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ZOLEDRONATE (Zoledronic Acid) – DRUG SAFETY INFORMATION

Form: Solution for injection 4mg/5mL vial
Administration by Intravenous Infusion (following dilution)

General:

- If there is evidence of damage to the packaging in transit please contact us prior to administration.
- Keep out of the reach and sight of children.
- Protect product from heat and store below 25^{o}C until ready to use.
- The expiry date for the product under the recommended storage conditions will be stated on the label once diluted should be used immediately and not stored beyond 24 h at 2-8 ^{o}C.
- **Single use only**: discard any unused product or diluted solution.

Handling and administration:

This medication is typically diluted and administered in the routine hospital environment.

Zoledronate is never given as a bolus injection. The diluted drug is added to a suitable volume of 0.9% NaCl for injection and administration as an intravenous infusion over 15 minutes through a securely placed intravenous catheter in a peripheral vein via a separate infusion line to other fluids. The drug should not be administered in Lactated Ringer's solution but can be administered in 5% glucose solution. In patients that are dehydrated, rehydration with suitable fluid therapy is recommended prior to administration of the zoledronate infusion.

There are few guidelines but in the interests of safety, pregnant women should not be involved in the dilution or administration of zoledronate. Non osseous bound drug is almost entirely excreted from the body in the urine with the highest concentrations in the first 72h after administration. Staff members who are pregnant or trying to conceive or owners should therefore not be involved in handling urine from treated patients.

Prevention of contamination:

- Routes of exposure to pharmaceutical agents include ingestion, inhalation, and absorption through the skin and mucous membranes.

- There are no specific guidelines on wearing PPE (gown, gloves, mask, eye protection) for dilution and administration of the medication however normal precautions to prevent exposure to pharmaceutical agents should be observed.

Disposal:

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Warnings and contraindications:

- Thrombophlebitis is possible at the site of intravenous administration.
- Renal injury is reported following the use of zoledronate in people at high doses but renal adverse events are rarely reported in companion animals. Monitoring of renal values would be appropriate however due to the concurrent renal effects of hypercalcaemia.
- Use of bisphosphonates prior to medical or surgical treatment to manage the tumour underlying the development of hypercalcaemia may result in the development of hypocalcaemia in the post surgical / post medical period.
- Concurrent use of aminoglycosides can cause severe hypocalcaemia.

Further information:

Further information is available on request by contacting us at info@chemopet.co.uk or by telephone: 01928 250052.