

# DRUG-RELATED OSTEONECROSIS OF THE JAW

INFORMATION FOR PATIENTS

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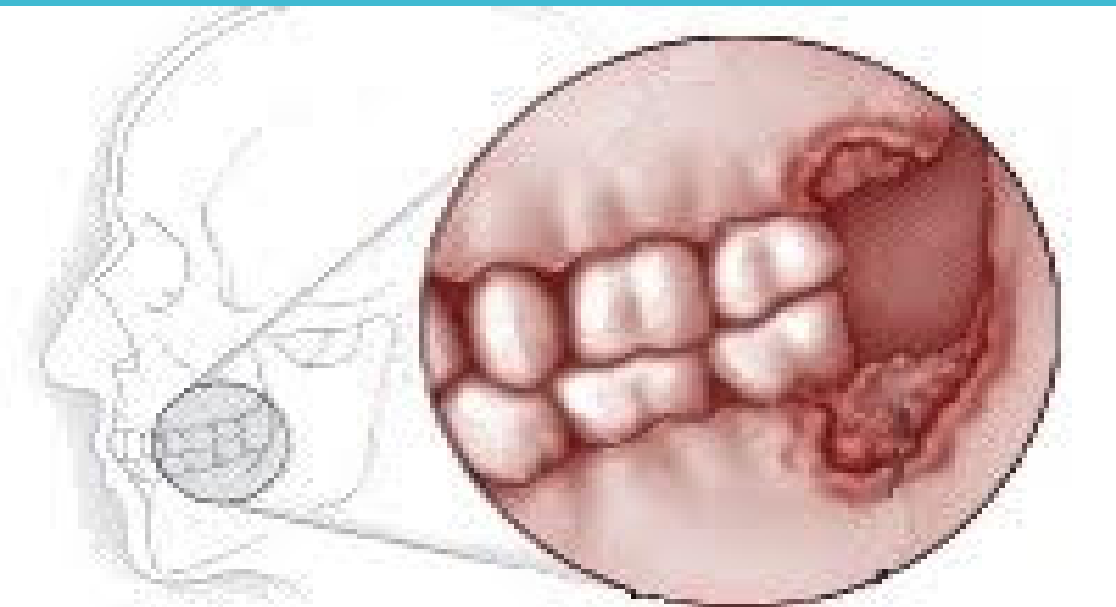
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## Dear Patient

If you are about to begin or have already been treated with **aminobisphosphonates or other drugs for treating bones at risk of osteonecrosis of the jawbones (see Table on page 10)**, a dental examination is recommended. The aim of this examination is to assess your oral health even if you have few or no teeth and/or you wear fixed/removable, partial or full dentures.

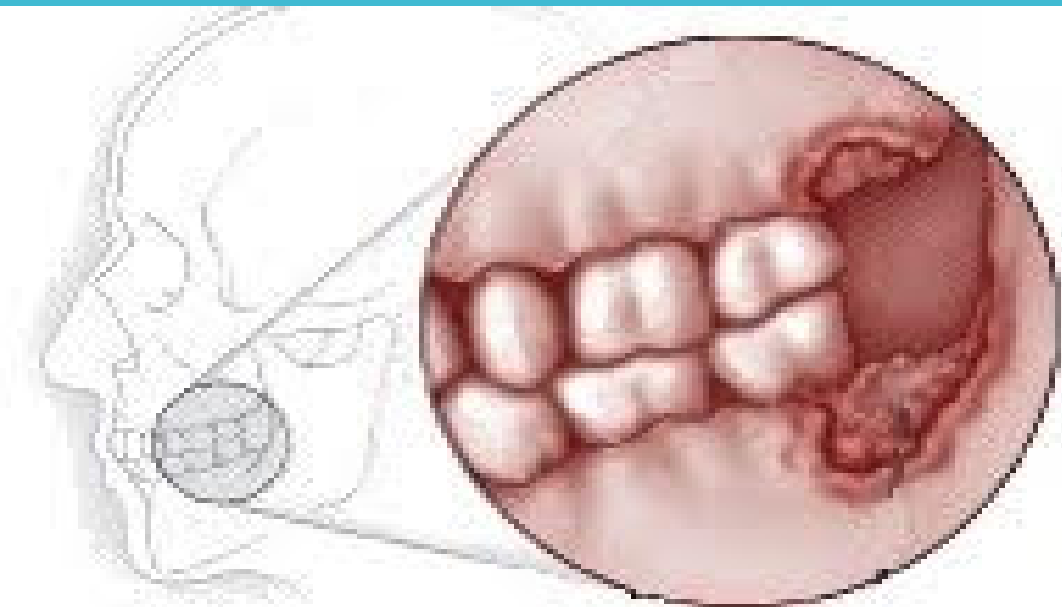
When you see your dentist or if you are already being/were treated with drugs which put you at risk of drug-related osteonecrosis, it is very important for you to communicate this to your dentist/doctor .

