**Systemic Anti-Cancer Therapy Protocol**

# Zoledronic Acid

**PROTOCOL REF: MPHAZOLST**
**(Version No: 1.0)**

## Approved for use in:

Prevention of skeletal related events in advanced malignancies involving bone metastases from solid tumours in patients. **This does not include treatment of hypercalcaemia or adjuvant breast cancer.**

## Dosage:

Dosage is dependent on creatinine clearance using the Cockcroft and Gault equation.

| Drug | Creatinine Clearance (mL/min) | Dosage | Route | Frequency |
|---|---|---|---|---|
| Zoledronic acid | >60 | 4mg | IV | Every 21-28 days |
| | 50-60 | 3.5mg | | |
| | 40-49 | 3.3mg | | |
| | 30-39 | 3mg | | |
| | < 30 | Contraindicated | | |

**Supportive treatments**

- Oral supplement of 500mg calcium and 400IU vitamin D daily (Adcal D3)
- Paracetamol for flu like symptoms if required

## Extravasation risk:

Zoledronic acid is not a vesicant

## Administration:

| Day | Drug | Dosage | Route | Diluent and Rate |
|---|---|---|---|---|
| 1 | Zoledronic acid | Dependent on creatinine clearance | IV | Diluted in 100mL of 0.9% w/v sodium chloride solution and given over 15 minutes |

Withdraw an appropriate volume of the concentrate needed, as follows:

- 5 ml for 4.0mg dose
- 4.4 ml for 3.5 mg dose
- 4.1 ml for 3.3 mg dose
- 3.8 ml for 3.0 mg dose

### Contra-indications:

- Hypersensitivity to the active substance, to other bisphosphonates or to any of the excipients
- Breast-feeding

### Drug interactions:

*Thalidomide*: Increased risk of renal impairment with concomitant thalidomide

*Aminoglycosides*: Increased risk of renal impairment

## Main Toxicities:

Serious side effects

Osteonecrosis of the jaw (dental assessment prior to treatment and withhold zoledronic acid for at least 3 weeks pre and post any dental intervention).

Common Side effects

- Flu like symptoms
- pain flare
- bone pain
- myalgia
- arthralgia
- hypocalcaemia
- hypophosphatemia

- Other side effects
- Numbness around mouth (sign of low calcium)
- Conjunctivitis
- Headache
- Renal impairment
- Nausea

## Investigations and treatment plan

**ALL PATIENTS ARE RECOMMENDED TO HAVE A DENTAL ASSESSMENT PRIOR TO COMMENCING TREATMENT BECAUSE OF THE POTENTIAL RISK OF OSTEONECROSIS OF THE JAW**

| | Pre | Cycle 1 | Cycle 2 | Cycle 3 | Cycle 4 | Comments |
|---|---|---|---|---|---|---|
| Informed Consent | X | | | | | |
| Clinical Assessment | X | | | | | |
| Dental assessment | X | | | | | |
| SACT Assessment (to include PS and toxicities) | X | X | X | X | X | Every cycle |
| FBC | X | | X | X | X | Every cycle |
| U&E & LFT | X | | X | X | X | Every cycle |
| CrCl | X | | X | X | X | Every cycle |
| Calcium | X | | X | X | X | Every cycle |
| Vitamin D levels | X | | X | X | X | Every cycle |
| Phosphate | X | | X | X | X | Every cycle |
| Magnesium | X | | X | X | X | Every cycle |
| Weight recorded | X | | X | X | X | Every cycle |
| Height recorded | X | | | | | |

*All investigations have a validity period of 7 days before treatment excluding Vitamin D levels which have a validity period of 28 days.

## References:

1. EMC. *Zoledronic acid 4mg/5ml concentrate for solution for infusion.* Available from https://www.medicines.org.uk/emc

2. R.Coleman, J.J Body et al. Bone health in cancer patients, ESMO Clinical practice guidelines. 2014 Vol 25.

3. NICE guidelines. *Vitamin D supplement use in specific population groups*. Available from: https://www.nice.org.uk/guidance/ph56