



Elanco Animal Health

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FOR IMMEDIATE RELEASE

**Elanco Animal Health Announces U.S. Food and Drug Administration (FDA) Approval of
Imrestor™ (pegbovigrastim injection)**

Greenfield, Ind. (March 17, 2016) — Today, Elanco Animal Health, a division of Eli Lilly and Company (NYSE: LLY), announced the approval of Imrestor™ (pegbovigrastim injection) – the first product of its kind for the dairy industry.

Available only by veterinary prescription, Imrestor is now FDA approved for the reduction in the incidence of clinical mastitis in the first 30 days of lactation in periparturient dairy cows and periparturient replacement dairy heifers. Imrestor is a protein that helps support the natural function of a dairy cow's immune system during the critical time around calving, when she is most vulnerable to mastitis.

"Imrestor is an innovative new approach for reducing clinical mastitis by proactively helping to restore the function of a cow's immune system," explained Paul Rapnicki, DVM, MBA, Associate Technical Advisor, Elanco Animal Health.

Pivotal efficacy studies conducted for FDA approval showed a 28 percent reduction in clinical mastitis incidence among cows and heifers that received Imrestor compared with control animals.¹ Mastitis is the most common disease among dairy cows, affecting as many as 1 in 4 cows.² Clinical mastitis affects each cow's potential leading to reduced conception rates³, an increased risk for another case of mastitis⁴, and lost milk production potential throughout the lactation⁵.

Dairy Cows Experience Immune Suppression At Calving

Immune suppression at calving can leave cows vulnerable to infection and an increased risk of mastitis.⁶ Dairy cows and heifers are in need of protection particularly at calving due to a decline in neutrophils – the primary type of white blood cell that recognizes and destroys harmful bacteria. Imrestor helps restore the function^{7*} and increase the number^{1,7*} of neutrophils at calving which helps the cow to fight invading bacteria that cause mastitis.

"We know that even the best producers need a little help protecting their dairy herds. Imrestor is a proactive approach that can help keep cows healthy and help reduce the frustration, financial strain and stress associated with treating mastitis," added Rapnicki.

Elanco shared news of the Imrestor approval today during a U.S. Department of Agriculture (USDA) meeting where antibiotic alternatives for use in food animals were discussed. Mastitis is the most common illness treated with antimicrobials in dairy cows⁸.

The launch of Imrestor is aligned with Elanco's eight-point antibiotic stewardship plan that ensures the responsible use of antibiotics, reduces shared-class antibiotic use and replaces antibiotics with alternatives. The plan was outlined by Elanco President Jeff Simmons at a White House antibiotic stewardship forum last year.

Available in pre-filled, single-dose syringes, Imrestor is administered with two injections – one seven days prior to the anticipated date of calving** and the other within 24 hours after calving – thus helping to protect the cow against mastitis when she needs it most.

Imrestor does not require a meat or milk withdrawal period. Imrestor will be available for purchase in 10, 50, and 100 dose pack sizes. The product availability date will be announced at a later time. Dairy producers are encouraged to contact their veterinarian to discuss incorporating Imrestor into their herd health program.

IMPORTANT SAFETY INFORMATION

Not for use in humans. Keep out of reach of children. In case of accidental self-injection, wash the site of injection thoroughly with clean running water. Foreign proteins such as pegbovigrastim have the potential to cause anaphylactic-type reactions. No withdrawal period or milk discard time is required when used according to the labeling. Do not use Imrestor to treat cows with clinical mastitis because effectiveness has not been demonstrated for this use. Some cases of hypersensitivity-type reactions have been observed in studies outside the United States within five minutes to two hours, occurring most often after the first administration of Imrestor. These reactions resolve within hours of onset with or without therapeutic intervention and have not been shown to reoccur with subsequent injections of Imrestor. For complete safety information, see product label attached.