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It is necessary to pay particular attention to looking after your teeth and gums, especially if you have taken or are taking bisphosphonates or other drugs for treating bones. These drugs can have undesirable effects on your oral health, including **osteonecrosis of the jaw (ONJ)**. This complication can occur spontaneously or after invasive procedures, including dental extractions.

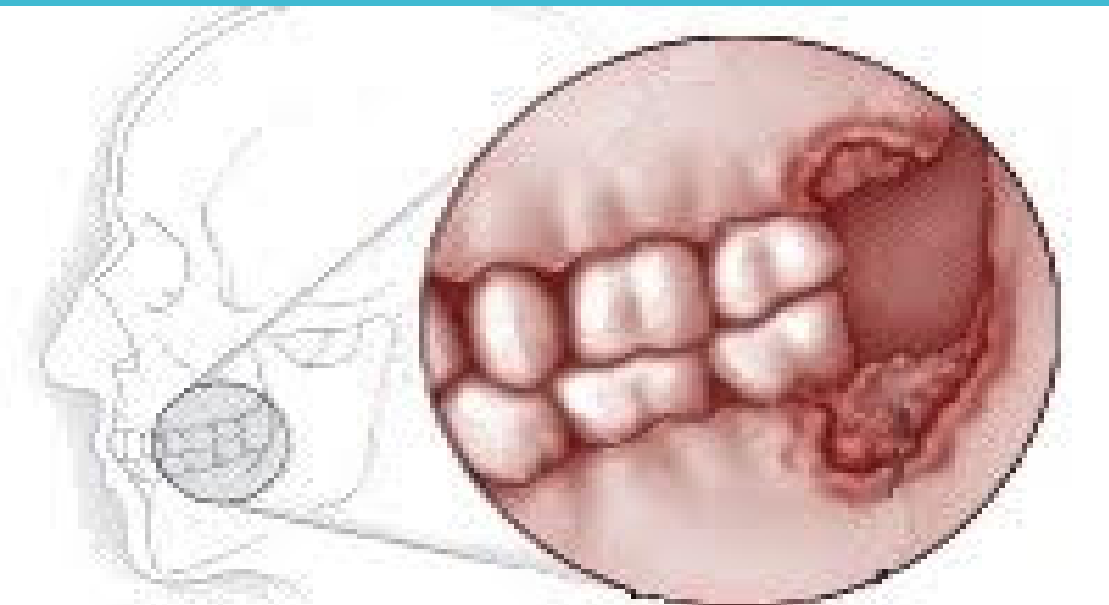
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Osteonecrosis of the jaw may not show any symptoms for weeks, months or years or it can appear with **pain, bone exposure** and/or **swelling** of either the mandible or the maxilla (the 2 jawbones).



