





# What should be considered when choosing or prescribing saliva substitutes?

Prepared by UK Medicines Information (<u>UKMi</u>) pharmacists for NHS healthcare professionals Before using this Q&A, read the disclaimer at <a href="https://www.sps.nhs.uk/articles/about-ukmi-medicines-qas/">https://www.sps.nhs.uk/articles/about-ukmi-medicines-qas/</a>
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# **Background**

Dry mouth or xerostomia is the feeling of oral dryness, which may or may not 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 Medicines 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 for patients complaining of a dry mouth and offers symptomatic relief to patients with insufficient salivary function (1). There are a variety of preparations available including artificial saliva replacements (e.g. gels, sprays and mouth rinses) and salivary stimulants (e.g. chewing gums and citric acid tablets). Properly balanced artificial saliva should be of neutral pH (7.0) and contain electrolytes (including fluoride) to correspond approximately to the composition of saliva (2). The acidic pH of some artificial saliva products may be inappropriate for dentate patients as this can lead to dental caries (2,3). Ideally, dentate patients should use a fluoride-containing preparation, as this may protect against caries (1). If a preparation without fluoride is used, dentate patients should use a toothpaste containing 1000-1500 parts per million (ppm) of fluoride (4). Some preparations are derived from animal products and may be unsuitable for vegetarians and people from certain religious groups (1).

## **Prescribing issues for dentists**

#### Which products can be prescribed on a dental NHS prescription?

When prescribing for NHS patients in primary care, dentists are restricted to items listed in the Dental Practitioners' Formulary (DPF) (5). As of June 2019, twelve artificial saliva products are listed in the DPF. The BNF notes which of these preparations can be dispensed for products prescribed generically (2). The products are (5):

- Artificial Saliva Gel, DPF (proprietary product: Biotene Oralbalance saliva replacement gel)
- Artificial Saliva Oral Spray, DPF (proprietary product: Xerotin oral spray)
- Artificial Saliva Pastilles, DPF (proprietary product: Salivix pastilles)
- Artificial Saliva Protective Spray, DPF (proprietary product: Aeguasyal oral spray)
- Saliva Stimulating Tablets (proprietary product: SST)

Five preparations are listed as prescribable only for indications approved by the Advisory Committee on Borderline Substances (ACBS) for patients suffering dry mouth as a result of having (or having undergone) radiotherapy or having sicca syndrome (5). Although the BNF recommends all prescriptions for borderline substances are endorsed 'ACBS', this is not compulsory and pharmacists will be reimbursed for supplying an item on the ACBS list whether it has been endorsed 'ACBS' by the prescriber or not (6). However, NHS England may question prescriptions for borderline substances not endorsed 'ACBS'.

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The ACBS products are (5):

- AS Saliva Orthana lozenges
- BioXtra oral gel
- BioXtra gel spray
- Glandosane
- Saliveze.

A further two preparations, AS Saliva Orthana spray and Salivix Plus pastilles, can also be prescribed.

The 'Appliances' section of the Drug Tariff lists several more artificial saliva substitutes (e.g. *Oralieve*), but as these are not included in the DPF, dentists cannot prescribe them on an NHS prescription (5).

Table 1 below lists artificial saliva products, key information about their formulation and whether or not they can be prescribed on a dental NHS prescription (FP10D); information on products that cannot be prescribed on a dental NHS prescription is also included for completeness.

### Which products can be prescribed on a dental private prescription?

Dentists are not restricted in the items they may prescribe privately and therefore any of the products in Table 1 can be prescribed on a private dental prescription (although they may be cheaper for the patient to purchase over the counter – see below) (2).

## Which products can be purchased from a pharmacy or dental surgery?

All currently available artificial saliva preparations may be purchased from a pharmacy. Most products cost less than a single NHS prescription charge – see table 1 (at the time of writing, the NHS prescription charge is £9 per item). It may be cheaper for patients who pay for their prescriptions to buy artificial saliva products from a pharmacy. Advise patients who pay for their prescriptions to check with the pharmacy if it would be cheaper to buy the product. Note that the cost of products can vary between retailers.

Dentists may 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 *Human Medicines Regulations 2012* or NHS dental contracts. For more information on supply of medicines by dentists, see UKMi Medicines Q&A When and how can dentists supply medicines?







