

TERIS Summary

TERIS Agent Number: 6800 Bibliographic Search Date: 12/2022
Agent Name: **REMDESIVIR**

Remdesivir is a nucleotide analog with broad-spectrum antiviral activity that is administered intravenously in the treatment of COVID-19 and other serious viral infections.

Magnitude of Teratogenic Risk to Child Born After Exposure During Gestation: UNDETERMINED

Quality and Quantity of Data on Which Risk Estimate is Based: VERY LIMITED

Comments: NONE

Summary of Teratology Studies:

MAJOR CONGENITAL ANOMALIES

No epidemiological studies of congenital anomalies among infants whose mothers were treated with remdesivir during pregnancy have been reported. Eleven women who were hospitalized with COVID-19 and received remdesivir during the second or third trimester of pregnancy delivered healthy infants in separate case reports (McCoy et al., 2020; Saroyo et al., 2021; Singh et al., 2022).

ADVERSE PREGNANCY AND NEONATAL OUTCOMES

No stillbirths or neonatal deaths were reported among 39 infants born to women with COVID-19 who were treated with remdesivir during pregnancy (Gutierrez et al., 2022). In the same study, no associations with composite adverse pregnancy and neonatal outcomes were reported among the group treated with remdesivir compared to 56 pregnant patients with moderate or severe COVID 19 who did not receive remdesivir treatment. No stillbirths or neonatal deaths were reported among 33 infants born to 64 women with severe or critical COVID-19 disease during the second or third trimester of pregnancy in one series (Pierce-Williams et al., 2020). Seventeen of the 64 women were treated with remdesivir.

In other case reports, two preterm infants (25 weeks and 29 weeks) were born to mothers with severe COVID-19 pneumonia who received several medications, including remdesivir, prior to delivery (Easterlin et al., 2020; Jacobson et al., 2021). Preterm delivery was attributed to maternal illness in both cases. A healthy full-term infant was born to a mother with severe COVID-19 pneumonia who received remdesivir in the third trimester (Dande et al., 2021).

Six pregnant women were given remdesivir in a randomized, controlled trial of four different medications designed to treat Ebola virus disease (Mulangu et al., 2019). No serious adverse neonatal events attributable to remdesivir were reported in this study.

ANIMAL TERATOLOGY STUDIES

Animal teratology studies of remdesivir conducted by the manufacturer have not been published in the peer-reviewed literature.

Selected References:

(Each paper is classified as a review [R], human case report [C], human epidemiological study [E], human clinical series [S], animal study [A], or other [O].)

Dande R, Qureshi A, Persaud K, Puri C, Zulfqar S, Awasthi S: Remdesivir in a pregnant patient with COVID-19 pneumonia. J Community Hosp Intern Med Perspect 11(1):103-106, 2021. [C]

Easterlin MC, De Beritto T, Yeh AM, Wertheimer FB, Ramanathan R: Extremely preterm infant born to a mother with severe COVID-19 pneumonia. J Investig Med High Impact Case Rep 8:1-5, 2020. [C]

Gutierrez R, Mendez-Figueroa H, Biebighauser JG, Bhalwal A, Pineles BL, Chauhan SP: Remdesivir use in pregnancy during the SARS-CoV-2 pandemic. J Matern Fetal Neonatal Med 35(25):9445-9451, 2022. [E]

Jacobson J, Antony K, Beninati M, Alward W, Hoppe KK: Use of dexamethasone, remdesivir, convalescent plasma and prone positioning in the treatment of severe COVID-19 infection in pregnancy: a case report. *Case Rep Womens Health* 29:e00273, 2021. [C]

McCoy JA, Short WR, Srinivas SK, Levine LD, Hirshberg A. Compassionate use of remdesivir for treatment of severe coronavirus disease 2019 in pregnant women at a United States academic center. *Am J Obstet Gynecol MFM* 2(3):100164. 2020. [S]

Mulangu S, Dodd LE, Davey RT Jr, Tshiani Mbaya O, Proschan M, Mukadi D, Lusakibanza Manzo M, Nzolo D, Tshomba Oloma A, Ibanda A, Ali R, Coulibaly S, Levine AC, Grais R, Diaz J, Lane HC, Muyembe-Tamfum J-J; PALM Writing Group: A randomized, controlled trial of ebola virus disease therapeutics. *N Engl J Med* 381(24):2293-2303, 2019. [E]

Pierce-Williams RAM, Burd J, Felder L, Khoury R, Bernstein PS, Avila K, Penfield CA, Roman AS, DeBolt CA, Stone JL, Bianco A, Kern-Goldberger AR, Hirshberg A, Srinivas SK, Jayakumaran JS, Brandt JS, Anastasio H, Birsner M, O'Brien DS, Sedev HM, Dolin CD, Schnettler WT, Suhag A, Ahluwalia S, Navathe RS, Khalifeh A, Anderson K, Berghella V: Clinical course of severe and critical COVID-19 in hospitalized pregnancies: a United States cohort study. *Am J Obstet Gynecol MFM* 2(3):100134, 2020. [S]

Saroyo YB, Rumondang A, Febriana IS, Harzif AK, Irwinda R: Remdesivir treatment for COVID 19 in pregnant patients with moderate to severe symptoms: serial case report. *Infect Dis Rep* 13(2):437-443, 2021. [C]

Singh R, Agrawal A, Asnani M: Remdesivir in pregnant patients with novel coronavirus disease 2019: case series. *J Obstet Gynaecol India* 72(Suppl 2):369-371, 2022. [C]

COVID-19 PREGNANCY STUDY

A pregnancy study has been established for women infected with, or exposed to, the SARS-CoV-2 coronavirus (which causes COVID-19) during pregnancy.

Healthcare providers are encouraged to enroll such patients, whether or not they have been treated with remdesivir, in the MotherToBaby Pregnancy Study by calling 877-311-8972 (<https://mothertobaby.org/join-a-study-form/>).