**In the majority of cases a diagnosis of osteonecrosis of the jaw can be made via a simple examination of the oral cavity. However, an X-ray is necessary to confirm diagnosis. Your doctor/dentist will, therefore, suggest one or more of the following tests:**

orthopantomography

an intraoral X-ray

computerised conebeam tomography

a dental scan

a CAT scan of the facial skeleton

oral and maxillo-facial magnetic resonance imaging

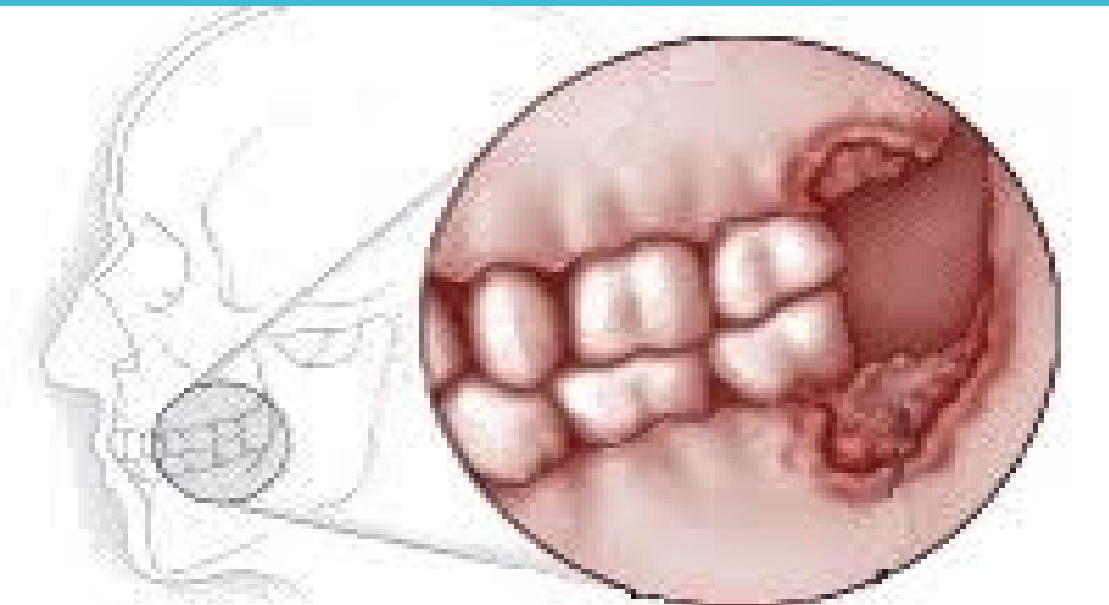
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## SIGNS AND SYMPTOMS OF OSTEONECROSIS OF THE JAW



**Bleeding**, swelling or infection of the gums

**Localised pain** of the maxilla (upper jawbone) or mandible (lower jaw bone), generally resistant to common anti-inflammatory drugs

**Swelling** of the soft tissue and face

Intra- and extraoral **fistulae** (holes) with pus

**Loose** and/or loss of teeth

Bad breath (halitosis)

Difficulties in maintaining oral hygiene and eating

Weight loss (often determinant)

Difficulties with speaking, eating and opening the mouth

Sensation of numbness and a heavy lower jawbone

Fracturing and loss of small bone parts

Wounds on the gum which do not heal

Exposure of the maxilla (upper jawbone) or mandible (lower jawbone)

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TELL YOUR DOCTOR/DENTIST  
IMMEDIATELY IF THERE ARE ANY  
CHANGES TO THE MUCOSA, GUMS,  
TEETH OR JAWBONE

