Pamidronate® 3mg/ml
Concentrate for solution for infusion.
Pamidronate Disodium

1. What Pamidronate 3mg/ml is what is it used for?

Pamidronate 3mg/ml is a medicine which affects the formation and destruction of bone in the form of a solution which can be given as a slow injection via a drip.

It is used in 3 ways:

- It reduces high levels of calcium in the blood caused by cancers.
- It inhibits bone destruction in patients with spread of breast cancer to the bones.
- It is used in patients with advanced multiple myeloma (a tumor of bone marrow cells).

2. Before Pamidronate 3mg/ml is administered to you:

Pamidronate 3mg/ml should not be used:

- If you are known or suspected to be hypersensitive (allergic) to Pamidronate disodium, to any of the excipients or other bisphosphonate medicines.

Special care should be taken with Pamidronate 3mg/ml:

- If you are pregnant.
- If you are on controlled sodium diet.
- If you have low levels of blood cells (RBC's, WBC's or Platelets).
- If you have undergone thyroid surgery.
- If you have heart problems.
- If you have liver problems.
- If you suffer from kidney disease.
- If you are taking other drugs that can affect kidneys.
- If you are taking other medicines that reduces calcium levels in blood (calcitonin or other bisphosphonates).
- If you undergo dental surgery.

Pregnancy and Breast Feeding:

Ask your doctor for advice before taking any medicine.

Pregnancy
If you are pregnant or likely to become pregnant, you should inform your doctor before taking Pamidronate disodium.

Breast-Feeding
If you are breast feeding, you must not take Pamidronate disodium.

3. How Pamidronate Disodium is administered to you?

Method and routes of administration
Pamdronate 3mg/ml is a solution which must be diluted and then given to you as slow injection via drip (IV infusion). Your doctor will use freshly prepared & clear solution and will not use the solution if particles are present.

Pamidronate disodium is given is given only to adults of 18 years and above, under the supervision of a physician with the facilities to monitor its effects.

Dosage:

The dose of medicine depends upon the medical condition, the levels of calcium in blood and how well the kidneys work. The usual dose per treatment course is between 15mg to 90mg. your doctor will decide how many infusions you need, how often it will be given and how long the therapy will be continued.

During treatment, blood tests to monitor electrolytes and urine samples to monitor renal function will be done.

Post administration of Pamidronate 3mg/ml:

If you experience paresthesia (pins and needles), tetany (muscle spasm particularly of the jaw or limbs) and hypotension (feeling

lightheadedness) during treatment with Pamidronate disodium, you should inform the medical staff who will give you calcium into your veins to reverse the symptoms. It is unlikely that these symptoms would occur however during the infusion.

4. Possible Side Effects

Like all medicines, Pamidronate Disodium 3mg/ml has side effects. Many of the following undesirable effects may have been related to your underlying disease.

Cases of bone damage (Osteonecrosis primarily of the jaw) - have been reported uncommonly predominantly in cancer patients treated with bisphosphonates including Pamidronate Disodium. Many of these patients had signs of local inflammation (osteomyelitis) and the majority reports patients with tooth extractions or other dental procedures. Osteonecrosis of jaw has multiple well-documented risk factors including a diagnosis of cancer, concomitant therapies (e.g. chemotherapy, radiotherapy, corticosteroids) and co-morbid conditions [e.g. anemia, blood clotting disorders (coagulopathies), infections and preexisting oral diseases]. Although causality has not been determined, patients should avoid dental surgery while on treatment with Pamidronate as recovery from the procedure may be prolonged.

Symptoms such as itchy rash, swelling of hands & feet, ankles, face, difficulty in swallowing or breathing – can be a severe allergic reaction. Immediately tell your doctor about it

Side Effects with Frequency Estimation:

Very common: more than 1 in 10 patients

- Fever & Influenza-like symptoms sometimes accompanied by tiredness, shivering, fatigue & flushing
- Low levels of calcium & phosphate in blood

Common: less than 1 in 10 patients

- Anemia, leukopenia & thrombocytopenia
- Low levels of potassium & magnesium
- Low levels of calcium (pins and needles, muscle cramps/spasm)
- Headache
- Inability to sleep
- Conjunctivitis (pinkeye)
- Hypertension
- Nausea, vomiting, anorexia, abdominal pain or diarrhea
- Rash
- High levels of serum creatinine

Uncommon: less than 1 in 100 patients

- Hypersensitivity
- Seizures
- Dizziness
- Lethargy
- Hypotension
- Severe bone damage (osteonecrosis)
- Reduced urine output

Rare: less than 1 in 1,000 patients

- Unusual fractures of thigh bone
- Change in kidney function (fluid retention, nausea & fatigue)
- Protein leak in urine associated with swelling of legs and abdomen (nephrotic syndrome)

Very Rare: less than 1 in 10,000 patients

- Anaphylactic shock
- Hypernatremia & Hyperkalemia (state of disorientation & arrhythmia's respectively)
- Confusion or hallucinations
- Episcleritis (pain & redness in the eye)
- Severe lung disease

Not Known: **Cannot be estimated from the available data**

- Irregular heart rhythm (atrial fibrillation)
- Orbital inflammation

5. Storing Pamidronate 3mg/ml

Shelf life after dilution in 5% glucose solution or in 0.9% NaCl solution:
Chemical and physical in-use stability has been demonstrated for 96 hours at 25 deg C.
Following dilution, the solution should be used immediately. If not used immediately, it should be stored at 2 – 8 deg C and used within 24 hours (if dilution has taken place in controlled and validated aseptic conditions)

6. Further information

Pamidronate 3mg/ml is presented in glass container (vials)

Each ml of solution contains:
3 mg of Pamidronate disodium as pamidroic acid 2.527mg
The 5ml vial (available in packs of 1, 4 or 10) contains 15mg of Pamidronate disodium
The 10ml vial (available in packs of 1, 4 or 10) contains 30mg of Pamidronate disodium
The 20ml vial (available in packs of 1, 4 or 10) contains 60mg of Pamidronate disodium
The 30ml vial (available in packs of 1, 4 or 10) contains 90mg of Pamidronate disodium

Not all pack sizes may be marketed.

Marketing authorization holder: Medac, Germany

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