



## Question: Can pilocarpine eye drops be used to treat dry mouth?

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### Summary

- Pilocarpine is not recommended as a first line treatment for dry mouth (xerostomia). Other topical products such as artificial saliva products should be tried first.
- Pilocarpine tablets (Salagen®) are unlicensed in Ireland but are licensed in the UK for the treatment of dry mouth.
- There is limited information available to support the use of pilocarpine eye drops as an alternative. The use of pilocarpine eye drops to treat a dry mouth is unlicensed.
- A recommended dose of 5mg-10mg three times daily of oral pilocarpine tablets would be approximately equivalent to pilocarpine 4% 3-5 drops (6mg-10mg) taken orally three times daily.

### Availability

Pilocarpine tablets are indicated for the treatment of dry mouth following irradiation for head and neck cancer and for dry mouth and dry eyes in Sjogren's syndrome.<sup>1,2,3,4</sup>

Unfortunately, pilocarpine tablets are not licensed in Ireland. Pilocarpine eye drops 2%w/v and 4%w/v are available in Ireland but they are not licensed for the treatment of dry mouth.<sup>5,6</sup>

Palliative Meds Info: Terms and Conditions

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### **Place in Therapy**

The Palliative Care Formulary (PCF) advises that generally in the management of dry mouth, topical measures (including the use of artificial saliva products) should be tried before considering the use of pilocarpine.<sup>7</sup> The PCF advises that it is less expensive to prescribe pilocarpine eye drops than tablets for the treatment of a drug-induced dry mouth.<sup>8</sup> However, notes that the use of eyedrops in this way is unlicensed.<sup>8</sup>

### **Mechanism of Action**

Pilocarpine is a parasympathomimetic (predominantly muscarinic) drug with mild adrenergic activity which stimulates secretion from exocrine glands, including salivary glands.<sup>8</sup> About 90% of patients with drug-induced dry mouth respond to pilocarpine with benefit seen immediately.<sup>9</sup>

### **Recommended Dose**

The PCF advises that 3 drops of pilocarpine 4%w/v is equivalent to 6mg orally.<sup>8</sup>

- **Xerostomia following irradiation for head and neck cancer.**

The recommended initial dose for adults is 5 mg three times daily with or immediately after meals (last dose always with evening meal).<sup>1,2</sup> The maximum therapeutic effect is normally obtained after 4 to 8 weeks of therapy. For patients who have not responded sufficiently after 4 weeks and who tolerate the dose of 5 mg three times daily, doses of up to a maximum of 30 mg daily may be considered.<sup>1,2</sup> The Palliative Care Formulary advises that doses up to 10mg four times daily can be used after four weeks.<sup>8</sup> However, higher daily doses are probably accompanied by an increase in drug-related adverse effects.<sup>2</sup> Therapy should be discontinued if no improvement in xerostomia is noted after 2 to 3 months of therapy.<sup>1,2,8</sup>

- **Treatment of symptoms of dry mouth and dry eyes in patients with Sjögren's syndrome.**

The recommended initial dose is 5 mg four times daily (with meals and at bedtime), if tolerated but response insufficient, may be increased to a maximum of 30 mg daily in divided doses. Treatment should be discontinued if no improvement is noted after 2–3 months.<sup>1,2</sup>

- **Treatment of drug-induced dry mouth**

Consideration should be given to the necessity of medications which contribute to dry mouth.

The PCF advises that in drug-induced dry mouth 5mg four times daily is generally effective.<sup>8</sup>

- Start with 5mg three times daily with meals and at bedtime, or 6mg if using eye drop formulation; this is 3 drops of a 4% solution.<sup>8</sup>
- If necessary and if tolerated, increase the dose to 10mg four times daily, after 2 days. If there is no improvement with 10mg four times daily stop after 4 days.<sup>8</sup>
- In patients with mild–moderate hepatic impairment, possibly start on a lower dose, e.g. 5mg twice daily and increase to 5mg four times daily if well tolerated.<sup>8</sup>

### **Contra-indications**

Bowel obstruction, asthma and COPD are contra-indications to the use of pilocarpine.<sup>9</sup>

### **Common Adverse Effects**

The most common adverse effect is sweating.<sup>9</sup> Other adverse effects include nausea, flushing, urinary frequency, intestinal colic and weakness.<sup>9</sup>

### **References:**

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- 4) Monograph Pilocarpine. Micromedex. Available from <http://www.micromedexsolutions.com>. Accessed on the 10/04/2017.
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- 7) Artificial saliva. Palliative Care Formulary. Available from [www.palliativedrugs.com](http://www.palliativedrugs.com). Accessed on the 10/04/2017.
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