## HOW TO AVOID OSTEONECROSIS

if you have still not taken any of the drugs in

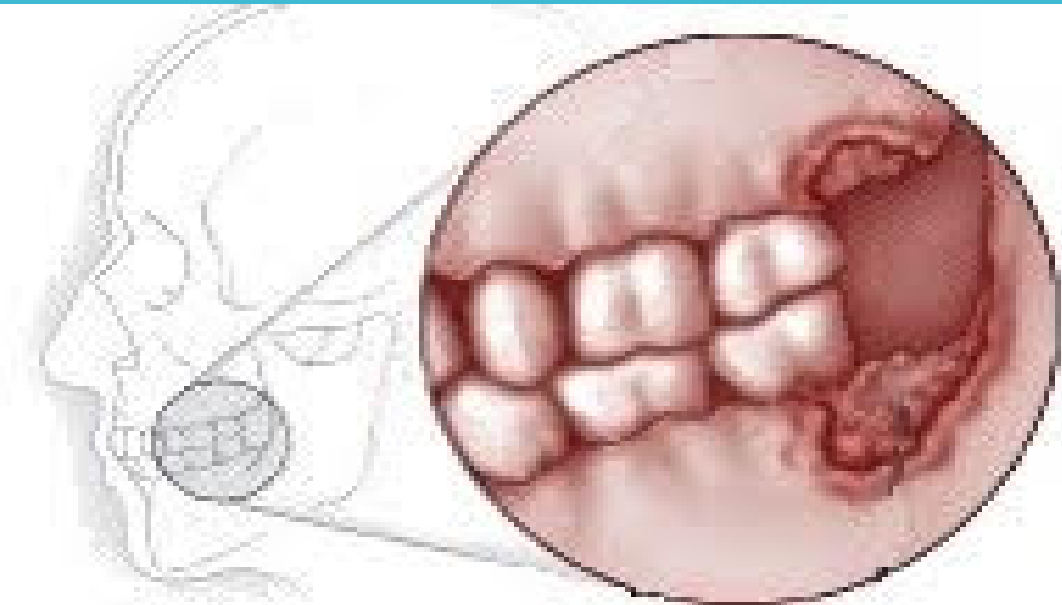
the Table *DRUGS ASSOCIATED AT RISK OF OSTEONECROSIS OF THE JAWBONE* on page 8

Ask your dentist for a panoramic X-ray of the dental arches and have a dental check-up to ensure your oral health. Tell your dentist/doctor that you are going to start treatment with drugs which could put at risk your oral health.

If your dentist considers it appropriate to perform **teeth extractions**, remember that treatment with drugs related to ONJ can only be commenced when the post-extraction site has completely healed (approximately 3 weeks from the last extraction).

Ask your dentist for advice about effective dental care at home (correct tooth brushing, use of floss and tongue hygiene).

All other dental treatment, not directly involving bone tissue (eg. treating carious lesions, root canal treatment, prosthetic treatment, periodontal mechanical therapy) can be performed after commencing treatment with **drugs which you put you at risk of developing osteonecrosis.**



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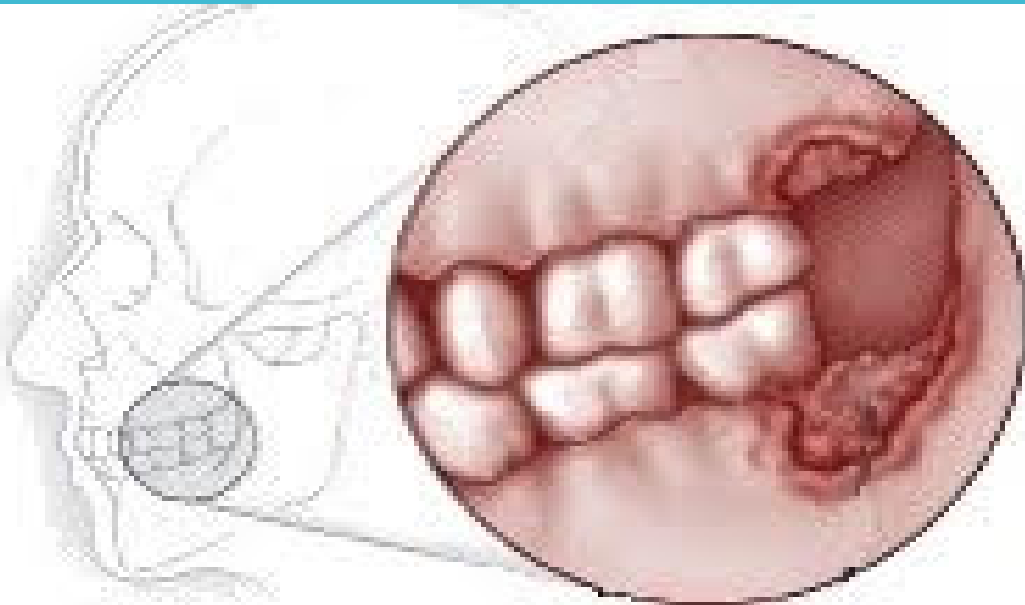


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## HOW TO AVOID OSTEONECROSIS

If you are taking or have taken in the past

drugs associated with a risk of osteonecrosis (see the Table *DRUGS ASSOCIATED AT RISK OF OSTEONECROSIS OF THE JAWBONE* on page 8)



Ask your dentist for a panoramic X-ray of the dental arches and have a dental check-up to assess your oral health. Tell your dentist/doctor that you are taking or have taken **aminobisphosphonates or another drug related to ONJ** (specify the trade name or molecule). If your dentist considers it appropriate to perform **teeth extractions**, your doctor may consider **suspending drug treatment**.