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*The clinical significance of this data has not been demonstrated

**4-10 days to accommodate management schedules

ABOUT ELANCO

Elanco provides comprehensive products and knowledge services to improve animal health and food-animal production in more than 70 countries around the world. We value innovation, both in scientific research and daily operations, and strive to cultivate a collaborative work environment for more than 6,500 employees worldwide. Together with our customers, we are committed to raising awareness about global food security, and celebrating and supporting the human-animal bond. Founded in 1954, Elanco is a division of Eli Lilly and Company. Our worldwide headquarters and research facilities are located in Greenfield, Indiana. Visit us at Elanco.com.

¹Elanco Animal Health, Data on File.

² Holland, J., et al. Assessing the farm-level cost of mastitis. *J. Dairy Sci.* 2015;98 (Suppl. 2):234. (Abstr 137)

³ Santos JEP. Effect of timing of first clinical mastitis occurrence on lactational and reproductive performance of Holstein dairy cows. *Anim Reprod.* 2004;80:31-45.

⁴ Pantoja JC, Hulland C, Ruegg PL. Somatic cell count status across the dry period as a risk factor for the development of clinical mastitis in the subsequent lactation. *J Dairy Sci.* 2009;92:139-148.

⁵ Wilson DJ, González RN, Hertl J, et al. Effect of clinical mastitis on the lactation curve: A mixed model estimation using daily milk weights. *J Dairy Sci.* 2004;87:2073-2084.

⁶ Aitken SL, Corl CM, Sordillo LM. Immunopathology of mastitis: insights into disease recognition and resolution. *J Mammary Gland Biol Neoplasia.* 2011;16:291-304.

⁷ Kimura K. et al. Effect of recombinant bovine granulocyte colony-stimulating factor covalently bound to polyethylene glycol injection on neutrophil number and function in periparturient dairy cows. *J Dairy Sci.* 2014;97:1-10.

⁸ Mitchell JM, Griffiths MW, McEwen SA, McNab WB, Yee AJ. Antimicrobial drug residues in milk and meat: causes, concerns, prevalence, regulations, tests, and test performance. *J Food Prot.* 1998 Jun; 61(6):742-56.

Imrestor™ pegbovigrastim injection

15 mg pegbovigrastim per 2.7 mL single dose syringe
For subcutaneous injection in periparturient dairy cows and periparturient replacement dairy heifers.

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION: Imrestor is a sterile injectable formulation of pegbovigrastim (an immunomodulator, bovine granulocyte stimulating factor) in single-dose syringes. Each syringe of Imrestor contains pegbovigrastim (15 mg), L-arginine hydrochloride (94 mg), L-arginine (40 mg), and citric acid monohydrate (17 mg).

INDICATIONS FOR USE: For the reduction in the incidence of clinical mastitis in the first 30 days of lactation in periparturient dairy cows and periparturient replacement dairy heifers.

DOSAGE AND ADMINISTRATION: This is a two-dose regimen. The same dose is used regardless of cow/heifer body weight. Remove surface dirt from the injection site area before injecting. Inject the entire contents of the syringe subcutaneously. Do not reuse the syringe.

Administer the first dose (syringe) 7 days prior to the cow's or heifer's anticipated calving date. If necessary, the first dose may be administered within a range of 4 to 10 days prior to the anticipated calving date to accommodate management schedules. Administer the second dose (syringe) within 24 hours after calving.

Animals that calve either less than or more than 7 days after the first dose should receive the second dose within 24 hours after calving.

Prior to administration, Imrestor should be visually inspected for particulate matter and discoloration. Imrestor is a clear, colorless solution and may contain a few small, translucent or white particles. Imrestor should not be used if it is discolored or cloudy, or if other particulate matter is present.

Do not shake or tap the syringe prior to use.

WARNINGS:

RESIDUE WARNING: No withdrawal period or milk discard time is required when used according to the labeling.

HUMAN WARNINGS: Not for use in humans. Keep out of reach of children.

USER SAFETY WARNINGS: In case of accidental self-injection, wash the site of injection thoroughly with clean running water. Foreign proteins such as pegbovigrastim have the potential to cause anaphylactic-type reactions. If you experience swelling or redness at the site of exposure, or more severe reactions such as shortness of breath, seek medical attention immediately and take the package insert with you. Report the event to Elanco Animal Health at 1-800-428-4441. To obtain a Safety Data Sheet, contact Elanco Animal Health at 1-800-428-4441.

PRECAUTIONS: Do not use Imrestor to treat cows with clinical mastitis because effectiveness has not been demonstrated for this use.

ADVERSE REACTIONS: Some cases of hypersensitivity-type reactions have been observed in studies outside the United States within five minutes to two hours, occurring most often after the first administration of Imrestor. Clinical signs may include elevated respiratory rate, dyspnea, urticaria, sweating, dependent edema, swollen mucous membranes, and/or hypersalivation, and, rarely death. These reactions resolve within hours of onset with or without therapeutic intervention and have not been shown to reoccur with subsequent injections of Imrestor. Abomasal ulcerations/erosions were observed in the Margin of Safety studies. (See Target Animal Safety section).

To report a suspected adverse drug event, contact Elanco Animal Health at 1-800-428-4441. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/AnimalVeterinary/SafetyHealth>.

CLINICAL PHARMACOLOGY: Endogenous granulocyte colony stimulating factor is a protein (cytokine) which induces increased production of mature neutrophils from bone marrow stem cells and activation of the functional capabilities of mature circulating neutrophils. Pegbovigrastim is a modified form of bovine granulocyte colony stimulating factor conjugated to polyethylene glycol (PEG). This PEGylation technology enables sustained biological activity of the protein. In one study, cows treated with 20 µg/kg pegbovigrastim displayed statistically significant increased absolute neutrophil counts relative to the untreated control group beginning 5 hours post-dosing. Absolute neutrophil counts peaked 36 hours post-dosing and remained elevated up to 12 days post-dosing.

EFFECTIVENESS: The effectiveness of Imrestor for the reduction in the incidence of clinical mastitis was demonstrated in a multi-site natural infection field study conducted at four sites in the U.S. and one site in France. A total of 801 healthy periparturient commercial dairy heifers and cows were enrolled and treated with Imrestor or saline by subcutaneous injection in the neck when they were identified as being approximately 7 days before their anticipated calving date (Day -7), and again within 24 hours after calving (Day 0).

Each quarter of each enrolled animal was evaluated at each milking from Days 3 to 30 to monitor the development of clinical mastitis. Animals developing clinical mastitis (using quarter health, milk quality, and California Mastitis Test [CMT] evaluations) through Day 30 were classified as treatment failures. Administration of Imrestor resulted in a statistically significant difference ($p = 0.025$) in the incidence of clinical mastitis (treatment failure rate) across all five sites with a difference in favor of the Imrestor-treated group (failure rate: 60/331 = 18.13%) compared to the saline-treated group (failure rate: 85/338 = 25.15%).

TARGET ANIMAL SAFETY:

Margin of Safety: In the first study, forty primiparous and multiparous Jersey cows were assigned to one of four treatments: saline control, 1X, 2X, or 3X the intended dose of Imrestor administered at Days -7 and -3 prior to anticipated calving date and within 24 hours after calving. Cows and heifers were monitored daily until 4 days postpartum. Calves were monitored daily for 14 days after birth. Measurements on cows included bodyweights, feed consumption, milk production, somatic cell counts, physical examinations, and clinical pathology. A complete postmortem examination was conducted on each adult animal. Measurements in calves included physical examinations, bodyweights, and hematology. There were no test article related findings associated with abnormal clinical observations, feed consumption, milk production, physical examinations, or urinalysis in adult animals. A mature neutrophilia was seen in all treated animals, regardless of dose group. This was considered a test article related change and consistent with the mechanism of action of Imrestor. No test article related hematology changes were observed in the calves. Observations of mastitis, metritis, and abomasal ulcers were documented, with more animals in the treated groups affected compared to the controls. Two animals (one each from 1X and 3X groups) had perforated abomasal ulcers found at necropsy.

