Synovetin OA

[Homogeneous Tin (^{117m}Sn) Colloid]
Veterinary Device for Use in Dogs

NAME: Synovetin OA®

Tin (^{117m}Sn) stannic colloid in ammonium salt. It is supplied as a 2–4 mCi (74–148 MBq)/mL suspension for intra-articular (IA) injection.

NET QUANTITY

Vials contain a prescribed dose up to 6.0 mCi (222 MBq) at the date and time to treat one dog.

1 mL of suspension contains 2–4 mCi (74–148 MBq) of tin (^{117m}Sn) stannic colloid in ammonium salt at the date and time of end use.

PRODUCT DESCRIPTION

Synovetin OA® is a conversion electron therapeutic veterinary device comprising a colloidal, sterile suspension with a pH between 6.5 and 8.0 where at least 90% of the particles have a size between 1.5 µm and 20 µm (ASTMA light scatter instrument). The ^{117m}Sn emits monoenergetic conversion electrons (significant energies: 127–156 keV; emission probability 113%) and imageable gamma radiation (159 keV; 86% abundance), accompanying low-energy emissions and Auger electrons (<22 keV) and X-rays (<30 keV). The half-life of ^{117m}Sn is 14 days. ^{117m}Sn decays to (stable) ^{117}Sn.

Excipients include ammonium carbonate ($(NH_4)_2CO_3$), ammonium chloride (NH_4Cl), ammonium iodide (NH_4I), and trace tin (Sn) salts.

MECHANISM OF ACTION

Synovetin OA® is a veterinary device consisting of a homogeneous tin colloid which emits discrete (<300 µm) low energy conversion electrons confined to the joint space. The colloid is composed of microparticles (1.5 µm to 20 µm) that are retained in the joint space of the dog. The particles are absorbed and retained by synoviocytes and macrophages in the synovium, resulting in apoptosis and reduction of inflammatory cells. Elimination of the pro-inflammatory cells reduces inflammation of the joint synovium, thereby reducing pain associated with synovitis. The data, including radiographic evidence, supports use in Grade 1, 2, and 3 osteoarthritis (OA) of the elbow joint.

CAUTION

Federal law restricts this device to sale by or on the order of a licensed veterinarian trained in the use of radioactive veterinary medical products.

Use of this product is restricted to facilities with a compatible Radioactive Materials (RAM) license.

INTENDED USE

Synovetin OA® is intended to reduce synovitis and associated pain of canine elbow joints afflicted with osteoarthritis.

WARNINGS

Do not exceed 6.0 mCi (222 MBq) of radiation activity per dog per treatment. Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental injection or ingestion by humans.

PRECAUTIONS

Injection should be performed only by a licensed veterinarian skilled in the delivery of intra-articular (IA) injections who is located at a facility that has a RAM license.

Rigorous aseptic technique must be ensured during injection.

DIRECTIONS FOR USE

Use the chart below to determine the appropriate dose. Doses were determined using the elbow joint.

For example, a dog weighing 25 lbs. receives an IA dose of 0.9 mCi in each elbow to be treated.

Dog Weight (lbs.)	Synovetin OA® Dose per Elbow Joint (mCi)*
15–19 lbs.	0.6
20–29 lbs.	0.9
30–39 lbs.	1.2
40–49 lbs.	1.5
50–59 lbs.	1.7
60–69 lbs.	1.9
70–79 lbs.	2.2
80–89 lbs.	2.4
90–99 lbs.	2.6
100–109 lbs.	2.8
110 lbs. and over	3.0

***Dose will be limited to 3.0 mCi/elbow joint when weight exceeds 110 lbs., with the total body dose not exceeding 6.0 mCi (i.e., two elbow joints in 110-lb. or greater-sized dogs).**

PREPARATION FOR USE

Synovetin OA® is provided in a 3 mL glass vial within a lead cylinder. Each vial is for use with a single dog.

The product should be stored in the cardboard shipping container until needed for use. The **prescribed dose** should be **administered on the date noted** on the certificate accompanying the Synovetin OA®; however, it can be administered the day before or after if circumstances require injection on a different day. Ensure use of proper personal protective equipment and precautions for handling radioactive medical products, including nitrile gloves, radiant shield, safety goggles, lead-lined gloves, head covers, booties, and surgical masks.

STEP 1: When ready to withdraw the dose into a syringe and prior to removing the shrink wrap around the lead cylinder, gently **shake the lead cylinder for approximately 30 seconds to ensure proper mixing** of the product.

STEP 2: Remove the shrink wrap from the lead cylinder and dispose of it appropriately.

STEP 3: Remove the lead cylinder lid, but do not remove the glass vial from the lead cylinder.

STEP 4: Remove the colored flip cap from the vial and retain for placement on the vial after the dose is withdrawn.

STEP 5: Attach a plastic syringe (3 mL or other appropriate volume) to a 22 ga. needle. Where practical, use a syringe shield to maintain operator radiation doses as low as reasonably achievable and to meet existing license conditions.

STEP 6: While holding the container at an approximate 45° angle, insert the needle through the septum.