

Declaration

The products Protefix® Adhesive Cream, Protefix® Adhesive Powder and Protefix® Adhesive Pads are Medical Devices in the European Union and are conform with the European Council Directive 93/42/EEC on Medical Devices.

These products were supervised in Germany by the competent authorities of the different states. The competent authority that is responsible for the supervision of Queisser Pharma, Flensburg is the Landesamt für Gesundheit und Arzneimittelsicherheit des Landes Schleswig-Holstein in Kiel.

This competent authority certifies that the products mentioned above may be labelled with CE and can be exported. This official certificate implicates that the quality of the products is in accordance with the regulations.

The product Protefix® Active Cleanser is considered as a cosmetic in the European Union and is conform with the European Council Directive 76/768/EEC on Cosmetics.

The competent authority that is responsible for the supervision of Queisser Pharma, Flensburg is the Veterinär- und Lebensmittelüberwachung of the City of Flensburg. This competent authority certifies that this product complies with the German Cosmetic law of the Federal Republic of Germany and therefore can be put on the market and can be exported. To meet the German Cosmetic Directive it is necessary to consider Good Manufacturing Praxis at the production of cosmetic products.

Queisser Pharma produces also Medical Products and every two years the supervising authority inspects Queisser Pharma for conformity with GMP. The quality assurance system of the company makes sure that all products were handled in the same way, not dependent on their status.

Flensburg, 06.06.2006

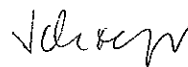
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Axel J. Jürgensen



i. A.

Dr. Renate Schreyer



SPC

1. Trade Name of the Medicinal Product

Protefix® Adhesive Cream

2. Qualitative and quantitative composition

Gantrez	30.00 g
Sodium carboxymethylcellulose	23.00 g
Viscous paraffin	31.73 g
White Vaseline	14.00 g
Silica colloidal anhydrous	1.10 g
Menthol	0.10 g
Azorubin E 122	0.04 g
Methyl-4-hydroxybenzoate	0.03 g

3. Pharmaceutical Form

Cream

4. Clinical Data

4.1. Therapeutic Indication

Adhesive Cream for application to dental prostheses

5. Other Properties

Shelf life 3 years

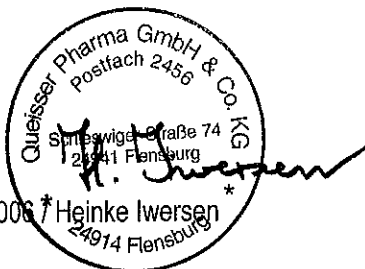
Storage condition Dry place < 25 °C

Package Cannula tube, Polyfoil in folding carton

Instruction: Protefix® Adhesive Cream is applied on the clean and wet denture.

Manufacturer: Queisser Pharma GmbH & Co. KG, Schleswiger Strasse 74, D-24941 Flensburg

06.06.2006 *Heinke Iwersen*



SPC

1. Trade Name of the Medicinal Product

Protifix® Adhesive Cushions

2. Qualitative and quantitative composition

Sodium alginate	28.00 g
Viscose fibre	50.00 g
Polypropylene fibre	22.00 g

3. Pharmaceutical Form

Cushion

4. Clinical Data

4.1. Therapeutic Indication

Adhesive Cushion for application to dental prostheses

5. Other Properties

Shelf life 4 years

Storage condition Dry place < 25 °C

Package OPP-foil in folding carton

Instruction: Protifix® Adhesive Cushions are dipped into lukewarm water and drained. Then they are placed onto the wet denture and pressed on it.

Manufacturer: Queisser Pharma GmbH & Co. KG, Schleswiger Strasse 74, D-24941 Flensburg

06.06.2006 # Heinke Iwersen *



SPC

1. Trade Name of the Medicinal Product

Protifix® Adhesive Powder

2. Qualitative and quantitative composition

Sodium alginate 100.00 g

3. Pharmaceutical Form

Powder

4. Clinical Data

4.1. Therapeutic Indication

Adhesive Powder for application to dental prostheses

5. Other Properties

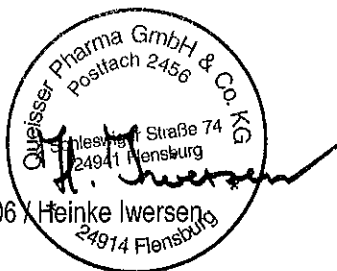
Shelf life 4 years

Storage condition Dry place < 25 °C

Package Plastic bottle in folding carton

Instruction: Protifix® Adhesive Powder is sprinkled thinly and uniformly onto the wet denture.

Manufacturer: Queisser Pharma GmbH & Co. KG, Schleswiger Strasse 74, D-24941 Flensburg



SPC

1. Trade Name of the Medicinal Product

Protefix® Active Cleanser

2. Qualitative and quantitative composition

Sodium bicarbonate	41.77 g
Potassium caroate	35.18 g
Sodium perborate	16.63 g
Citric acid	5.65 g
Sodium lauryl sulphate	0.47 g
Peppermint	0.30 g
Dyestuff	0.07 g

3. Pharmaceutical Form

effervescent-tablets

4. Clinical Data

4.1. Therapeutic Indication

Cleaning tablet for the cleansing of dental prostheses

5. Other Properties

Shelf life 3 years

Storage condition Dry place < 25 °C

Package Aluminium composite-foil in folding carton

Instruction: One Protefix® Active Cleanser tablet is dissolved in half a glass of lukewarm water. The denture is to be placed in the glass. After 15 minutes in the solution the denture is clean and fresh.

Manufacturer: Queisser Pharma GmbH & Co. KG, Schleswiger Strasse 74, D-24941 Flensburg

06.06.2006 / Heiko Iwersen