A second study evaluated the margin of safety of pegbovigrastim in multiparous Holstein dairy cows. Forty-five multiparous Holstein dairy cows were assigned to one of five treatments: saline control, 1X, 2X, 2.5X, or 3X the recommended dose of one syringe of pegbovigrastim administered subcutaneously on Day -7 relative to the anticipated calving date and within 24 hours after calving. Cows were monitored daily until 14 days postpartum. Measurements included bodyweights, feed consumption, milk production, somatic cell counts, physical examinations, and clinical pathology, including reticulocyte counts and fecal occult blood. A postmortem examination that focused on the gastrointestinal tract, uterus, and mammary tissue was conducted on each cow. Calves were not evaluated in this study. There were no test article related findings associated with abnormal clinical observations, feed consumption, milk production, or physical examinations. A mature neutrophilia was observed in all treated animals which was consistent with the Imrestor mechanism of action and was similar to what was observed in the first margin of safety study. Treated animals had a greater number of mild gastrointestinal erosions and small areas of reddened or thinned mucosa along various portions of the gastrointestinal tract as compared to the control animals. No abomasal ulcers were seen on necropsy.

It was concluded from these studies that abomasal ulcerations/erosions could be test article related. However, given the lack of clinical signs associated with such gastrointestinal pathology in conjunction with the mild nature of the erosions in the second study, it was concluded that these findings were not clinically relevant.

Injection Site Safety: Injection site safety was evaluated following the injection of Imrestor into healthy periparturient dairy cows. Results of the injection site toleration study showed that subcutaneous injections of pegbovigrastim administered 14 days prior to slaughter in 6 cows had no gross lesions and would require no carcass trim at slaughter. Additionally, subcutaneous injections of pegbovigrastim administered approximately 12 hours prior to slaughter in 6 cows caused minimal acute local tissue reactions generally characterized by focal hemorrhage and edema and would be removed along with the hide at the time of slaughter and would not result in any carcass trim.

Reproductive Safety: Animals in the effectiveness study were also evaluated for reproductive safety. This study included 801 animals: 401 control animals and 400 treated animals. Variables measured included daily health observations on cows and calves, mortality, gestation length, percent live births, and first service conception rates following treatment. There were no statistically significant differences between treated and control animals for these reproductive variables.

STORAGE INFORMATION: Store under refrigeration (2° to 8°C; 36° to 46°F). DO NOT FREEZE. Avoid prolonged exposure to sunlight. Excursions of up to 24 hours at room temperature (15° to 30°C; 59° to 86°F) are allowed after receipt.

DISPOSAL: Dispose of used syringes in a leak-resistant, puncture-resistant container in accordance with applicable Federal, state and local regulations.

HOW SUPPLIED: 10, 50 or 100 single-dose syringe packages with each syringe containing 15 mg of pegbovigrastim.

NADA 141-392. Approved by FDA.

Manufactured for Elanco Animal Health, a Division of Eli Lilly and Company, Indianapolis, IN 46285.

For technical assistance or to report suspected adverse drug events, contact Elanco Animal Health at 1-800-428-4441.

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Imrestor™ inyección de pegbovigrastim

jeringa con 15 mg de pegbovigrastim por 2.7 ml como dosis única
Para inyección subcutánea en vacas lecheras periparturientas y vaquillas lecheras periparturientas de reemplazo.

PRECAUCIÓN: Las leyes federales (EE. UU.) establecen que el uso de este fármaco se restrinja a veterinarios con licencia o bajo indicación de estos.

DESCRIPCIÓN: Imrestor es una formulación inyectable estéril de pegbovigrastim (un inmunomodulador, factor estimulador de granulocitos bovinos) en jeringas de dosis única. Cada jeringa de Imrestor contiene pegbovigrastim (15 mg), clorhidrato de L-arginina (94 mg), L-arginina (40 mg) y ácido cítrico monohidrato (17 mg).

