What should be considered when choosing or prescribing saliva substitutes?

Prepared by UK Medicines Information (UKMi) pharmacists for NHS healthcare professionals
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Background
Dry mouth or xerostomia is the feeling of oral dryness, which may be associated with poor functioning of salivary glands. There are a number of causes for a lack of saliva production including loss of secretory tissue in the salivary glands, neurological disease and as a side effect of some drugs (1). Patients with a persistently dry mouth may have poor oral hygiene and are at increased risk of dental caries, periodontal disease and oral infections (2). This Q&A addresses choice of saliva substitutes for dry mouth and prescribing issues around these, particularly for dental practitioners.

Answer
Which saliva substitute?
The use of saliva substitutes may be helpful to patients complaining of a dry mouth and offers symptomatic relief for patients with insufficient salivary function (1). There are a variety of preparations available including artificial saliva replacements (e.g. gels, sprays and mouth rinses) or salivary stimulants (e.g. chewing gums, citric acid tablets). Properly balanced artificial saliva should be of a neutral pH and contain electrolytes (including fluoride) to correspond approximately to the composition of saliva. The acidic pH of some artificial saliva products may be inappropriate for dentate patients as these can cause dental caries (2,3). Ideally, dentate patients should use a fluoride-containing preparation, as this may protect against caries (1). Fluoride-containing preparations include BioXtra gel mouth spray and Salivix Plus (see table). If a preparation without fluoride is used, a fluoride mouthwash should also be used daily in dentate patients (3). Some preparations are derived from animal products and may be unsuitable for vegetarians and people from certain religious groups (1).

Prescribing issues for dentists
As of October 2017, ten artificial saliva preparations are included in the list of preparations approved for prescribing by dental practitioners on NHS prescriptions, known as the Dental Practitioners’ Formulary (DPF). ‘Artificial saliva protective spray DPF’, ‘Artificial saliva oral spray DPF’, ‘Artificial saliva gel DPF’, ‘Artificial saliva pastilles DPF’ and ‘Artificial saliva substitute spray DPF’ can be prescribed for any condition causing dry mouth. The only preparation that can be dispensed against a prescription for:

- ‘Artificial saliva protective spray DPF’ is Aequasyal oral spray,
- ‘Artificial saliva oral spray DPF’ is Xerotin oral spray,
- ‘Artificial saliva gel DPF’ is Biotène Oralbalance saliva replacement gel,
- ‘Artificial saliva pastilles DPF’ are Salivix pastilles,
- ‘Artificial saliva substitute spray’ is AS Saliva Orthana spray.

Saliva Stimulating Tablets (SST) may be prescribed on a dental prescription, for dry mouth in patients with impaired salivary gland function and patent salivary ducts (2).

The four other artificial saliva substitute preparations are included in the BNF as borderline substances. None of the products are licensed medicines, although some are classed as medical devices (e.g. BioXtra products). Indications approved by the Advisory Committee on Borderline Substance (ACBS) include sicca syndrome and xerostomia due to radiotherapy (2). Although the BNF recommends that all prescriptions for borderline substances are endorsed ‘ACBS’, pharmacists will

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Always be paid for supplying an item on the ACBS list whether or not it has been endorsed ‘ACBS’ by the prescriber (4). Primary care organisations may follow up prescriptions for borderline substances not endorsed ‘ACBS’.

All of the available artificial saliva preparations may be purchased from a pharmacy and most of the products cost the same or less than a prescription charge. The majority of artificial saliva products can be prescribed on a dental NHS prescription (see table). The Prescription Pricing Authority (PPA) has confirmed that only formulations listed in the Drug Tariff may be prescribed. For example, BioXtra moisturising gel may be prescribed but BioXtra toothpaste may not (5,6). Dentists are not restricted in the items they may prescribe privately and therefore any of the products can be prescribed on a private dental prescription. Dentists may also sell artificial saliva preparations directly to patients. As none of the artificial saliva preparations are licensed medicines, their sale and supply is not regulated by the Medicines Act or the NHS dental contract.

Table: Available saliva substitutes and preparations to treat dry mouth

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<tr>
<td>Aequasyal (formerly Aquoral) Bluechip Healthcare</td>
<td>Oral spray 40mL</td>
<td>Yes a</td>
<td>&gt;£10 b</td>
<td>Neutral</td>
<td>No</td>
<td>No</td>
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<td>AS Saliva Orthana A.S. Pharma</td>
<td>Oral spray 50mL</td>
<td>Yes c</td>
<td>£7.25</td>
<td>Neutral</td>
<td>No</td>
<td>Yes d</td>
<td>No</td>
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<tr>
<td></td>
<td>Oral spray 500mL refill</td>
<td></td>
<td>£51.18</td>
<td>Neutral</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
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<td></td>
<td>Lozenges (30)</td>
<td>No</td>
<td>£5.18</td>
<td>Neutral</td>
<td>No</td>
<td>Yes d</td>
<td>No</td>
<td>No</td>
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<td></td>
<td>Glandosane Fresenius Kabi</td>
<td>Aerosol spray 50mL (lemon, neutral, peppermint)</td>
<td>Yes i</td>
<td>~ £7 n</td>
<td>Acidic</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td>BioXtra products for dry mouth RIS Products</td>
<td>Saliva replacement gel 50g</td>
<td>Yes g</td>
<td>£7.65</td>
<td>Neutral</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td></td>
<td>Moisturising gel 40mL</td>
<td>Yes l</td>
<td>£7.25</td>
<td>Acidic</td>
<td>No</td>
<td>Yes l</td>
<td>Yes k</td>
<td>No</td>
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<tr>
<td></td>
<td>Gel mouth spray 50mL</td>
<td>Yes l</td>
<td>£7.25</td>
<td>Neutral</td>
<td>Yes l</td>
<td>Yes l</td>
<td>No</td>
<td>No</td>
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<tr>
<td></td>
<td>Toothpaste 50mL</td>
<td>No</td>
<td>&lt; £7</td>
<td>Acidic</td>
<td>Yes m</td>
<td>Yes l</td>
<td>No</td>
<td>No</td>
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<td></td>
<td>Mouthrinse 250mL</td>
<td>No</td>
<td>&lt; £7</td>
<td>Neutral</td>
<td>Yes m</td>
<td>Yes l</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Glandosane Fresenius Kabi</td>
<td>Aerosol spray 50mL (lemon, neutral, peppermint)</td>
<td>Yes i</td>
<td>~ £7 n</td>
<td>Acidic</td>
<td>No</td>
<td>No</td>
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Available through Specialist Pharmacy Service at www.sps.nhs.uk
**Products available**

