Gohibic™ (vilobelimab) Injection 200 mg/20 mL

# GOHIBIC FORMULARY KIT

## FDA-AUTHORIZED FOR EMERGENCY USE

**The U.S. Food and Drug Administration has issued an EUA for the emergency use of GOHIBIC for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO). However, GOHIBIC is not FDA-approved for this use.[1]**

GOHIBIC has not been approved but has been authorized for emergency use by FDA under an EUA, for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO).

The emergency use of GOHIBIC is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization revoked sooner.



INFLA-00001 12/2023

inflaRx

Gohibic (vilobelimab) Injection 200 mg/20 mL

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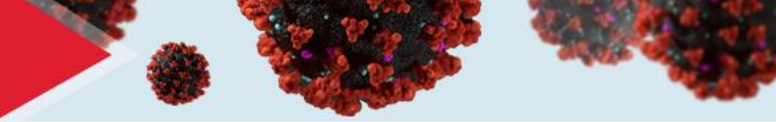


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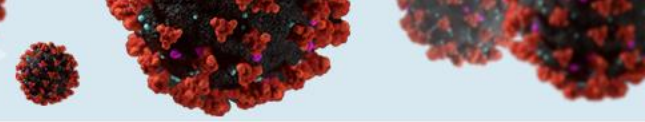
# EMERGENCY USE AUTHORIZATION (EUA)



**The U.S. Food and Drug Administration has issued an EUA for the emergency use of GOHIBIC (vilobelimab) for the treatment of coronavirus disease 19 (COVID-19) in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation (IMV), or extracorporeal membrane oxygenation (ECMO). However, GOHIBIC is not FDA-approved for this use.**

**GOHIBIC has not been approved but has been authorized for emergency use by FDA under an EUA, for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV or ECMO.**

**The emergency use of GOHIBIC is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization revoked sooner.**

Please visit GOHIBIC.com for more information

Gohibic (vilobelimab) Injection 200 mg/20 mL

# CRITERIA FOR ISSUANCE OF EUA

**Per the FDA 'Emergency Use Authorization (EUA) for Vilobelimab (IFX-1)**

**Center for Drug Evaluation and Research (CDER) Review':[1]**

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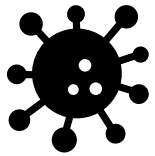
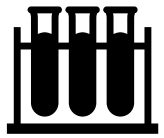
"SARS-CoV-2 can cause **a serious or life-threatening disease** or condition, including **severe respiratory illness**, to humans infected by this virus"



"Based on the totality of scientific evidence available to FDA, it is reasonable to believe that GOHIBIC may be **effective for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV, or ECMO**…and the known and potential benefits of GOHIBIC outweigh the known and potential risks of such product"



"There is **no adequate, approved, and available alternative to the emergency use of GOHIBIC** for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV, or ECMO"

Please visit GOHIBIC.com for more information

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References [1]Emergency Use Authorization (EUA) for Vilobelimab (IFX-1) Center for Drug Evaluation and Research (CDER) Review, Pg 9-10 Section 2.2, April 2023.

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# PRODUCT INFORMATION

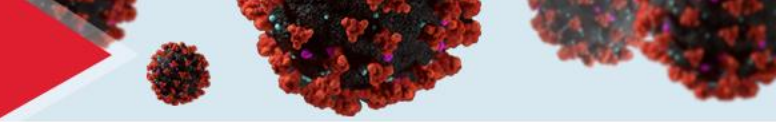
- **The FDA has issued an EUA for the emergency use of GOHIBIC for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV or ECMO.**
- **GOHIBIC has not been approved for this indication.**

| | |
|---|---|
| **PHARMACODYNAMICS** | • In the GOHIBIC group, the median plasma concentrations of C5a decreased from 118.29 ng/mL at baseline to 14.53 ng/mL by Day 8 and remained at approximately this level up to Day 30 after the initiation of treatment.<br>• In the placebo group, the median concentrations of C5a remained approximately at the elevated baseline level (104.62 ng/mL) during the study up to Day 30 after the initiation of the treatment.<br>The direct clinical relevance of C5a plasma concentration reduction is unclear. |
| **PHARMACOKINETICS** | Elimination half-life:<br>• 95 hours in healthy subjects<br>Pre-dose plasma samples were collected in patients with severe COVID-19 pneumonia requiring IMV or ECMO. Following intravenous infusion of GOHIBIC 800 mg on Days 1, 2, and 4, the pre-dose geometric mean (geometric CV%) plasma concentration of GOHIBIC on Day 8 was 137.9 µg/mL (51%). No drug interaction studies have been conducted with GOHIBIC. |
| **TREATMENT SETTING** | GOHIBIC is for use in a hospital intensive care unit (ICU) setting within 48 hours of receiving IMV or ECMO. |
| **HOW SUPPLIED** | GOHIBIC is provided in single-dose vials at a concentration of 200 mg/20 mL (10 mg/mL). Each mL also contains dibasic sodium phosphate (0.97 mg), monobasic sodium phosphate (0.4 mg), polysorbate 80 (0.5 mg), sodium chloride (8.8 mg), and Water for Injection. The pH is 6.6 – 7.3.<br>Each carton of GOHIBIC, measuring 3 3/4² x 3 3/4² x 2 1/2², contains 4 vials representing a single dose of 800 mg. |

