

STELARA® (ustekinumab)

tested in two embryo-fetal development toxicity studies. Pregnant cynomolgus monkeys were administered ustekinumab at doses up to 45 mg/kg during the period of organogenesis either twice weekly via subcutaneous injections or weekly by intravenous injections. No significant adverse developmental effects were noted in either study. In an embryo-fetal development and pre- and postnatal development toxicity study, three groups of 20 pregnant cynomolgus monkeys were administered subcutaneous doses of 0, 22.5, or 45 mg/kg ustekinumab twice weekly from the beginning of organogenesis in cynomolgus monkeys to Day 33 after delivery. There were no treatment-related effects on mortality, clinical signs, body weight, food consumption, hematology, or serum biochemistry in dams. Fetal losses occurred in six control monkeys, six 22.5 mg/kg-treated monkeys, and five 45 mg/kg-treated monkeys. Neonatal deaths occurred in one 22.5 mg/kg-treated monkey and in one 45 mg/kg-treated monkey. No ustekinumab-related abnormalities were observed in the neonates from birth through six months of age in clinical signs, body weight, hematology, or serum biochemistry. There were no treatment-related effects on functional development until weaning, functional development after weaning, morphological development, immunological development, and gross and histopathological examinations of offsprings by the age of 6 months. **Nursing Mothers** Caution should be exercised when STELARA® is administered to a nursing woman. The unknown risks to the infant from gastrointestinal or systemic exposure to ustekinumab should be weighed against the known benefits of breast-feeding. Ustekinumab is excreted in the milk of lactating monkeys administered ustekinumab. IgG is excreted in human milk, so it is expected that STELARA® will be present in human milk. It is not known if ustekinumab is absorbed systemically after ingestion; however, published data suggest that antibodies in breast milk do not enter the neonatal and infant circulation in substantial amounts. **Pediatric Use** Safety and effectiveness of STELARA® in pediatric patients have not been evaluated. **Geriatric Use** Of the 2266 psoriasis subjects exposed to STELARA®, a total of 131 were 65 years or older, and 14 subjects were 75 years or older. Although no differences in safety or efficacy were observed between older and younger subjects, the number of subjects aged 65 and over is not sufficient to determine whether they respond differently from younger subjects. **OVERDOSAGE:** Single doses up to 4.5 mg/kg intravenously have been administered in clinical studies without dose-limiting toxicity. In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions or effects and appropriate symptomatic treatment be instituted immediately. **PATIENT COUNSELING INFORMATION:** Instruct patients to read the Medication Guide before starting STELARA® therapy and to reread the Medication Guide each time the prescription is renewed. **Infections** Inform patients that STELARA® may lower the ability of their immune system to fight infections. Instruct patients of the importance of communicating any history of infections to the doctor, and contacting their doctor if they develop any symptoms of infection. **Malignancies** Patients should be counseled about the risk of malignancies while receiving STELARA®. **Allergic Reactions** Advise patients to seek immediate medical attention if they experience any symptoms of serious allergic reactions.

Prefilled Syringe Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, License No. 1864 at Baxter Pharmaceutical Solutions, Bloomington, IN 47403

Vial Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, License No. 1864 at Cilag AG, Schaffhausen, Switzerland

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EL FUTURO DOCTOR

¿Por qué Salud Global?

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¿Por qué nos debería importar la salud de personas de otros lugares? La respuesta no es simple. Sin embargo, hay respuestas obvias.

Las enfermedades no respetan fronteras. Así, la pandemia causada por el virus de inmunodeficiencia humana (VIH) ya afecta a más de 34 millones de personas alrededor del mundo. La malaria afecta a 225 millones y se estima que cada 45 segundos muere un niño en África por su causa. Hechos como este nos llevan a pensar en dimensiones éticas y morales al responder a nuestra pregunta. Miles de niños mueren por malnutrición o por enfermedades que se pueden curar con medicinas que están al alcance de nuestras manos a diario. ¿Es esto justo? ¿Estamos preparados para aceptar estas muertes sin antes haber tomado las medidas para prevenirlas?

“Salud global” estudia estos problemas transnacionales y nace de la preocupación que existe por el continuo aumento de disparidades en el cuidado de la salud alrededor del mundo.

Como futuros profesionales de la salud, debemos entender esta problemática y considerarla seriamente en nuestra formación. Por ejemplo, las experiencias en ayuda humanitaria son muy enriquecedoras a nivel personal y profesional y, nos brindan competencia cultural, permitiéndonos interactuar con personas de diferentes razas, estratos sociales y religiones, así como promover humildad, flexibilidad, tolerancia y la habilidad de escuchar y entender a otros. Finalmente, desarrolla nuestra creatividad y las habilidades médicas en lugares donde los recursos son escasos.

Con esta motivación fundamos la iniciativa “UCC Global Health... On a Mission” en la Universidad Central del Caribe. Nuestro propósito es despertar el interés en el tema de Salud Global en profesionales de la salud y en aquellos interesados en trabajar por un mundo más saludable, mediante talleres de capacitación, actividades educativas, viajes misioneros e investigación a nivel internacional. **G**

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