Ask your dentist for advice about effective dental care at home (correct tooth brushing, use of floss and tongue hygiene).

All other dental treatments not directly involving bone tissue (eg. treating carious lesions, root canal treatment, prosthetic treatment, periodontal

**WARNING!!**

**IN CASE OF INVASIVE DENTAL PROCEDURES, ASK YOUR DENTIST TO SPEAK WITH YOUR DOCTOR!!**

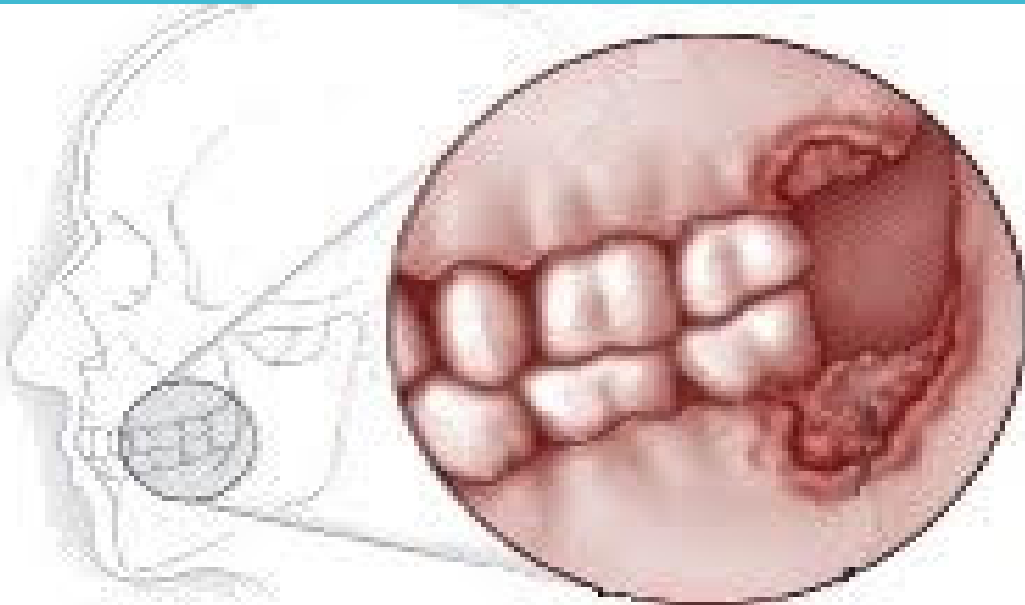
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# DRUGS ASSOCIATED AT RISK OF OSTEONECROSIS OF THE JAWBONE



