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

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Summary

- Pilocarpine is not recommended as a first line treatment for a dry mouth. Other topical products such as artificial saliva products should be tried first.
- Pilocarpine tablets are indicated for the treatment of a dry mouth.
- Pilocarpine tablets are unlicensed in Ireland. There is limited information available to support the use of pilocarpine eye drops as an alternative.
- 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.
- The use of pilocarpine eye drops to treat a dry mouth is unlicensed.

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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.\textsuperscript{1,2,3,4} Unfortunately, pilocarpine tablets are unlicensed in Ireland. Pilocarpine eye drops 2\% w/v and 4\% w/v are available but they are not licensed for the treatment of dry mouth.\textsuperscript{5,6}

Place in Therapy
The Palliative Care Formulary (PCF) advises that generally, topical measures (including the use of artificial saliva products) should be tried before using pilocarpine.\textsuperscript{7} It states that it is less expensive to prescribe pilocarpine eye drops than tablets for the treatment of a drug-induced dry mouth.\textsuperscript{8}

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

Recommended Dose
The Palliative Care Formulary (PCF) advises that 3 drops of pilocarpine 4\% is equivalent to 6mg orally.\textsuperscript{8}

- **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).\textsuperscript{1,2} 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.\textsuperscript{1,2} The Palliative Care Formulary
advises that doses up to 10mg four times daily can be used.\textsuperscript{8} However, higher daily doses are probably accompanied by an increase in drug-related adverse effects.\textsuperscript{2} Therapy should be discontinued if no improvement in xerostomia is noted after 2 to 3 months of therapy.\textsuperscript{1,2}

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

The recommended initial dose is 5 mg 4 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.\textsuperscript{1,2}

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

The Palliative Care Formulary advises that in drug-induced dry mouth 5mg four times daily is generally effective\textsuperscript{8}:

  - 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.\textsuperscript{8}
  - If necessary and if tolerated, increase the dose to 10mg four times daily, after 2 days if the dry mouth is drug-induced, and after 4 weeks if radiation-induced. If there is no improvement with 10mg four times daily stop after 4 days if the dry mouth is drug-induced, and after 12 weeks if radiation-induced.\textsuperscript{8}
  - 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.\textsuperscript{8}

**Contra-indications**

Bowel obstruction, asthma and COPD are contra-indications to the use of pilocarpine.\textsuperscript{9}
Common Adverse Effects

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

References:


