

TERIS Summary

TERIS Agent Number: 6866
Agent Name: **NIRMATRELVIR / RITONAVIR**

Bibliographic Search Date: 12/2022

Nirmatrelvir/Ritonavir is a combination of two protease inhibitor antiviral drugs that is administered orally in the treatment of COVID-19.

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 born to women who were treated with nirmatrelvir and ritonavir during pregnancy have been reported.

ADVERSE PREGNANCY AND NEONATAL OUTCOMES

Among 25 women who were treated with nirmatrelvir and ritonavir for COVID-19 in the second half of pregnancy, only two (8%) delivered low birth weight babies and 12 (48%) underwent caesarean delivery; nine of these were scheduled (Garneau et al., 2022). No other information on neonatal outcomes was reported in this case-series. In another case-series of seven pregnant women who received nirmatrelvir and ritonavir at some point during their pregnancy, no adverse fetal effects were found, but four pregnancies remained ongoing at the time of publication (Loza et al., 2022).

ANIMAL TERATOLOGY STUDIES

Animal teratology studies of nirmatrelvir and ritonavir as a combination drug conducted by the manufacturer have not been published in the peer-reviewed literature.

PLEASE SEE AGENT SUMMARY ON RITONAVIR FOR INFORMATION ON A RELATED DRUG THAT HAS BEEN STUDIED.

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].)

Garneau WM, Jones-Beatty K, Ufua MO, Mostafa HH, Klein SL, Burd I, Gebo KA: Analysis of clinical outcomes of pregnant patients treated with nirmatrelvir and ritonavir for acute SARS-CoV-2 infection. *JAMA Netw Open* 5(11):e2244141, 2022. [S]

Loza A, Farias R, Gavin N, Wagner R, Hammer E, Shields A: Short-term Pregnancy outcomes after nirmatrelvir-ritonavir treatment for mild-to-moderate coronavirus disease 2019 (COVID-19). *Obstet Gynecol* 140(3):447-449, 2022. [S]