WHAT ARE	WHAT THEY ARE USED FOR
Alendronic acid (Alendronate)	<ul style="list-style-type: none"> <li>✓ Treatment of post-menopausal osteoporosis</li> <li>✓ Treatment of osteoporosis in men at high risk of fractures</li> <li>✓ Treatment and prevention of glucocorticoid-induced osteoporosis</li> </ul>
Ibandronic acid (Ibandronate)	<ul style="list-style-type: none"> <li>✓ Prevention of skeletal events in patients with breast cancer and bone metastases</li> <li>✓ Treatment of malignant hypercalcemia</li> <li>✓ Treatment of post-menopausal osteoporosis in patients at high risk of fractures</li> </ul>
Neridronic acid (Neridronate)	<ul style="list-style-type: none"> <li>✓ Treatment of osteogenesis imperfecta</li> <li>✓ Treatment of Paget's disease of bone</li> </ul>
Pamidronic acid (Pamidronate)	<ul style="list-style-type: none"> <li>✓ Prevention of skeletal events in patients with breast cancer and bone metastases/multiple myeloma with bone lesions</li> <li>✓ Treatment of malignant hypercalcemia</li> </ul>
Risedronic acid (Risedronate)	<ul style="list-style-type: none"> <li>✓ Prevention of skeletal events in post-menopausal osteoporosis</li> <li>✓ Treatment of osteoporosis in men at high risk of fractures</li> <li>✓ Prevention of skeletal events in patients with prolonged corticosteroid post-menopausal systemic therapy</li> </ul>
Zoledronic acid (Zoledronate)	<ul style="list-style-type: none"> <li>✓ Prevention of skeletal events in patients with solid tumors with bone metastases</li> <li>✓ Treatment of neoplastic hypercalcemia</li> <li>✓ Treatment of multiple myeloma</li> <li>✓ Treatment of post-menopausal osteoporosis</li> <li>✓ Treatment of osteoporosis in men at high risk of fractures, including those with a recent low-trauma hip fracture</li> <li>✓ Treatment of Paget's disease of bone</li> </ul>
Etidronic acid	<ul style="list-style-type: none"> <li>✓ Treatment of Paget's disease of bone</li> </ul>
Clodronic acid	<ul style="list-style-type: none"> <li>✓ Treatment of post-menopausal osteoporosis</li> <li>✓ Treatment of multiple myeloma</li> <li>✓ Treatment of neoplastic osteolysis</li> <li>✓ Treatment of primary hyperparathyroidism</li> </ul>
Denosumab	<ul style="list-style-type: none"> <li>✓ Treatment of post-menopausal osteoporosis and treatment of men at high risk of fractures</li> <li>✓ Treatment of bone loss associated with hormone ablation therapy in men with prostate cancer and increased risk of fractures</li> <li>✓ Prevention of skeletal complications in adults with bone disseminated solid tumors</li> </ul>
Sunitinib	<ul style="list-style-type: none"> <li>✓ Treatment of renal cell carcinoma (RCC)</li> <li>✓ Treatment of gastrointestinal stromal tumors (GIST)</li> <li>✓ Treatment of primitive neuroectodermal tumor (pNET)</li> </ul>
Sorafenib	<ul style="list-style-type: none"> <li>✓ Treatment of hepatocellular carcinoma (HCC)</li> <li>✓ Treatment of renal cell carcinoma (RCC)</li> </ul>
Cabozantinib	<ul style="list-style-type: none"> <li>✓ Treatment of medullary thyroid carcinoma</li> <li>✓ Treatment of renal cell carcinoma (RCC)</li> </ul>
Bevacizumab	<ul style="list-style-type: none"> <li>✓ Treatment of metastatic breast cancer</li> <li>✓ Treatment of metastatic colorectal cancer (mCRC)</li> <li>✓ Treatment of small cell lung cancer (NSCLC)</li> <li>✓ Treatment of glioblastoma</li> <li>✓ Treatment of metastatic renal cell carcinoma (mRCC)</li> </ul>
Aflibercept	<ul style="list-style-type: none"> <li>✓ Treatment of metastatic colorectal cancer (mCRC)</li> </ul>
Everolimus	<ul style="list-style-type: none"> <li>✓ Treatment of metastatic breast cancer</li> <li>✓ Treatment of renal cell carcinoma (RCC)</li> <li>✓ Treatment of pancreatic neuroendocrine tumor</li> </ul>
Temsirolimus	<ul style="list-style-type: none"> <li>✓ Treatment of advanced renal cell carcinoma (RCC)</li> <li>✓ Treatment of mantle cell lymphoma</li> </ul>

