# Breastfeeding and Medication

## Clinically extremely vulnerable, Covid 19 infection and breastfeeding

The clinically extremely vulnerable (CEV) are at particular risk of being admitted to hospital with symptoms of covid 19 and have been offered medication should they have a positive PCR. https://www.gov.uk/government/publications/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19. This factsheet provides the available information on the drugs for breastfeeding mothers. There are currently no published studies on any of them and this is not a recommendation but a digest of available data to discuss with clinicians.

### Breastfeeding transfer of Covid 19

There is currently no evidence to suggest that the COVID-19 virus can transfer into breast milk. There is evidence that maternal antibodies generated in response to COVID-19 virus do pass into breast milk. The long-term well-established benefits of breastfeeding are highly likely to outweigh any potential risks of transmission of the virus through breastmilk (RCOG, Walker, UK Government, NHS & WHO June 2020). Breastmilk is the best source of nutrition for infants and provides protection against many illnesses.

### Precautions against passing on Covid 19 to your baby

If you have confirmed COVID-19 or have symptoms you should take all possible precautions to avoid spreading the virus to your baby, including washing your hands for 20 seconds before touching your baby, sterilising any breast pump or bottles and washing your hands after changing nappies. Consider wearing a face covering or fluid-resistant face mask while feeding or caring for the baby. Babies should not wear a face covering or mask as they may risk suffocation.

If you are too unwell to breastfeed you may still be able to express milk for your baby. Pump equipment and bottles need to be sterilised according to manufacturer's instructions.


January 2022 *The information on this sheet is based upon my professional experience as a pharmacist with a specialised interest in the safety of drugs in breastmilk, supported by evidence from expert sources. However, I cannot take responsibility for the prescription of medication which remains with the healthcare professionals involved. I am happy to discuss the evidence by email wendy@breastfeeding-and-medication.co.uk*

## Clinically Extremely Vulnerable (CEV)

The government published additional guidance on the treatment of the CEV population who have impaired immune responsehttps://www.gov.uk/government/publications/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19 in December 2021.

Following a positive PCR test, most of these patients will be contacted by a local NHS coronavirus medicines team to assess whether they might benefit from treatments. Some of this population will be breastfeeding.

2 types of COVID-19 treatment are available sotrovimab (Xevudy) and molnupiravir (Lagevrio). There is no experience to date of using these drugs during breastfeeding and there is currently limited information.

The UK government currently recommends sotrovimab as a third-line treatment for patients who test positive for COVID-19 following their admission to hospital, but first-line for eligible non-hospitalised patients.

**Sotrovimab (Xevudy®)**

- Sotrovimab is a monoclonal antibody directed against the SARS-CoV-2 virus that causes COVID-19. No information is available on the clinical use of sotrovimab during breastfeeding. Because sotrovimab is a large protein molecule, the amount in milk is likely to be very low. It is also likely to be partially destroyed in the infant's gastrointestinal tract and absorption by the infant is probably minimal. Until more data become available, sotrovimab should be used with caution during breastfeeding, especially while nursing a new-born or preterm infant. (LactMed database https://www.ncbi.nlm.nih.gov/books/NBK571318/)
- There is no published evidence for use in breastfeeding. However, **negligible levels are anticipated in milk, and very limited absorption from the infant's gastro-intestinal tract expected due to the drug's properties.** Therefore, infant side effects are unlikely. Theoretically, absorption may be increased slightly in the neonatal period due to increased gastrointestinal permeability. Monitor the infant for adequate feeding and hypersensitivity reactions ( https://www.sps.nhs.uk/medicines/Sotrovimab/)
- It is not known whether the ingredients of Xevudy can pass into breast milk. Tell your healthcare professional if you are breast-feeding before you receive Xevudy. (Patient Information Leaflet https://www.gov.uk/government/publications/regulatory-approval-of-xevudy-sotrovimab/patient-information-leaflet-for-xevudy)

However, in April 2022 the US Food and Drug Administration (FDA) revoked its authorisation of sotrovimab for treating COVID-19, owing to the increasing proportion of COVID-19 cases caused by the Omicron BA.2 sub-variant. In its decision, the FDA said clinical pharmacology data for sotrovimab suggested that the authorised dose of the drug was unlikely to be effective against the SARS-CoV-2 Omicron BA.2 variant. The Omicron BA.2 variant has been the dominant COVID-19 variant in the UK since the middle of February 2022, according to an update from the UK Health Security Agency (UKHSA) published on 25 March 2022, which added that BA.2 was estimated to account for approximately 93.7% of COVID-19 cases in England and continued to demonstrate a "substantial growth advantage". Prof Penny Ward, visiting professor in pharmaceutical medicine at King's College

London commented that "Given the time taken to sequence, it is unlikely to be possible to sequence to confirm which strain the patient is affected by and only then administer the product to individuals affected by a sensitive strain, so I personally think it is inappropriate to continue to use sotrovimab at this point," she added (https://pharmaceutical-journal.com/article/news/thousands-receive-covid-19-monoclonal-antibody-despite-efficacy-concerns?fbclid=IwAR3JFlfOPPn6IbG9lqtNmuytqTmNy98Cj97KcIeDm3-kuzXTqZmoWpPzFmw)
In the UK Dr Laura Squire commented that "The MHRA is carefully reviewing emerging data for sotrovimab, including in response to new variants, and we continue to seek advice from the independent scientific advisory body, the Commission on Human Medicines, to determine if its benefit risk balance remains favourable," she added. "As part of this ongoing review, we are in contact with the FDA and are looking closely at the data supporting their decision. Patient safety is our top priority."

