorhexidine.

6.3. Shelf Life

Three years

In-use shelf life of 1 month after first opening Tarodent.

6.4. Special Precautions for Storage

Do not store above 25°C. Store in original container.

6.5. Nature and Contents of Container

Amber polyethylene terephthalate bottles with polypropylene child resistant, tamper evident closures.

Each bottle contains 300 ml and is supplied with a polypropylene measuring cup.

6.6. Instruction for Use/Handling

None

7. Marketing Authorisation Holder

Taro Pharmaceuticals (UK) Ltd
First Floor
Prince of Wales House
3 Bluecoats Avenue
Hertford
Hertfordshire
SG14 1PB

8. Marketing Authorisation Number

PL 15842/0009

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25/04/2006

10 DATE OF REVISION OF THE TEXT

25/04/2006

**TARODENT 0.2% MOUTHWASH
PL 15842/0009**

BRaille LABELLING



TARODENT

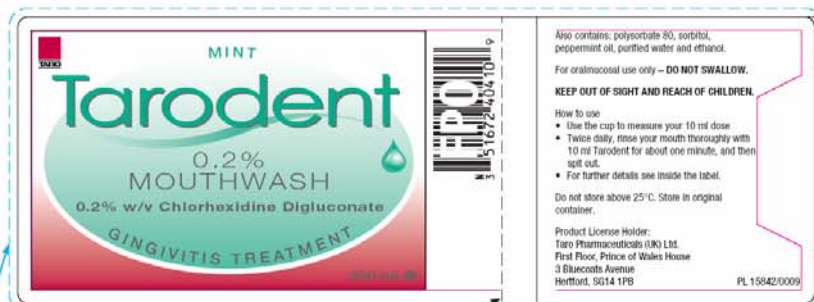
TARODENT 0.2% MOUTHWASH PL 15842/0009

PRODUCT INFORMATION LEAFLET AND LABEL

PMS 200 PMS BLACK PMS 339

APPROVAL				
DATE: 12/21/05	LPK#: 70941-1205-0	ART COPY CTRL.#		
PASS#	UPC#	PHARMACOD#		
DEPARTMENT	SIGNATURE	NO	YES	DATE
PRODUCTION				
ART				
MARKETING				
ENGINEERING				
G.C.				
REG.				
MEDICAL OFFICER				
CLIENT				

THIS COLOR PROOF INDICATES COLOR BREAK ONLY AND MAY NOT ACCURATELY REFLECT ACTUAL PRODUCTION COLOR. IF YOU HAVE ANY QUESTIONS OR COMMENTS PLEASE CALL TARO PHARMACEUTICALS-ART DEPARTMENT 800-544-1448



Perforation ← booklet area →

63mm 45mm 44mm 44mm 43mm

<p>immersing them in the mouthwash for 15 minutes twice a day.</p> <p>You will need to take Tarodent for about one month to treat gum disease. For denture sore mouth or oral thrush, continue using the mouthwash for two days after healing has occurred.</p> <p>If you are having dental surgery, rinse as directed by your dentist.</p> <p>WHEN USING TARODENT</p> <p>Like all medicines Tarodent can have side effects.</p>	<p>It may cause staining of your teeth and tongue. This is not permanent and can be prevented by brushing with toothpaste before using the mouthwash and avoiding tannin-containing food and drink (e.g. tea, coffee, red wine) for one hour before using the mouthwash. Sometimes the stain may need to be removed by a simple scale and polish by your dentist or hygienist.</p> <p>Some changes in the way things taste and possibly a burning sensation of the tongue may occur when you first use the</p>	<p>mouthwash. These effects normally go away with further use of the mouthwash.</p> <p>Peeling of the skin on the inside of your mouth may occur. If this happens dilute Tarodent in the same amount of fresh tap water before rinsing. If peeling does not stop, consult your doctor or pharmacist.</p> <p>Very rarely, Tarodent can cause the salivary glands in your cheeks to swell. If this happens stop taking the mouthwash. The effects should then go away.</p>	<p>Sometimes chlorhexidine digluconate can cause a skin rash and, rarely, can cause allergic reactions (rash, itching or shortness of breath).</p> <p>If you are worried about these or any other side effect not mentioned here, please talk to your doctor or pharmacist. If you or a child swallows Tarodent, drink milk, egg white, or take gelatin or mild soap and contact your doctor.</p>	<p>STORING TARODENT MOUTHWASH</p> <p>Keep out of reach and sight of children. Do not store above 25°C. Store in original container. Do not use after the expiry date printed on the label.</p> <p>This leaflet was prepared in March 2005. 70941-1205-0 PL 15842/0009</p>
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65mm

Background area with Bleeds 2 m"m

<p>different time of the day and rinse your mouth with water before using the mouthwash. Avoid bleaching any fabrics which have been in contact with the mouthwash as brown stains may appear.</p> <p>HOW TO USE TARODENT</p> <p>Rinse your mouth, twice daily, with 10 ml of mouthwash for one minute and then spit it out. DO NOT SWALLOW. When treating dental sore mouth, dentures should also be cleaned by</p>	<p>BEFORE USING TARODENT</p> <p>Do not use if you are allergic to Chlorhexidine Digluconate or any other ingredient in Tarodent. Keep the medicine away from eyes and ears. If any of the mouthwash does get into the eyes, wash out straight away with water. If you are pregnant, consult your doctor before using Tarodent. Toothpastes may stop Tarodent working properly if used immediately before the mouthwash. To prevent this, use the toothpaste first or at a</p>	<p>WHAT IS TARODENT USED FOR?</p> <p>It is an antibacterial mouthwash used to:</p> <ul style="list-style-type: none"> Prevent dental plaque Treat and prevent gingivitis (gum disease) Promote gum healing after surgery Manage dental sore mouth and oral thrush Manage recurring mouth ulcers and maintain good mouth hygiene 	<p>WHAT IS TARODENT?</p> <p>Tarodent contains: 0.2% of the active ingredient, Chlorhexidine Digluconate. It also contains polysorbate 80, sorbitol, ethanol, peppermint oil and purified water. Each bottle contains 300 ml.</p> <p>The Marketing Authorisation Holder and manufacturer is Taro Pharmaceuticals (UK) Ltd, First Floor, Prince of Wales House, 3 Bluecoats Avenue, Hertford, SG14 1PB.</p>	
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65mm

43mm 44mm 44mm 45mm 63mm