
Novartis Pharmaceuticals Corporation

59 Route 10

East Hanover, NJ 07936

**Appendix 8:
Patient Information Form
(Bisphosphonates and ONJ)**

Zometa[®] (zoledronic acid) Injection

and

Aredia[®] (pamidronate disodium) Injection

Submitted: February 1, 2005

Oncologic Drugs Advisory Committee Meeting

March 4, 2005

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| Patient Demographics | | | | |
|-----------------------|-------------------------------|-------|---------------------------------|-----|
| Date of Birth: | | | | |
| | day | month | year | Age |
| Gender: | <input type="checkbox"/> Male | | <input type="checkbox"/> Female | |
| Adverse Event Report: | | | | |

| Drug Information | | | | | | |
|------------------|---------------|----|---------------|-------------------------|-------------|-----------|
| Drug Name | Therapy Dates | | Indication(s) | Dosing at time of event | | |
| | From | To | | Dose | Formulation | Frequency |
| Aredia | | | | | | |
| Zometa | | | | | | |

| | | |
|--------------------------------------|-------------|--|
| Oral Surgeon/ Dentist: | Name/Title: | |
| | Address: | |
| | Telephone: | |
| Oncologist: | Name/Title: | |
| | Address: | |
| | Telephone: | |
| Other Healthcare Professional: | Name/Title: | |
| | Address: | |
| | Telephone: | |

| | | | |
|--|--|-----|----|
| | | Yes | No |
|--|--|-----|----|

| Osteonecrosis of the Jaw: Diagnosis & Treatment | |
|---|---|
| (if multiple dates of diagnosis are present, this page may be photocopied for additional use) | |
| Diagnosis (type of osteonecrosis) | |
| Date of Diagnosis | |
| Anatomical Site(s) | |
| Concurrent Factors (e.g., tooth extraction, other dental procedures) | |
| Method of Diagnosis | <input type="checkbox"/> Clinical |
| | <input type="checkbox"/> Imaging (specify) |
| | <input type="checkbox"/> Biopsy (specify) |
| | <input type="checkbox"/> Other (specify) |
| Treatment | |
| Date(s) of Treatment | |
| Outcome | <input type="checkbox"/> Resolved (specify date) <input type="checkbox"/> Treatment ongoing <input type="checkbox"/> Unknown |

| Dental Medications & Treatments | | | | |
|--|----------------|------------|--------------|--------------|
| Please list current dental medication/treatments with special attention to the following: | | | | |
| Use of anesthetics in dental procedures (especially those with vasoconstrictors) <input type="checkbox"/> No <input type="checkbox"/> Yes (specify below) | | | | |
| Antibiotics <input type="checkbox"/> No <input type="checkbox"/> Yes (specify below) | | | | |
| Medication/Treatment | Dose & Regimen | Indication | Date Started | Date Stopped |
| | | | | |
| | | | | |
| | | | | |

| Oncology Medications (within 24 Months prior to diagnosis of Osteonecrosis) | | | | |
|---|---------------------------|-------------------|---------------------|---------------------|
| List oncology medications with special attention to the following: Chemotherapy <input type="checkbox"/> No <input type="checkbox"/> Yes (specify below) Corticosteroids <input type="checkbox"/> No <input type="checkbox"/> Yes (specify below) | | | | |
| Medication | Dose & Regimen | Indication | Date Started | Date Stopped |
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| Healthcare Professional reporter information | |
|---|-----------------|
| Name _____ | Specialty _____ |
| Signature _____ | Date _____ |
| Prepared by _____ | |