Table 1: Available saliva substitutes and preparations to treat dry mouth (5)

<b>Product</b> Manufacturer	Formulation	Prescribable by dentists on NHS? (7)	рН	Contains fluoride?	Contains animal- derived ingredients?	Contains gluten?	Contains sugar?*	Contains sweetener?	Retail cost <sup>#</sup>
Aequasyal a (formerly Aquoral) Laboratoires Carilene	Oral spray 40mL	Yes <sup>b</sup>	6.7-7.44	No	No	No	No	Aspartame	£13.00
AS Saliva Orthana CCMed	Oral spray 50mL	Yes	Neutral	No	Porcine-derived mucin	No	No	Xylitol	£6.90
	Oral spray 500mL refill								£48.90
	Lozenges (30)	Yes <sup>c</sup>	Neutral	No		No	No	Sorbitol	£6.35
Biotène Oralbalance GSK	Saliva replacement gel 50g	Yes <sup>d</sup>	Neutral	No	No	No	No <sup>e</sup>	Sorbitol Xylitol	£7.50
	Dry Mouth antibacterial toothpaste original 100mL	No	Neutral	1450ppm	No	No	No	Sodium saccharin Sorbitol Sucralose	£4.06
	Dry Mouth antibacterial toothpaste original 75mL	No	Neutral	1450ppm	No	No	No	Sodium saccharin Sorbitol Sucralose	£4.99
	Dry Mouth moisturising mouthwash 500mL	No	Neutral	No	No	No	No	Sorbitol Xylitol	£7.99
BioXtra products for dry mouth RIS Products	Oral gel 40mL	Yes <sup>c</sup>	5.5	No	Colostrum, lactoperoxidase and lactoferrin (milk-derived) Lysozyme (egg-derived)	Yes <sup>f</sup>	2.8mg dextrose per gram of gel	Sorbitol Xylitol	£7.25
	Gel mouth spray 50mL	Yes <sup>c</sup>	7.0	150ppm	Colostrum and lactoperoxidase (milk-derived)	No	No	Sodium saccharin Sorbitol Xylitol	£7.25
	Mild toothpaste 50mL	No	6.1	1500ppm	Colostrum, lactoperoxidase and lactoferrin (milk-derived) Lysozyme (egg-derived)	No	2.5mg dextrose per gram of toothpaste	Sodium saccharin Sorbitol Xylitol	£3.40

# **Medicines Q&As**







Product Manufacturer	Formulation	Prescribable by dentists on NHS? (7)	рН	Contains fluoride?	Contains animal- derived ingredients?	Contains gluten?	Contains sugar?*	Contains sweetener?	Retail cost <sup>#</sup>
BioXtra products for dry mouth RIS Products	Ultra Mild mouthrinse 250mL	No	7.0	Yes 1500ppm	Colostrum, lactoperoxidase and lactoferrin (milk-derived) Lysozyme (egg-derived)	No	No	Xylitol	£4.50
Glandosane Fresenius Kabi	Aerosol spray 50mL (lemon, natural, peppermint)	Yes <sup>c</sup>	5.75	No	No	No	No	Sorbitol	£7.99
Oralieve Oralieve UK / EPC Ltd	Moisturising mouth gel 50mL	No	5.9	No	Milk proteins	No	Yes <sup>g</sup>	Sorbitol Xylitol	£7.50
	Moisturising mouth spray 50mL	No	5.9	No	Milk proteins	No	Yes <sup>g</sup>	Xylitol	£6.99
	Ultra mild toothpaste 75mL	No	5.9	1450ppm	Milk proteins	No	Yes <sup>g</sup>	Sorbitol Xylitol	£4.99
	Alcohol free mouthrinse 300mL	No	5.9	225ppm	Milk proteins	No	Yes <sup>g</sup>	Xylitol	£4.99
Saliveze Wyvern Medical Ltd	Oral spray 50mL	Yes <sup>c</sup>	Neutral	No	No	No	No	Sorbitol	£6.29
<i>Salivix</i> Galen	Spray 50mL	No	4.0	42ppm	No	No	No	Xylitol	£7.50
	Pastilles (50)	Yes <sup>h</sup>	Acidic <sup>i,j</sup>	No	E120 colourant (derived from Peruvian insects) Beeswax	No	No	Maltitol Xylitol	£6.30
Salivix Plus Galen	Pastilles (50)	Yes <sup>h</sup>	Acidic i,k	16ppm	E120 colourant (derived from Peruvian insects) Beeswax	No	No	Maltitol Xylitol	£7.00
SST <sup>a</sup> Primiuslab	SST are listed in the DPF; however, at the time of writing, they do not appear to be commercially available and the manufacturer was unresponsive to requests for information.								

# **Medicines Q&As**







Product Manufacturer	Formulation	Prescribable by dentists on NHS? (7)	рН	Contains fluoride?	Contains animal- derived ingredients?	Contains gluten?	Contains sugar?*	Contains sweetener?	Retail cost <sup>#</sup>
Xerostom Curaprox UK	Saliva substitute gel 25mL	No	6.0-7.0	No	No	No	No	Xylitol	£5.99
	Mouth spray 15mL	No	6.5-7.5	No	No	No	No	Xylitol	£4.49
	Dental gum (10)	No	Neutral	No	Beeswax Shellac	No	No	Sorbitol Xylitol	£3.99
	Mouthwash 250mL	No	6.5-7.5	230ppm	No	No	No	Xylitol	£5.49
	Pastilles (30)	No	Neutral	225ppm	Beeswax Shellac	No	No	Xylitol	£4.99
	Toothpaste 50mL	No	6.5-7.5	1450ppm	No	No	No	Sodium saccharin Xylitol	£4.99
Xerotin <sup>a</sup>	Oral spray 100mL	Yes¹	7.0	No	No	No	No	Sorbitol	£12.00

