Package leaflet: Information for the user

Disodium Pamidronate 10mg/mL Concentrate for Solution for Infusion

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

1. Why Disodium Pamidronate is prescribed

Disodium Pamidronate is used to treat or prevent bone pain due to cancer spread, or multiple myeloma.

2. Why you should not be given Disodium Pamidronate

You should not be given Disodium Pamidronate if you:

- are allergic to Disodium Pamidronate, any other bisphosphonate, or any of the other ingredients of this medicine (listed in section 6).
- are pregnant
- are breastfeeding

3. How Disodium Pamidronate should be given

Disodium Pamidronate is given by a slow injection into a vein (intravenous infusion).

4. Possible side effects

Sleepiness and dizziness may rarely occur with Disodium Pamidronate. If these side effects get worse, or you experience any of the following side effects, tell your doctor or nurse:

- changes in the way you think or feel, including thoughts of harming yourself or others
- high blood calcium levels (hypercalcaemia) due to tumours
- osteonecrosis of the external auditory canal
- symptoms of bone pain

5. What to do if you think you are allergic to Disodium Pamidronate

Contact your doctor and dentist immediately if you experience any problems with your:

- teeth
- mouth

6. Additional information

If you have frequent infusions of Disodium Pamidronate over a prolonged period of time your doctor may perform blood tests during your treatment to monitor calcium and phosphate levels in the blood. Your doctor will then adjust your treatment accordingly.

Disodium Pamidronate may interfere with the results of bone scans. Please tell your doctor or nurse if you are due to have bone scans.

You should drink plenty of fluids during treatment so that you do not dehydrate.

Other medicines and Disodium Pamidronate

Tell your doctor or nurse if you are taking, have recently taken or might take other medicines, including non-prescription medicines (available from a pharmacy) or herbal products, because they may affect Disodium Pamidronate or be affected by it.

1. Liver problems

Some medicines may affect the way Disodium Pamidronate works, or Disodium Pamidronate may affect the way some medicines work.

2. Anti-cancer medicines

Disodium Pamidronate is administered concomitantly with commonly used anti-cancer medicines and, in particular with single agents and combination regimens that may contain cisplatin, docetaxel, erlotinib, tamoxifen, aminoglycosides or any other anti-cancer medicines with potential nephrotoxic, neurotoxic or myelosuppressive properties. Patients with previous or current renal impairment should be monitored closely for hypercalcaemia since these drugs may increase the risk of this condition.

3. Intravenous bisphosphonates

If you have frequent infusions of Disodium Pamidronate over a prolonged period of time your doctor may perform blood tests during your treatment to monitor calcium and phosphate levels in the blood. Your doctor will then adjust your treatment accordingly.

Disodium Pamidronate may interfere with the results of bone scans. Please tell your doctor or nurse if you are due to have bone scans.

You should drink plenty of fluids during treatment so that you do not dehydrate.
If you give more Disodium Pamidronate than you should

A doctor or nurse will give you the medicine. If you think you have received too much Disodium Pamidronate, please tell your doctor or nurse immediately. Signs that you may have been given too much medicine include nausea and vomiting, a fast and weak pulse and blood pressure that is too low.

If you think you have received a dose of Disodium Pamidronate

A doctor or nurse will give you the medicine. If you think you have received too much, please tell your doctor immediately.

A. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects of Disodium Pamidronate usually occur within the first 48 hours of treatment and then disappear again.

Always report side effects. If you experience difficulty breathing, shortness of breath, swelling of the face, lips or eyes or any symptoms linked to an allergic reaction (allergic shock) with a sudden decrease in blood pressure, contact your doctor immediately.

Side effects of Disodium Pamidronate usually occur within the first 48 hours of treatment and then disappear again. They most frequently occur during treatment and then disappear again.

• muscle cramps
• local intolerance (pain, redness, swelling or tenderness)
• bone pain, joint or muscle pain or general aches and pains
• constipation or diarrhoea
• reduction of lymphocytes (white cells) in the blood
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• bone pain, joint or muscle pain or general aches and pains
• constipation or diarrhoea
• reduction of lymphocytes (white cells) in the blood

Common: Reactions at the infusion site (pain, redness, swelling, and tenderness) may occur at the site of the injection. Some patients may develop muscle cramps or local intolerance (pain, redness, swelling or tenderness).

Common: The following symptoms have occurred in patients administered disodium pamidronate: fatigue, headache, fever and flu-like symptoms, such as feeling unwell, shivering, tiredness and hot or cold sweats.

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