# Technical Data Sheet
## NitrAdine® Disinfecting Tablet

## GENERAL INFORMATION

<table>
<thead>
<tr>
<th>Article No.</th>
<th>8.000.00.X.0.0.00</th>
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</thead>
<tbody>
<tr>
<td>Commercial names</td>
<td>NitrAdine Denture, NitrAdine Ortho&amp;Junior, NitrAdine Sport Guard, DiabetXPro</td>
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<tr>
<td>Brand</td>
<td>NitrAdine®</td>
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| Description | \textbf{A breakthrough in denture hygiene technology}  
Nitrade disinfectant tablets are a fast and effective formula for the treatment of Candida albicans on dentures and orthodontic appliances. Disinfecting effervescent tablets work effectively after only 15 minutes. Using of these tablets results in a substantial reduction and/or elimination of:  
• Candida albicans;  
• Staphylococcus aureus;  
• Pseudomonas aeruginosa;  
• Herpes simplex Virus.  
In vitro evaluation data on the sanitization effectiveness of contaminated dentures (with known microbial flora) is available on request. (See Point 5 under heading “Additional Technical Information”). |
| Toxicity & safety | Nitradine disinfectant tablets are for external use only. They may not be inhaled, applied directly into the mouth and should not be swallowed. Tablets should be kept out of reach of children.  
The tablet itself can be slightly irritating if it comes into direct contact with skin or eyes. If this occurs, rinse immediately with plenty of water and seek medical advice. Do not drink the solution.  
If the product is applied according to the instructions on the product packaging there is no health risk by using Nitradine® Denture and Nitradine® Ortho & Junior tablets daily.  
Irritation Test Report Data is available on request.  
The ingredients are listed and accepted for the use in the US and Europe. |
| Composition (patent) | Citric Acid  
Sodium Lauryl Sulfate  
Lactose Monohydrate  
Sodium Bicarbonate  
Sodium Chloride  
Potassium Monopersulfate  
Sodium Carbonate  
Peppermint Flavour  
PVP |
| Manufactured by | \textbf{bonyf AG, Liechtenstein}  
(Swiss Made) |
| Produced for | MSI- Laboratories AG |
| Shelf life | 3 years |
REGULATORY AND LEGAL ASPECTS

<table>
<thead>
<tr>
<th>Classification</th>
<th>Medical Device Class IIB</th>
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<tbody>
<tr>
<td>FDA Classification</td>
<td>510K Number issued by the Food and Drug Authority in the US: K051342</td>
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<tr>
<td>Target audience</td>
<td>Denture and appliance wearers with candida induced denture Stomatitis.</td>
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<td>EN 14885:2006</td>
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<td>EN 13624:2003</td>
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<td>EN 13727:2004</td>
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<td>EN 14476:2005</td>
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PACKAGING

| Size/Quantities:          | Nitradine® Denture |
|                          | Nitradine® Ortho & Junior – 12-20-64 Tablets |
| Blister Paper            | One Side Coated Paper + LDPE + Matt Aluminium foil + LDPE special N The paper conforms to R.E.A.C.H Directive 1907/2006 and complies with all the restrictions set out in the European Directives concerning packaging intended to come in direct contact with foodstuff. |
| Product box              | Pre-printed cardboard |
| Instructions for use     | Instructions for use (taken from instruction sheet for Nitradine® Seniors): |
|                         | 1) Before using Nitradine® Denture, brush, cleanse and rinse the denture as usual. |
|                         | 2) Immerse the denture in a glass of lukewarm water (approx. 150ml), or in the Nitradine Denture Disinfecting Box filled with lukewarm water. |
|                         | 3) Add one tablet. Use only one upper or one lower denture with one tablet. |
|                         | 4) Make sure the denture is fully covered with water. For regular bacteria and yeast infection, allow the denture to soak for 15 minutes in the solution. To ensure that your denture is free of all viruses, soak your denture for 1 hour in the solution. |
|                         | 5) Remove the denture from the solution and rinse well under water before replacing the denture in the mouth. If a taste should remain on your denture after replacing it in your mouth, place the denture in lukewarm water for 10 minutes. |
| Recommended dosage:     | One tablet two times per week, in conjunction with the daily use of Nitradine® SHINE Removable Appliance Toothpaste. |
| Intensive treatment:    | If recommended by your Dentist/Orthodontist, use the tablet initially every day for two weeks. After this two week period has elapsed, use two times per week as part of your cleansing routine. |
### ADDITIONAL INFORMATION

