

**Oxfordshire Clinical Commissioning Group, Oxford University
Hospitals NHS Trust and Oxfordshire Health NHS Foundation Trust
Shared Care Protocol and Information for GPs**

Pentoxifylline for the management of osteoradionecrosis

This shared care guideline provides the necessary information and guidance for the shared care of adult patients requiring Pentoxifylline and Tocopherol therapy

This shared care agreement states how prescribing and monitoring responsibilities can be shared between the specialist and primary care. Shared care should only take place when all parties, including the patient and/or parent/guardian agree. A GP should only take on the prescribing if he/she has been provided with all the necessary information from the specialist and feels that it was within his/her competency to do so. APCO have agreed that if these conditions are met then this medicine is suitable for shared care under this protocol.

Summary

Pentoxifylline and Tocopherol are useful in the medical management of Osteoradionecrosis of the Jaws (ORN).

Their use for this indication is unlicensed, but supported by the current clinical literature.

Background

Current management of ORN is extremely difficult.

The only trial of medical management using a combination of Pentoxifylline and alpha tocopherol was extremely successful and as the only alternative is often prolonged pain / disability of patient or extensive ablative / reconstructive surgery, medical management is to be encouraged.

References;

British Journal of Oral and Maxillofacial Surgery 2012; 50: 41–44.

British Journal of Oral and Maxillofacial Surgery 2008;46:653–60.

Journal of Clinical Oncology 1999;17:3283–90.

Head Neck 2005;27:114–23.

International Journal Radiation Oncology Biology and Physics 2010,
doi:10.1016/j.ijrobp.2010.03.029

Indications

Management of patients with a diagnosis of Osteoradionecrosis of the Jaws.

Prescribing Information

Prescriptions to be commenced by the treating specialist Oral & Maxillofacial Surgeon, who will write to the patients General Medical Practitioner asking them to provide a repeat prescription for the duration of treatment.

Prescriptions will generally be for Pentoxifylline 400mg BD PO, together with Tocopherol 1000 units PO OD.

The evidence suggests that most patients will need to be prescribed this for 6 -12 months, although a small cohort may have to continue longer or need repeated courses.

Prescriptions to continue until the condition has satisfactorily healed. The Oral & Maxillofacial Surgeon will keep the patient under review and inform the General Medical Practitioner when this is the case.

Adverse Effects

Nausea, vomiting, diarrhoea, dizziness, agitation, sleep disturbances, headache; *rarely* angina, hypotension; *very rarely* bleeding; *also reported* intrahepatic cholestasis, tachycardia, flushing, thrombocytopenia (from BNF)

Contra-indications/Cautions

Hypotension, coronary artery disease; avoid in acute porphyria (from BNF)

Pregnancy and Lactation

Manufacturer advises avoid—no information available (From BNF)

Drug Interactions (refer also to BNF or SPC; include significance of interaction)

[Ketorolac](#)

increased risk of bleeding when pentoxifylline given with ketorolac(avoid concomitant use)

[NSAIDs](#)

possible increased risk of bleeding when pentoxifylline given with NSAIDs

Note: See also Aspirin. Interactions do not generally apply to topical NSAIDs

[Theophylline](#)

Pentoxifylline increases plasma concentration of theophylline

Monitoring

No specific monitoring required

Patient Information Leaflet

The OMFS specialist will provide an information leaflet to the patient when first prescribing medication.

Shared Care Responsibilities

Shared care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and/or parent/guardian and accepted by them. Patients should be under regular follow-up which provides an opportunity to discuss drug therapy.

a) Aspects of care for which the Hospital Consultant is responsible:

- Write to the GP requesting shared care and outline shared care protocol criteria.
- Liaise with GP regarding changes in disease management, drug dose, missed clinic appointments.
- Ensure clinical supervision of the patient is done by follow-up as appropriate.
- Ensure the patient and/or parent/guardian understands the nature and complications of drug therapy and their role in reporting adverse effects promptly.
- Provide clear instruction to GP on when therapy needs to be referred back to specialist.
- Provide clear information to GP on when to stop therapy.
- Be available to give advice to GP and patient and/or parent/guardian.
- Provide supply of tocopherol to the patient

b) Aspects of care for which the GP is responsible:

- Prescribe pentoxifylline according to a written protocol.
- Advise the Hospital Consultant of any clinical changes or adverse effects where appropriate.
- Monitor for adverse effects as detailed above.

c) Aspects of care for which the Patient and/or Parent/Guardian is responsible:

- Report any adverse effects to their GP and/or consultant

- Attend for regular monitoring as outlined in patient information leaflet.

Contact Details

Named specialist Oral & Maxillofacial Surgeon looking after the patient.

Annual Cost of Medicine in Primary Care

Calculations from Oxford University Hospital Medicines Committee

a. Average duration of treatment (days)	182
b. Average number of dosage units per day	2
c. Cost per dosage unit	£ 0.23
d. Cost per standard course (a x b x c)	£82.63
e. Additional costs per patient per course (e.g.: monitoring, administration, training)	£ 0
f. Total annual cost per patient (d + e)	£ 826.30

Number of New Patients per Annum

Exact patient numbers unknown. ORN may affect 5-20% of patients who have radiotherapy for head and neck cancer (approx. 150 patients per year across Thames valley network). Most require no specific treatment, but it is estimated 30% of patients with ORN would benefit from Pentoxifylline (in combination with Tocopherol). Estimated 10 new patients a year.