**Molnupiravir (Lagevrio®)**

- If you are breast-feeding or are planning to breastfeed, tell your doctor before taking this medicine**. Breast-feeding is not recommended during treatment and for 4 days after the last dose of Lagevrio**. This is because it is not known if Lagevrio gets into breast milk and will be passed to the baby. (Patient Information Leaflet https://www.medicines.org.uk/emc/product/13044/smpc#PREGNANCY)
- There is no published evidence relating to use in breastfeeding is available, but it is likely to pass into breast milk. Molnupiravir is administered as a short course and has a short half-life, so risk of accumulation in the infant is low. The manufacturer's state that breastfeeding is not recommended during treatment and for 4 days after the last dose. This is to ensure infant exposure via breast milk is completely avoided. Long term, high dose studies in infant animals showed toxicity in growing cartilage. Clinical significance of short-term exposure during breastfeeding is unknown. If exposed via breast milk, as a precaution, monitor infant for poor feeding, adequate weight gain, vomiting and diarrhoea. Individuals of childbearing potential, including breastfeeding women, should use effective contraception for the duration of treatment and for 4 days after the last dose (https://www.sps.nhs.uk/medicines/molnupiravir/

**Paxlovid® (**Paxlovid PF-07321332 and ritonavir)

On December 31, 2021, the MHRA licensed Paxlovid in the treatment of covid-19 to keep patients out of hospital and prevent serious illness. https://www.gov.uk/government/news/oral-covid-19-antiviral-paxlovid-approved-by-uk-regulator Dec 31 2021

Based on the clinical trial data, Paxlovid is most effective when taken during the early stages of infection and so the MHRA recommends its use as soon as possible and within five days of the start of symptoms. It has been authorised for use in people aged 18 and above who have mild to moderate COVID-19 infection and at least one risk factor for developing severe illness. Such risk factors include obesity, older age (>60 years), diabetes mellitus, or heart disease.

Paxlovid consists of 2 medicines: nirmatrelvir and ritonavir.

Take 2 pink tablets of nirmatrelvir with 1 white tablet of ritonavir by mouth 2 times each day (in the morning and in the evening) for 5 days. For each dose, take all 3 tablets at the same time.

• Swallow the tablets whole. Do not chew, break, or crush the tablets.

• Take PAXLOVID with or without food. (FDA fact sheet for patients, parents, and caregivers emergency use authorization of paxlovid for coronavirus disease 2019 (covid-19) https://www.fda.gov/media/155051/download)

Paxlovid is not recommended during pregnancy and in people who can become pregnant and who are not using contraception. Breastfeeding should be interrupted during treatment. These recommendations are because laboratory studies in animals suggest that high doses of Paxlovid may impact the growth of the foetus. If you are breast-feeding or are planning to breastfeed, tell your healthcare provider before taking this medicine. **Breast-feeding is not recommended during treatment and for 7 days after the last dose of Paxlovid**. This is because it is not known if Paxlovid gets into breast milk and will be passed to the baby.
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https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1044404/Paxlovid_PIL.pdf

**Remdesevir (Veklury®)**

Information from one patient indicates that milk levels of remdesivir and its active metabolite are very low in milk. Remdesivir is poorly absorbed orally, and the metabolite is only partially absorbed orally, so infants are not likely to absorb clinically important amounts of the drug from breastmilk. Newborn infants have received remdesivir therapy with no serious adverse drug reactions.[1-3] Given this limited information, it does not appear that mothers receiving remdesivir need to avoid nursing, but until more data are available, remdesivir should be used with careful infant monitoring during breastfeeding. The most common adverse effects reported after intravenous infusion include elevated aminotransferase and bilirubin levels and other liver enzyme elevations, diarrhoea, rash, renal impairment and hypotension (LatMed https://www.ncbi.nlm.nih.gov/books/NBK556881/).

In the published literature there is a study of one women who developed COVID-19 two days after giving birth. She was given 200mg remdesivir on the first day and then 100mg daily for a further 4 days (Wada YS, Saito J, Hashii Y, et al. Remdesivir and human milk: A case study. J Hum Lact. 2022). The authors estimated that the relative infant doses of remdesivir and its metabolite were 0.007% and 1.6%, well below the 10% level seen as compatible with breastfeeding. The half life of the metabolite was estimated to be 9.3 hours. The baby was not breastfed during treatment as this was not permitted in Japan despite the WHO recommendation. On discharge she resumed breastfeeding and continued for 6 months although with supplementation. The conclusion of the authors was that "Given the low amount of Remdesivir in the participant's milk, the inclusion of antibodies to Severe Acute Respiratory Syndrome Coronavirus 2, which can be expected to protect the infant from infection, and various other benefits of human milk, suggests that breastfeeding is safe during treatment with Remdesivir."

**Evusheld® (tixagevimab co-packaged with cilgavimab)**

Although Evusheld, an antibody which has shown both preventative and therapeutic activity against COVID-19 and is also still effective vs the Omicron variants, is approved for use to prevent COVID-19 among immunocompromised patients unable to respond to vaccination by the MHRA it seems currently unavailable. Evusheld is given as two injections of 150 mg tixagevimab and 150 mg cilgavimab at different sites, preferably in the gluteal muscles. There are no data on the excretion of tixagevimab and cilgavimab in human milk (https://www.gov.uk/government/publications/regulatory-approval-of-evusheld-tixagevimabcilgavimab/summary-of-product-characteristics-for-evusheld)

## References


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