INDICACIONES DE USO: Para la reducción de la incidencia de mastitis clínica en los primeros 30 días de lactancia en vacas lecheras periparturientas y vaquillas lecheras periparturientas de reemplazo.

DOSIS Y ADMINISTRACIÓN: Este es un régimen de dos dosis. Se usa la misma dosis independientemente del peso corporal de la vaca o vaquilla. Retirar la suciedad superficial del sitio de inyección antes de inyectar. Inyectar todo el contenido de la jeringa por vía subcutánea. No volver a usar la jeringa.

Administre la primera dosis (jeringa) 7 días antes de la fecha prevista de parto de la vaca o la vaquilla. Si es necesario, la primera dosis se puede administrar dentro de un intervalo de 4 a 10 días antes de la fecha prevista de parto para adaptarse a los horarios de administración. Administre la segunda dosis (jeringa) dentro de las 24 horas posteriores al parto.

Los animales que paren en un período de menos o más de 7 días después de la primera dosis también deben recibir la segunda dosis dentro de las 24 horas después del parto.

Antes de la administración, Imrestor se debe inspeccionar visualmente para observar si hay material particulado y decoloración. Imrestor es una solución transparente e incolora y puede contener algunas pequeñas partículas translúcidas o blancas. No se debe usar Imrestor si está decolorado o turbio, o si hay presencia de otro material particulado. No agite ni golpee la jeringa antes de usar.

ADVERTENCIAS:

ADVERTENCIA ACERCA DE RESIDUOS: No es necesario un tiempo de espera ni un tiempo de descarte de leche cuando se usa de acuerdo con las indicaciones de la etiqueta.

ADVERTENCIAS PARA SERES HUMANOS: No se debe usar en los seres humanos. Mantenga fuera del alcance de los niños.

ADVERTENCIAS DE SEGURIDAD PARA EL USUARIO: En caso de autoinyección accidental, lave el sitio de la inyección minuciosamente con agua corriente limpia. Las proteínas extrañas, como pegbovigrastim, tienen el potencial de causar reacciones de tipo anafilácticas. Si tiene hinchazón o enrojecimiento en el área de la exposición, o reacciones más graves, como falta de aire, busque atención médica de inmediato y lleve el prospecto con usted. Informe el hecho a Elanco Animal Health al 1-800-428-4441. Para obtener una hoja de datos de seguridad, comuníquese con Elanco Animal Health al 1-800-428-4441.

PRECAUCIONES: No use Imrestor para tratar vacas con mastitis clínica porque no se ha demostrado la efectividad para este uso.

REACCIONES ADVERSAS: Algunos casos de reacciones de hipersensibilidad se han observado en estudios llevados a cabo fuera de los Estados Unidos. Estas reacciones se manifestaron entre cinco minutos y dos horas, más frecuentemente después de la primera administración de Imrestor. Los signos clínicos pueden incluir frecuencia respiratoria elevada, disnea, urticaria, sudoración, edema dependiente, membranas mucosas hinchadas y/o hipersalivación y, muy rara vez la muerte. Estas reacciones se resuelven en cuestión de horas de su aparición con o sin intervención terapéutica, y no se ha mostrado que vuelvan a ocurrir con las inyecciones subsiguientes de Imrestor. Se observaron úlceras/erosiones del abomaso en el margen de los estudios de seguridad. (Consulte la sección Seguridad objetivo de los animales).

Para informar una sospecha de evento adverso del fármaco, comuníquese con Elanco Animal Health al 1-800-428-4441. Para obtener información adicional sobre cómo informar la experiencia adversa de los fármacos de animales, comuníquese con la FDA al 1-888-FDA-VETS o visite <http://www.fda.gov/AnimalVeterinary/SafetyHealth>.

