

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 post-natal 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.

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

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# Haciendo la diferencia

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Desde pequeña, soñaba con ayudar a los demás con súper poderes como los de la mujer maravilla. Con el pasar del tiempo, aprendí que con fuerza de voluntad y un corazón dispuesto a servir, se puede hacer una gran diferencia. No se trata de cambiemos el mundo solos, sino de poner ese granito de arena que tiene un impacto restaurador en una persona.

Conocí a un ser muy especial trabajando voluntariamente en una ronda nocturna; él es adicto y deambulante. Me esmeré en darle la ayuda que él necesitaba para que permaneciera en un hogar de tratamiento, pero a pesar de los esfuerzos, volvió a recaer.

Entendí que la adicción es una enfermedad crónica y recurrente. Hoy por hoy, sigo tratando con el mismo empeño de ayudarlo a volver a salir de las calles y sé que con mis acciones no estoy cambiando el mundo, pero al menos sé que estoy contribuyendo a cambiar su mundo. Y eso hace toda la diferencia. **G**