UK Public Assessment Report

Care Chlorhexidine Digluconate 0.2% w/v Antiseptic Mouthwash Aniseed Flavour

PL 00240/0373

Thornton & Ross Limited
Lay Summary

Care Chlorhexidine Digluconate 0.2% w/v Antiseptic Mouthwash Aniseed Flavour (chlorhexidine digluconate)

This is a summary of the Public Assessment Report (PAR) for Care Chlorhexidine Digluconate 0.2% w/v Antiseptic Mouthwash Aniseed Flavour (PL 00240/0373). Care Chlorhexidine Digluconate 0.2% w/v Antiseptic Mouthwash Aniseed Flavour will be referred to as Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour throughout this report, for ease of reading. It explains how Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

For practical information about Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour and what is it used for?

With the exception of the flavouring system this medicine is the same as Care Chlorhexidine Digluconate 0.2% w/v Antiseptic Mouthwash (PL 00240/0118), which is already authorised. The company that makes Care Chlorhexidine Digluconate 0.2% w/v Antiseptic Mouthwash has agreed that its scientific data can be used as a basis for the grant of an identical licence, Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour (informed consent).

Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour is used to treat and prevent gingivitis (gum disease). It is also used for the treatment of oral thrush and denture sores, for maintaining oral hygiene and in cases of gum ulceration.

How does Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour work?

Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour contains the active substance chlorhexidine digluconate, which is a disinfectant and an antiseptic. This active substance reduces the formation of dental plaque and fights infection in the mouth.

How is Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour used?

Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour is for use in the mouth only and should not be swallowed. In adults, the elderly and children 10 ml of the mouthwash should be measured into the cup provided and then rinsed around the mouth thoroughly for about 1 minute. The mouthwash should then be spat out. Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour should be used twice a day.

Please read the label of the bottle for further information on dosing recommendations, the route of administration and the duration of treatment.

Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour can be obtained without a prescription.
What benefits of Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour have been shown in studies?
Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour is considered identical to the previously granted marketing authorisation for Care Chlorhexidine Digluconate 0.2% w/v Antiseptic Mouthwash (PL 00240/0118), with the same benefits and risks. No new studies have been provided for Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour but reference is made to the studies for Care Chlorhexidine Digluconate 0.2% w/v Antiseptic Mouthwash.

What are the possible side effects from Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour?
Like all medicines, this medicine can cause side effects, although not everybody gets them.

For information about side effects that may occur with using Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour, please refer to the PIL or the Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare Products Regulatory Agency website.

Why is Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour approved?
No new or unexpected safety concerns arose from this application. It was, therefore, considered that the benefits of Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour outweigh the risks, and the grant of this marketing authorisation was recommended.

What measures are being taken to ensure the safe and effective use of Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour?
A Risk Management Plan (RMP) has been developed to ensure that Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour is used as safely as possible. Based on this plan, safety information has been included in the SmPC and the PIL for Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients and healthcare professionals will be monitored and reviewed continuously as well.

Other information about Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour
The marketing authorisation was granted in the UK to Thornton & Ross Limited on 17 December 2014 (PL 00240/0373).

For more information about using Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour, read the PIL, or contact your doctor or pharmacist.

This summary was last updated in February 2015.

The full PAR for Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour follows this summary.
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I Introduction
Based on the review of the data on quality, safety and efficacy, the UK granted a marketing authorisation to Thornton & Ross Limited for the medicinal product Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour (PL 00240/0373) on 17 December 2014.

Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour is indicated:
- to aid prevention of dental plaque formation
- to aid the treatment and prevention of gingivitis
- for the maintenance of oral hygiene
- to promote gingival healing following periodontal surgery
- for the management of recurrent oral ulceration
- for the treatment of denture stomatitis and oral thrush

Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour is a General Sales List medicine (legal status GSL).

This application was submitted as an abridged simple application, according to Article 10c of Directive 2001/83/EC, as amended. The application cross-refers, and claims to be identical to Care Chlorhexidine Digluconate 0.2% w/v Antiseptic Mouthwash (PL 00240/0118), which was granted to Thornton & Ross Limited on 7 September 2004, except for a simple change in flavour.

This medicinal product contains the active substance chlorhexidine digluconate. Chlorhexidine digluconate is a bisbiguanide antiseptic and disinfectant, which is bactericidal or bacteriostatic against a wide range of gram negative and gram positive vegetative bacteria, yeasts, dermatophyte fungi and lipophilic viruses. The antimicrobial activity covers most of the important species occurring in the oral microflora.

No new data have been submitted and none are required for this simple application, as the data are identical to those of the previously granted, cross-referred product.
II Quality aspects

II.1 Introduction
This is a simple, piggyback (informed consent) application for Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour submitted under Article 10c of Directive 2001/83/EC, as amended.

The application cross-refers to Care Chlorhexidine Digluconate 0.2% w/v Antiseptic Mouthwash (PL 00240/0118). The current application is considered valid.

Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour contains the active substance chlorhexidine digluconate at a concentration of 0.2% w/v, which is equivalent to 1.0% v/v Chlorhexidine Gluconate Solution. The excipients present in the mouthwash are hydrogenated polyoxyl castor oil, menthol, anise oil, ethanol (96%), aspartame E951 and purified water. The qualitative and quantitative composition of these excipients is identical to that of the cross-reference product, except for the change in flavour resulting in the inclusion of anise oil and the deletion of peppermint oil.

Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour is packed into a 300 ml amber polyethylene terephthalate (PET) bottle with a high-density polyethylene (HDPE)/polypropylene (PP) tamper-evident child-resistant closure, with expanded polyethylene (EPE) Saranex liner. A 30 ml CE-marked polypropylene dosing cup is included with the packaging.

This packaging is identical to that of the cross-reference product.

II.2 Drug Substance
Chlorhexidine digluconate
The drug substance specification is identical to that of the cross-reference product and is acceptable.

II.3 Medicinal Product
Pharmaceutical development
Confirmation was provided, by an appropriately qualified person, that the Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour is identical to the cross-reference product, except for the product name and the flavour. A change in the flavour system has been reviewed and has been accepted as a simple change of flavour, in accordance with the National informed consent procedure.

Manufacture of the product
The proposed manufacturing sites are consistent with those registered for the cross-reference product. Evidence of Good Manufacturing Practice (GMP) compliance has been provided, which is identical to that of the cross-reference product.

The proposed manufacturing process and batch size are identical to that of the cross-reference product and are acceptable.
None of the excipients contain materials of animal or human origin.

**Finished Product Specification**
The proposed finished product specification is identical to that of the reference product, except for the change to the description of the odour of the product as a result of the change in flavour. This is acceptable.

**Stability of the product**
The proposed shelf-life for Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour is 2 years unopened, and 28 days once opened. This is identical to that of the cross-reference product.

The storage conditions for Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour are “Do not store above 25 °C”, which are identical to that of the cross-reference product.

**II.4 Discussion on chemical, pharmaceutical and biological aspects**
The quality data for this application are consistent with those previously assessed for the marketing authorisation for Care Chlorhexidine Digluconate 0.2% w/v Antiseptic Mouthwash (PL 00240/0118) and, as such, have been judged to be satisfactory. The grant of a marketing authorisation is recommended.

**III Non-clinical aspects**
As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new non-clinical data has been supplied and none are required.

No Environmental Risk Assessment (ERA) has been performed as the proposed product will be used in the same way as the cross-referenced product and it is not expected that there will be a change in the environmental exposure following the approval of this application.

The grant of a marketing authorisation is recommended.

**IV Clinical aspects**
As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new clinical data have been supplied and none are required.

**Risk Management Plan (RMP)**
The applicant has submitted an RMP, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour.

A summary of safety concerns and risk minimisation measures, as approved in the RMP, are listed below:
Summary table of safety concerns

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<thead>
<tr>
<th>Important identified risks</th>
<th>Discolouration of oral surfaces</th>
<th>Taste disturbance</th>
<th>Oral desquamation</th>
<th>Parotid swelling</th>
<th>Allergy to the active ingredient</th>
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<td>Included in SPC section(s)</td>
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<td>4.8 Undesirable effects</td>
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Summary table of risk minimisation measures

<table>
<thead>
<tr>
<th>Safety concern</th>
<th>Routine risk minimisation measures</th>
<th>Additional risk minimisation measures</th>
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<tbody>
<tr>
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<td>4.3 Contraindications</td>
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<td>4.4 Special warnings and precautions for use</td>
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<td>4.8 Undesirable effects</td>
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| Important potential risks             |                                    |                                      |
| None                                  | N                                  | NA                                   |

| Missing information                    |                                    |                                      |
| None                                  | None                               | NA                                   |

The pharmacovigilance statement and the CV of the Qualified Person for Pharmacovigilance were provided, and are acceptable.

The grant of a marketing authorisation is recommended.
V  **User consultation**
The applicant has confirmed that the label-leaflet for Care Chlorhexidine Digluconate Mouthwash Aniseed Flavour is identical in all respects to the user tested label-leaflet for Care Chlorhexidine Digluconate 0.2%w/v Antiseptic Mouthwash except for the product name and design panel. User testing was, therefore, not required and has not been submitted with this application.

VI  **Overall conclusion, benefit/risk assessment and recommendation**
The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-reference product, except for a simple change in flavour. The benefit/risk assessment is, therefore, considered to be positive.

The Summary of Product Characteristics (SmPC), and patient information label-leaflet are satisfactory, in line with current guidelines and consistent with the cross-reference product. In accordance with Directive 2012/84/EU, the current approved UK versions of the SmPC and patient information label-leaflet for this product are available on the MHRA website.
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Steps taken after the initial procedure with an influence on the Public Assessment Report (Type II variations, PSURs, commitments)

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