FARMACOLOGÍA CLÍNICA: El factor estimulante de colonias de granulocitos endógeno es una proteína (citocina) que induce una mayor producción de neutrófilos maduros a partir de células madre de médula ósea y activación de las capacidades funcionales de los neutrófilos circulantes maduros. Pegbovigrastim es una forma modificada del factor estimulante de colonias de granulocitos bovinos conjugado a poliethylenglicol (PEG). Esta tecnología de PEGilación hace posible una actividad biológica sostenida de la proteína. En un estudio, las vacas tratadas con 20 µg/kg de pegbovigrastim mostraron un aumento significativo desde el punto de vista estadístico en los recuentos absolutos de neutrófilos con relación al grupo de control no tratado a partir de 5 horas después de la dosis. Los recuentos absolutos de neutrófilos alcanzaron su punto máximo 36 horas después de la administración de la dosis y permanecieron elevados hasta 12 días después de la dosis.

EFFECTIVIDAD: La efectividad de Imrestor para reducir la incidencia de mastitis clínica se demostró en un estudio de campo multicéntrico sobre infección natural realizado en cuatro centros en EE. UU. y uno en Francia. Se inscribió un total de 801 vacas y vaquillas lecheras comerciales, periparturientas y saludables, y se trataron con Imrestor o solución salina mediante inyección por vía subcutánea en el cuello cuando se identificaba que estaban aproximadamente a 7 días de la fecha estimada de parto (Día -7) y nuevamente dentro de las 24 horas después del parto (Día 0). En cada ordeño se evaluó cada cuartil de cada animal inscrito desde el Día 3 hasta el 30 para monitorear el desarrollo de mastitis clínica.

Los animales que desarrollaron mastitis clínica (usando las evaluaciones de los cuartiles salud, calidad de la leche y Prueba de Mastitis de California [California Mastitis Test, CMT]) hasta el Día 30 se clasificaron como fracasos del tratamiento. La administración de Imrestor produjo una diferencia significativa desde el punto de vista estadístico ($p = 0.025$) en la incidencia de mastitis clínica (tasa de fracaso del tratamiento) en los cinco centros con una diferencia a favor del grupo tratado con Imrestor (tasa de fracaso: 60/331 = 18.13 %) en comparación con el grupo tratado con solución salina (tasa de fracaso: 85/338 = 25.15 %).

SEGURIDAD ANIMAL OBJETIVO:

Margen de seguridad: En el primer estudio, se asignaron cuarenta vacas Jersey primíparas y múltiparas a uno de cuatro tratamientos: control con solución salina y 1, 2 o 3 veces la dosis prevista de Imrestor administrada los Días -7 y -3 antes de la fecha prevista de parto y dentro de las 24 horas después del parto. Las vacas y vaquillas se monitorearon a diario hasta 4 días después del parto. Los terneros se monitorearon diariamente durante 14 días después del parto. Las mediciones de las vacas incluyeron peso corporal, consumo de alimentos, producción de leche, recuentos de células somáticas, exámenes físicos y patología clínica. Se llevó a cabo una autopsia completa en cada animal adulto. Las mediciones de los terneros incluyeron exámenes físicos, peso corporal y hematología. Hubo hallazgos no relacionados con el artículo de prueba asociados con observaciones clínicas anormales, consumo de alimentos, producción de leche, exámenes físicos o análisis de orina en animales adultos. Se observó una neutrofilia madura en todos los animales tratados, independientemente del grupo de dosis. Esto se consideró como un cambio relacionado con el artículo de prueba y congruente con el mecanismo de acción de Imrestor. No se observaron cambios hematológicos relacionados con el artículo de prueba en los terneros. Se documentaron observaciones de mastitis, metritis y úlceras abomasales, con más animales en los grupos tratados afectados, en comparación con los grupos de control. En la necropsia se hallaron dos animales (uno de cada grupo de 1 vez y 3 veces) que tenían perforadas las úlceras abomasales.

