European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

QUADRAMET

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is QUADRAMET?

QUADRAMET is a solution for injection containing the active substance samarium [^{153}Sm] lexidronam pentasodium.

What is QUADRAMET used for?

QUADRAMET is used to relieve bone pain in patients with multiple painful osteoblastic skeletal metastases (when cancer has spread to the bones). Osteoblastic metastases are a type of bone metastasis where new bone tissue grows rapidly. QUADRAMET is only used in bone metastases that can take up a type of chemical called bisphosphonates, as this means that the metastases will also take up QUADRAMET. Before receiving QUADRAMET patients should have a bone scan using bisphosphonates radiolabelled with technetium-99m [^{99m}Tc] as markers, to check that their metastases are of the type that QUADRAMET can be used for.
The medicine can only be obtained with a prescription.

How is QUADRAMET used?

QUADRAMET should only be handled and given by someone who is authorised to use radioactive medicines and after full oncological (cancer) evaluation. The dose of QUADRAMET is calculated based on the patient's body weight to provide a specific dose of radioactivity (37 mega becquerels per kilogram body weight). The medicine is given by slow intravenous injection (into a vein) over one minute. Patients who respond to QUADRAMET generally have relief of their pain within one week of treatment. The pain relief may last for up to four months.

How does QUADRAMET work?

QUADRAMET is a radiopharmaceutical product. Its active substance is samarium [^{153}Sm] lexidronam pentasodium. It is a complex (a type of chemical) made up of a radioactive element, samarium-153 (^{153}Sm), bound to another chemical called 'ethylene diamine tetra methylene phosphonic acid' (EDTMP).
When QUADRAMET is injected into a patient, the complex is distributed around the body via the bloodstream. Because EDMTP has a high affinity for bone tissue, it accumulates in the bone, especially in areas of rapid bone growth such as osteoblastic metastases. As a result, the radiation brought by the samarium-153 can act locally and help to relieve the bone pain.

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How has QUADRAMET been studied?
QUADRAMET has been studied in 373 patients in three main studies. In two of these, the effectiveness of QUADRAMET was compared with that of placebo (a dummy treatment). The main measure of effectiveness was the reduction of pain. This was measured using various means, such as visual or descriptive scales, analgesic (painkiller) use, and assessment by the doctor.

What benefit has QUADRAMET shown during the studies?
QUADRAMET was effective in providing pain relief from osteoblastic bone metastases, and, where it was compared with placebo, more effective than placebo. In one of the studies, which involved patients with bone metastases from prostate cancer, the patients' use of opioid analgesics (such as morphine) was also reduced following treatment with QUADRAMET.

What is the risk associated with QUADRAMET?
The main side effects of QUADRAMET are a reduction in red and white blood cell and platelet counts. The following side effects have also been reported: asthenia (weakness), nausea (feeling sick), vomiting, diarrhoea, peripheral oedema (fluid retention), headaches, hypotension (low blood pressure), dizziness, myasthenia (muscle weakness), confusion and sweating. For the full list of all side effects reported with QUADRAMET, see the Package Leaflet.
QUADRAMET should not be used in people who may be hypersensitive (allergic) to EDTMP or to phosphonates (similar chemical compounds). It should not be used in pregnant women or in patients who have had chemotherapy or hemi-body external radiotherapy in the previous six weeks. QUADRAMET should not be used at the same time as any chemotherapy that affects the bone marrow or at the same time as other bisphosphonate medicines if these can interact with the way QUADRAMET fixes to bone metastases.

Why has QUADRAMET been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that QUADRAMET's benefits are greater than its risks for the relief of bone pain in patients with multiple painful osteoblastic skeletal metastases. The Committee recommended that QUADRAMET be given marketing authorisation.

Other information about QUADRAMET:
The European Commission granted a marketing authorisation valid throughout the European Union for QUADRAMET to CIS bio international on 5 February 1998. The marketing authorisation was renewed on 5 February 2003 and on 5 February 2008.

The full EPAR for QUADRAMET is available here.

This summary was last updated in 12-2007.