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<tr>
<td>Saliveze Wyvern Medical Ltd</td>
<td>Oral spray 50mL</td>
<td>Yes ^1</td>
<td>&lt; £7</td>
<td>Neutral</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Saliva Stimulating Tablets Primiulab</td>
<td>Tablets (100)</td>
<td>Yes</td>
<td>£9.14</td>
<td>Acidic ^2</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No ^f</td>
</tr>
<tr>
<td>Salivix Galen</td>
<td>Pastilles (50)</td>
<td>Yes ^g</td>
<td>&lt; £7</td>
<td>Acidic ^f</td>
<td>No</td>
<td>Yes ^r</td>
<td>No</td>
<td>No ^e</td>
</tr>
<tr>
<td>Salivix Plus Galen</td>
<td>Pastilles (50)</td>
<td>No</td>
<td>&lt; £7</td>
<td>Acidic ^q</td>
<td>Yes ^s</td>
<td>Yes ^r</td>
<td>No</td>
<td>No ^e</td>
</tr>
<tr>
<td>Xerotin Norgine</td>
<td>Oral spray 100mL</td>
<td>Yes ^1</td>
<td>&gt; £7 ^u</td>
<td>Neutral</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No ^i</td>
</tr>
</tbody>
</table>

A pH of 7 is considered neutral; a pH of <7 is considered acidic (8).

Notes to support table above:

a- May be prescribed as ‘Artificial saliva protective spray’.
b- Estimated retail price calculated from trade price of £9.85.
c- May be prescribed as ‘Artificial saliva substitute spray’.
d- Contains porcine-derived gastric mucin.
e- Contains xylitol.
f- Contains sorbitol.
g- May be prescribed as ‘Artificial saliva gel’.
h- Biotene contains glucose oxidase, an enzyme added to inhibit bacteria growth. This is not a sugar.
i- Can be prescribed for indications approved by the ACBS.
j- Contains animal products – traces of milk protein extract from cow’s milk and egg white proteins.
k- Gluten can be present in hydrogenated starch hydroxyxlate.
l- Contains 150ppm fluoride.
m- Contains 1450ppm fluoride.
n- Estimated retail price calculated from trade price of £5.68.
o- Contains calcium phosphate dibasic as a buffer to prevent dental caries.
p- May be prescribed as ‘Artificial saliva pastilles’.
q- Contains calcium lactate and sodium phosphate to act as a buffer to protect teeth.
r- Contains E120 colourant derived from Peruvian insects.
s- Contains 0.016mg fluoride per pastille.
t- May be prescribed as ‘Artificial saliva oral spray’.
u- Estimated retail price calculated from trade price of £6.86.

**Summary**

- Dry mouth is a complaint often presented to dental practitioners.
- There are a number of products available to manage this condition, however not all are suitable for every individual.
- Dentate patients in particular should avoid preparations with an acidic pH, due to increased risk of dental decay. Also, a fluoride-containing preparation is preferable for these patients.
- Dental practitioners should be aware that not all preparations may be prescribed on a dental NHS prescription. All available products can be purchased from a pharmacy without a prescription.
Limitations

- Formulations and prices may be subject to change; the information contained in this document is to our knowledge accurate at the time of publication.
- Products listed as 'gluten-free' means they do not contain gluten-containing ingredients, but it does not necessarily mean the product was manufactured in a gluten-free environment.
- This is not a complete list of all products on the market to treat dry mouth.

References

6. Personal communication with Prescription Processing Help Desk. Prescription Pricing Authority. 31/12/08.

Quality Assurance

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May 2017

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Date of check
November 2017

Search strategy
In addition to the references above, the following sources were used to assemble the table of artificial saliva replacement products:

1. In-house databases/resources
2. Manufacturer (Bluechip Healthcare 20/7/17, email) Manufacturer (A.S. Pharma/CCMed 23/5/17, email) Manufacturer (GSK 14/6/17, email) Manufacturer (RIS Products 23/5/17, email) Manufacturer (Fresenius Kabi 12/7/17, email) Manufacturer (Wyvern Medical Ltd/CCMed 17/5/17, email) Manufacturer (Primiuslab 20/6/17, email) Manufacturer (Galen 24/5/17, email) Manufacturer (Norgine 17/5/17, email)