#### Notes to support table above:

- a- At time of writing, there is no UK distributor therefore there may be difficulty in obtaining this product.
- b- May be prescribed as 'Artificial saliva protective spray'.
- c- Can be prescribed for indications approved by the ACBS.
- d- May be prescribed as 'Artificial saliva gel'.
- e- Biotène Oralbalance gel contains glucose oxidase, an enzyme added to inhibit bacteria growth. This is not a sugar.
- f- Gluten can be present in hydrogenated starch hydroxylate.
- g- Oralieve products contain glucose [0.001%]. However this is used as a starter for the glucose oxidase element of the product and so is effectively 'consumed' in that process; as such, it has no cariogenic effect.
- h- May be prescribed as 'Artificial saliva pastilles'.
- i- Contains calcium lactate and sodium phosphate to act as a buffer to protect teeth.
- j- pH of five Salivix pastilles dissolved in 90ml purified water is 4.7.
- k- pH of five Salivix Plus pastilles dissolved in 90ml purified water is 4.5.
- I- May be prescribed as 'Artificial saliva oral spray'.

\*Prices obtained from the December 2019 C+D Monthly Pricelist, manufacturer websites and UK retailer websites (see bibliography).

<sup>\*</sup>Definition of sugar: European Union legislation refers to sugars as 'all monosaccharides and disaccharides present in food, but excludes polyols'; monosaccharides include glucose, fructose and galactose, disaccharides include sucrose and maltose (8,9).







# **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 dentate patients.
- Dental practitioners should be aware that not all preparations may be prescribed on a dental NHS prescription. However, all available products can be purchased from a pharmacy without a prescription.
- Table 1 lists artificial saliva products, key information about their formulation and whether or not they can be prescribed on a dental NHS prescription.

#### **Limitations**

- Formulations may be subject to change; the information contained in this document is, to our knowledge, accurate at the time of preparation.
- Products are listed as 'gluten-free' if they do not contain gluten-containing ingredients, but it does not necessarily mean the product was manufactured in a gluten-free environment.
- Cost of individual products can vary significantly when purchased over the counter, depending on the retail outlet.
- This is not a complete list of all products on the market to treat dry mouth.

#### References

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- 3. Lewis MAO, Jordan RCK. A Colour Handbook of Oral Medicine. London: Manson Publishing Ltd; 2004, p166-7.
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  - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\_data/file/605266/Delivering\_better\_oral\_health.pdf.
- 5. NHS Business Service Authority. Drug Tariff [Internet] June 2019. Part XV and Part XVIIA [cited 20/6/19]. Available from: <a href="https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff">www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff</a>.
- Pharmaceutical Services Negotiating Committee [Internet] May 2015. Dispensing Factsheet: Prescription endorsements [cited 5/12/19]. Available from: <a href="https://psnc.org.uk/wp-content/uploads/2013/06/CPN-Factsheet-Prescription-Factsheet-May-15.pdf">https://psnc.org.uk/wp-content/uploads/2013/06/CPN-Factsheet-Prescription-Factsheet-May-15.pdf</a>.
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- 8. EU (2011) Regulation (EU) No 1169/2011 of the European parliament and of the Council on the provision of food information to consumers. Official Journal of the European Union [Internet] (2011) L 304 p. 18–63 [cited 5/12/19]. Available from: <a href="https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF">https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF</a>.
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## **Bibliography**

The following sources were used to assemble the table of saliva substitutes:

- Manufacturer's websites. Accessed May-September 2019.
- Personal communication with manufacturers by email. February-September 2019.
- December 2019 Chemist + Druggist Monthly Pricelist.

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## Search strategy (June - December 2019)

- 1. In-house databases/resources.
- 2. Monthly Index of Medical Specialities (www.mims.co.uk)
- 3. Online retail outlets.
- 4. Internet search (<u>www.google.co.uk</u> product and/or manufacturer name).
- 5. EUR-Lex (<a href="https://eur-lex.europa.eu/homepage.html">https://eur-lex.europa.eu/homepage.html</a> food information)
- 6. Scientific Advisory Committee on Nutrition (<a href="www.gov.uk/government/groups/scientific-advisory-committee-on-nutrition">www.gov.uk/government/groups/scientific-advisory-committee-on-nutrition</a>)
- 7. Pharmaceutical Services Negotiating Committee (https://psnc.org.uk/)
- 8. NHS Business Services Authority (<u>www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/dictionary-medicines-and-devices-dmd</u>)