En un segundo estudio se evaluó el margen de seguridad de pegbovigrastim en vacas lecheras Holstein múltiparas. Se asignaron cuarenta y cinco vacas lecheras Holstein múltiparas a uno de cinco tratamientos: control con solución salina y 1, 2, 2.5 y 3 veces la dosis recomendada de una jeringa de pegbovigrastim administrada por vía subcutánea el Día -7 relativo a la fecha prevista de parto y dentro de las 24 horas siguientes al parto. Se monitorearon las vacas a diario hasta 14 días después del parto. Las mediciones incluyeron peso corporal, consumo de alimentos, producción de leche, recuentos de células somáticas, exámenes físicos y patología clínica, incluido el recuento de reticulocitos y la prueba de sangre oculta en heces. Se llevó a cabo una autopsia en cada vaca que se centró en el tracto gastrointestinal, el útero y el tejido mamario. No se evaluaron los terneros en este estudio. Hubo hallazgos no relacionados con el artículo de prueba asociados con observaciones clínicas anormales, consumo de alimentos, producción de leche o exámenes físicos. Se observó una neutrofilia madura en todos los animales tratados que fue congruente con el mecanismo de acción de Imrestor y fue similar a lo que se observó en el primer margen del estudio de seguridad. Los animales tratados tenían una mayor cantidad de erosiones gastrointestinales leves y áreas pequeñas de mucosa enrojecida o más delgada en varias porciones del tracto gastrointestinal, en comparación con los animales de control. En la necropsia no se observaron úlceras abomasales.

A partir de estos estudios, se concluyó que las úlceras o erosiones abomasales podrían estar relacionadas con el artículo de prueba. Sin embargo, debido a la falta de signos clínicos asociados con esta patología gastrointestinal junto con la naturaleza leve de las erosiones en el segundo estudio, se concluyó que estos hallazgos no eran clínicamente relevantes.

Seguridad en el lugar de la inyección: Se evaluó la seguridad en el lugar de la inyección luego de la inyección de Imrestor en vacas lecheras periparturientas saludables.

Los resultados del estudio de tolerancia en el lugar de la inyección mostraron que las inyecciones subcutáneas de pegbovigrastim administradas 14 días antes del sacrificio en 6 vacas no provocaron lesiones macroscópicas y no requerirán el recorte de la res muerta en el momento del sacrificio. Además, las inyecciones subcutáneas de pegbovigrastim administradas aproximadamente 12 horas antes del sacrificio en 6 vacas provocaron reacciones agudas mínimas en el tejido local, por lo general caracterizadas por edema y hemorragia focal, y se podrían eliminar junto con el cuero en el momento del sacrificio sin provocar ningún recorte de la res muerta.

Seguridad para la reproducción: También se evaluó la seguridad para la reproducción en los animales que estaban en el estudio de efectividad. Este estudio incluyó 801 animales: 401 animales de control y 400 animales tratados. Las variables que se midieron incluyeron observaciones de salud diarias en vacas y terneros, mortalidad, duración de la gestación, porcentaje de nacimientos vivos y tasas de concepción con el primer servicio después del tratamiento. No hubo diferencias significativas desde el punto de vista estadístico entre los animales tratados y los animales de control para estas variables reproductivas.

INFORMACIÓN SOBRE ALMACENAMIENTO: Almacene refrigerado (2° a 8 °C; 36° a 46 °F). NO CONGELAR. Evite la exposición prolongada a la luz solar. Se permiten desviaciones de hasta 24 horas a temperatura ambiente (15° a 30 °C; 59° a 86 °F) después de recibido.

ELIMINACIÓN: Deseche las jeringas en un recipiente resistente a las pérdidas y las punciones de acuerdo con las disposiciones federales, estatales y locales vigentes.

PRESENTACIÓN: Paquetes de 10, 50 o 100 jeringas de dosis única. Cada jeringa contiene 15 mg de pegbovigrastim.

NADA 141-392. Aprobado por la FDA.

Fabricado para Elanco Animal Health, una división de Eli Lilly and Company, Indianapolis, IN 46285.

Para obtener asistencia técnica o informar una sospecha de eventos adversos del fármaco, comuníquese con Elanco Animal Health al 1-800-428-4441.

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