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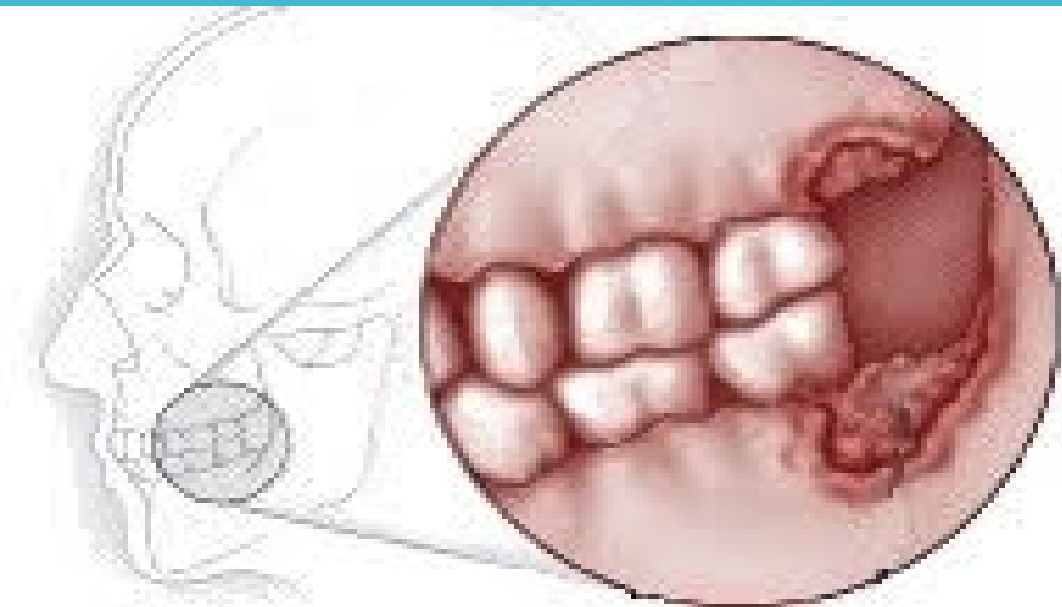
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If you want, contact  
italian local public health offices  
regarding an initial examination  
for drug-related osteonecrosis

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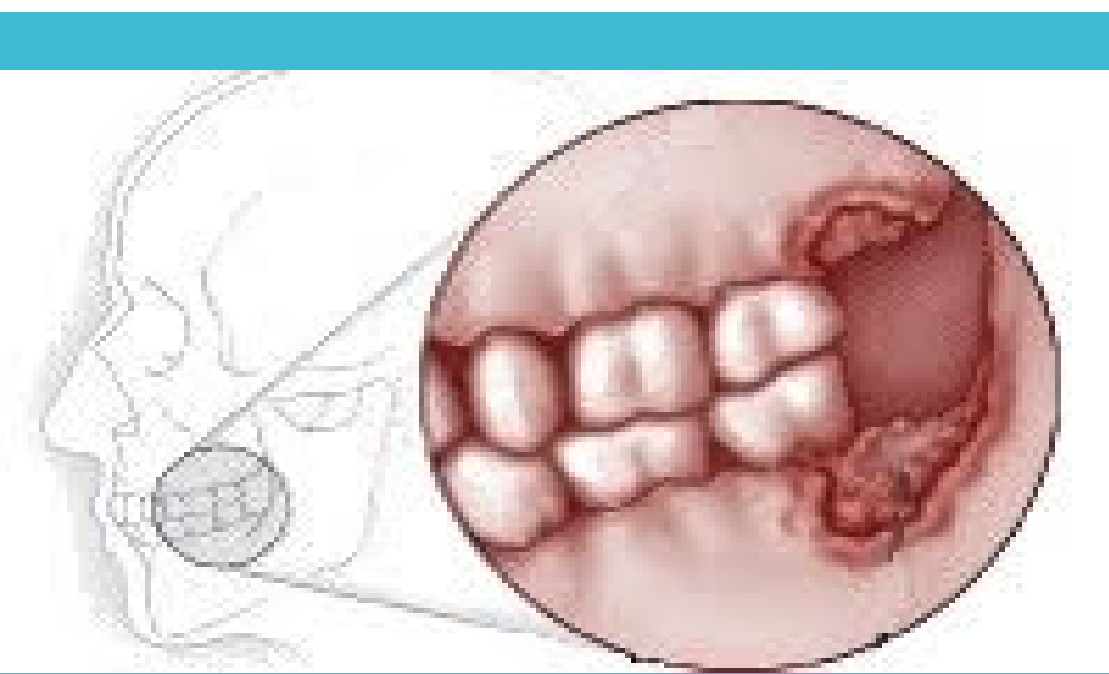
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