

# Síndrome de muerte súbita en atletas

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## STELARA® (ustekinumab)

which may increase the risk of an allergic reaction to a dose of allergen immunotherapy. Therefore, caution should be exercised in patients receiving or who have received allergen immunotherapy, particularly for anaphylaxis.

**USE IN SPECIFIC POPULATIONS: Pregnancy** *Pregnancy Category B* There are no studies of STELARA® in pregnant women. STELARA® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. No teratogenic effects were observed in the developmental and reproductive toxicology studies performed in cynomolgus monkeys at doses up to 45 mg/kg ustekinumab, which is 45 times (based on mg/kg) the highest intended clinical dose in psoriasis patients (approximately 1 mg/kg based on administration of a 90 mg dose to a 90 kg psoriasis patient). Ustekinumab was 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 3117 psoriasis subjects exposed to STELARA®, a total of 183 were 65 years or older, and 21 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:** "See FDA-approved patient labeling (Medication Guide)." 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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El síndrome de muerte súbita en deportistas es más difundido que otras condiciones patológicas con mayor prevalencia. La razón es obvia: se presenta en personas jóvenes, conocidas por la población y que aparentan tener una salud perfecta. El síndrome es menos común en mujeres y su incidencia se incrementa con la edad. Por razones aún no aclaradas, suele presentarse con más frecuencia en los periodos de entrenamiento. Es más frecuente en atletas que utilizan o han utilizado esteroides anabólicos u otras formas de dopaje.

Por debajo de los 35 años de edad, las causas que más se citan en la literatura médica son:

1. La cardiomiopatía hipertrófica;
2. Las arterias coronarias aberrantes;
3. La aterosclerosis prematura;
4. La displasia ventricular derecha arritmogénica;
5. El síndrome de Marfan;
6. La hipertrofia ventricular izquierda idiopática;
7. El prolapso de la válvula mitral;
8. El síndrome de Wolff-Parkinson-White;
9. El síndrome QT prolongado;
10. La miocarditis de diferentes etiologías,
11. El vasoespasmó de una o más arterias coronarias;
12. La enfermedad de Kawasaki;
13. El trauma pectoral severo; y
14. El golpe de calor.

Sobre los 35 años de edad, las causas más frecuentes son:

1. La aterosclerosis coronaria;
2. La cardiomiopatía hipertrófica;
3. Las arterias coronarias aberrantes;
4. La displasia ventricular derecha;
5. El síndrome de Marfan;
6. La hipertrofia ventricular izquierda idiopática;
7. El prolapso de la válvula mitral;
8. El síndrome de Wolff-Parkinson-White;
9. El síndrome QT prolongado;
10. Las miocarditis de varias etiologías; y
11. El vasoespasmó de las arterias coronaria

El tratamiento es preventivo y requiere de un control médico especializado y adecuado. 