

UKMI Q&A 190.8

Saliva substitutes: Choosing and prescribing the right product.

Prepared by UK Medicines Information (UKMi) pharmacists for NHS healthcare professionals

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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. 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.

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 AS *Saliva Orthana* oral spray and *BioXtra* gel mouth spray and mouthrinse (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 March 2015, 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 *Aequasyl* oral spray (formerly *Aquoral* 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 salivary gland impairment (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 (2). Although the BNF recommends that all prescriptions for borderline substances are endorsed 'ACBS', pharmacists will 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

| Products available (Manufacturer) | Formulation | Prescribable by dentists on NHS? | Retail price (7) | pH | Fluoride containing? | Animal derived ingredients? | Gluten free? | Sugar free? |
|--|---|----------------------------------|-------------------|---------|----------------------|-----------------------------|--------------|------------------|
| <i>Aequasyl</i> (formerly <i>Aquoral</i>) (Bluechip Healthcare) | Oral spray 40mL | Yes ^a | >£10 ^b | Neutral | No | No | Yes | Yes |
| <i>AS Saliva Orthana</i> (CC Med) | Oral spray 50mL | Yes | £7 - £10 | Neutral | Yes ^c | Yes ^d | Yes | Yes |
| | Oral spray 100mL refill | | | | | | | |
| | Lozenges (30) | Yes ^e | < £7 | Neutral | No | Yes ^d | Yes | Yes ^f |
| <i>Biotene Oralbalance</i> ^g (GSK) | Saliva replacement gel 50g | Yes ^h | £7 - £10 | Neutral | No | No | Yes | Yes ⁱ |
| <i>BioXtra</i> products for dry mouth (RIS Products) | Moisturising gel 40mL | Yes ^e | £7 - £10 | Neutral | No | Yes ^j | Yes | Yes |
| | Gel mouth spray 50mL | Yes ^e | £7 - £10 | Neutral | Yes ^k | Yes ^j | Yes | Yes |
| | Toothpaste 50mL | No | < £7 | Neutral | Yes ^l | Yes ^j | Yes | Yes |
| | Mouthrinse 250mL | No | < £7 | Neutral | Yes ^l | Yes ^j | Yes | Yes |
| <i>Glandosane</i> (Fresenius Kabi) | Aerosol spray 50mL (lemon, neutral, peppermint) | Yes ^e | ~ £7 ^m | Acidic | No | No | Yes | Yes ^f |
| <i>Saliveze</i> (Wyvern) | Oral spray 50mL | Yes ^e | < £7 | Neutral | No | No | Yes | Yes |

| Products available (Manufacturer) | Formulation | Prescribable by dentists on NHS? | Retail price (7) | pH | Fluoride containing? | Animal derived ingredients? | Gluten free? | Sugar free? |
|---|------------------|----------------------------------|-------------------|---------------------|----------------------|-----------------------------|--------------|------------------|
| Saliva Stimulating Tablets (Primiuslab) | Tablets (100) | Yes | £7 - £10 | Acidic ⁿ | No | No | Yes | Yes ^f |
| Salivix (Galen) | Pastilles (50) | Yes ^o | < £7 | Acidic ^p | No | Yes ^q | Yes | Yes |
| Xerotin (SpePharm) | Oral spray 100mL | Yes ^r | > £7 ^s | Neutral | No | No | Yes | Yes ^f |

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- Contains 4.2mg/L sodium fluoride.
- d- Contains porcine-derived gastric mucin.
- e- Can be prescribed for indications approved by the ACBS.
- f- Contains sorbitol.
- g- The manufacturer advises avoiding use with toothpastes containing detergents, including foaming agents such as sodium lauryl sulphate. See [UKMi Medicines Q&A: What are the excipients in toothpastes?](#) for a table of available toothpastes and the excipients they contain.
- h- May be prescribed as 'Artificial saliva gel'.
- i- Biotene contains glucose oxidase, an enzyme added to inhibit bacteria growth. This is not a sugar.
- j- Contains animal products – traces of milk protein extract from cow's milk and egg white proteins.
- k- Contains 150ppm fluoride.
- l- Contains 1500ppm fluoride.
- m- Estimated retail price calculated from trade price of £5.52.
- n- Contains calcium phosphate dibasic as a buffer to prevent dental caries.
- o- May be prescribed as 'Artificial saliva pastilles'.
- p- Contains calcium lactate and sodium phosphate to act as a buffer to protect teeth.
- q- Contains E120 colourant derived from Peruvian insects.
- r- May be prescribed as 'Artificial saliva oral spray'.
- s- Estimated retail price calculated from trade price of £6.86.

Limitations

Formulations may be subject to change, but the information contained in this document is to our knowledge accurate at the time of publication.

References

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Search strategy/Bibliography

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