**Standard Languages**
- **Standard Language:** English
- **Other languages available on request:**

**Storage**
- Store cool (withstands max. 50 °C), dark and dry.

**Delivery**
- 6 weeks after initial order

### Scientific References

### Studies
1. TD Nitradine Effectiveness of clinical and microbial biofilm control in female denture wearers. Univ. of Sao Paulo, Brasil. Silva-Lovato1, CH; De Weaver, BZ; Paranjos, HFO1, Watanabe, E1; Pisani, MX1, Souza, RF1 and Ito, IY.
2. TD Nitradine Double blind random placebo controlled trial to test the efficacy of MI Ortho-Junior on oral candida levels in URA patients. Univ. of Malta, Malta.

### Caution
For external use only. Discard solution after use. Do not use if allergic to any of the ingredients or to persulfates. Do not put tablet in mouth. Tablet powder may cause eye damage. Do not drink the solution or use as a mouthwash. Rinse denture well before replacing it in your mouth. Discontinue use and seek medical attention if any irritation, swelling or pain develops following the first or any later use. Consult instructions for use. Store in a dry place. For single use only.

| Additional Technical Information | 1. Safety Material Data Sheet  
| | 2. Confirmation of Conformity  
| | 3. Risk Analysis  
| | 4. Skinethic Irritation Test (Report 02TB0701)  
| | 5. Toxic Oral Irritation Test (Report 06-1177-G2)  
| | 6. Study Report of the In Vitro evaluation data of the sanitisation effectiveness of contaminated dentures with known microbial flora available. Study conducted by Dr R.Tom Glass, Professor of Pathology and Oral Medicine and Dr Robert S. Conrad, Professor of Microbiology and Earl L. Blewett, PhD, Associate Professor of Microbiology at the Oklahoma State University in Tulsa, Oklahoma USA.  
| | 7. Sterlab report: Biocompatibility assays. |
29. TD Nitradine in vitro cleansing efficacy of NitrAdine tabs vs competitors. R&D lab bonyf AG.
30. TD Nitradine In vitro evaluation of Medical disinfecting tablets efficacy against candida albicans, escherichia coli, pseudomonas aeruginosa, streptococcus mutans and streptococcus pyogenes. IPAS.
33. TD Nitradine Effects of denture cleaning agents on candida grown on denture acrylic. Univ. Cardiff, UK
34. TD Nitradine Abstract BSDR 2009 Camiilieri Malta. Aims: To evaluate the efficiency of NitrAdine™ tablets in the reduction of Candida levels, biofilm formation and appliance odour levels in upper. Glasgow Caledonian University UK.
35. TD NITRADINE SUR LE FIL. Advertising in Magazin Sur Le Fil.
41. TD Nitradine L'Orthodontiste. Advertising in Magazin L'Orthodontiste.
42. TD NITRADINE Dentist News le monde & dentaire. Advertising in Magazin Dentist News le monde & dentaire.
43. TD NITRADINE Dossierdepresse. Le Faou Conseil.
47. TD Nitradine Prevention of oral infections induced by removable prosthesis colonized with opportunistic biofilm forming micro-organisms. Bart De Wever, Bart Van de Vannet & Tom Coenye.
49. TD NITRADINE L'importance d'une bonne hygiene buccale pendant le traitement orthodontique amovible. Fédération Francaise d'Orthodontie.