Please visit GOHIBIC.com for more information

**References:**GOHIBIC Fact Sheet for Healthcare Providers, InflaRx Inc. April 2023.

# PRODUCT INFORMATION



| | |
|---|---|
| **PREPARATION** | Using aseptic technique, dilute and prepare GOHIBIC for intravenous infusion before administration.<br>• For the recommended dose of 800 mg GOHIBIC, dilute 80 mL of GOHIBIC in 170 mL of 0.9% Sodium Chloride at room temperature.<br>• Use a 250 mL infusion bag of 0.9% Sodium Chloride solution USP and the follow steps below:<br>  • Withdraw 80 mL of 0.9% Sodium Chloride solution USP from the infusion bag and discard.<br>  • Withdraw the 80 mL of GOHIBIC from the vials and add slowly to the 0.9% Sodium Chloride solution USP infusion bag to a final concentration of 3.2 mg/mL.<br>To mix the solution, gently invert the bag to avoid foaming. |
| **ADMINISTRATION** | • Visually inspect for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if discoloration or visible particles are present.<br>• Administer diluted GOHIBIC via intravenous infusion over 30 - 60 minutes.<br>• Avoid concomitant administration of GOHIBIC with other drugs in the same intravenous line. |
| **STORAGE** | • Store unopened vials refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze. Do not shake.<br>• Diluted GOHIBIC must be used within 4 hours when stored at room temperature 20°C to 25°C (68°F to 77°F).<br>• Diluted GOHIBIC stored under refrigeration at 2°C to 8°C (36°F to 46°F) must be used within 24 hours.<br>• After removal of diluted GOHIBIC from the refrigerator stored at 2°C to 8°C (36°F to 46°F), it must be left to acclimatize to room temperature prior to administration. |
| **SHELF LIFE** | Please refer to the product vial or carton for expiration date. |

Please visit GOHIBIC.com for more information

**References:** GOHIBIC Fact Sheet for Healthcare Providers, InflaRx Inc. April 2023.

# PRODUCT INFORMATION

| | |
|---|---|
| **NDC* of CARTON CONTAINING 4 VIALs[1]** | **83000-0110-04*** |
| **WEBSITE** | GOHIBIC.com |
| **FOR ADDITIONAL QUESTIONS[2]** | **To report possible adverse events or product complaints, call InflaRx GmbH at the toll-free number 1-888-254-0602 and choose option 1 or 2, respectively.**<br>**To request medical information, call the toll-free number 1-888-254-0602 and choose option 3, or email medical.affairs@inflarx.de.** |

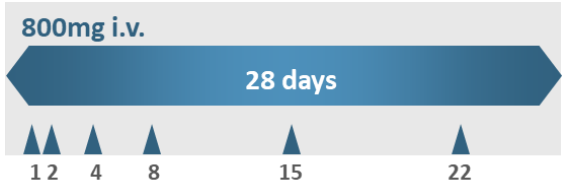
*NDC=National Drug Code; NDCs are listed as 11-digit codes for hospital institutional ordering and billing.

**200 mg/20 mL vilobelimab = 1 vial x 4 = 800 mg/80 mL = 1 dose**

Please visit GOHIBIC.com for more information

References:[1] Daiily Med, Search Gohibic or vilobelimab; [2]GOHIBIC Fact Sheet for Healthcare Providers, InflaRx Inc. April 2023.[5]

# DOSING AND ADMINISTRATION

| | |
|---|---|
| **DOSINGS AND ADMINISTRATION** | • **Recommended dosage of GOHIBIC is 800 mg administered by intravenous infusion after dilution, for a maximum of 6 (six) doses over the treatment period as described below. (2.1)**<br>• **Start treatment within 48 hours of intubation (Day 1), followed by administration of GOHIBIC on Days 2, 4, 8, 15 and 22 as long as the patient is still hospitalized (even if discharged from ICU). (2.1)**<br>  |
| **PREPARATION AND ADMINISTRATION** | **PREPARATION:**<br>• Using aseptic technique, dilute and prepare GOHIBIC for intravenous infusion before administration.<br>• For the recommended dose of 800 mg GOHIBIC, dilute 80 mL of GOHIBIC in 170 mL of 0.9% Sodium Chloride at room temperature.<br>• Use a 250 mL infusion bag of 0.9% Sodium Chloride solution USP and the follow steps below:<br>• Withdraw 80 mL of 0.9% Sodium Chloride solution USP from the infusion bag and discard.<br>• Withdraw the 80 mL of GOHIBIC from the vials and add slowly to the 0.9% Sodium Chloride solution USP infusion bag to a final concentration of 3.2 mg/mL.<br>• To mix the solution, gently invert the bag to avoid foaming. |

Please visit GOHIBIC.com for more information

**References:** GOHIBIC Fact Sheet for Healthcare Providers, InflaRx Inc. April 2023.

# DOSING AND ADMINISTRATION (continued)

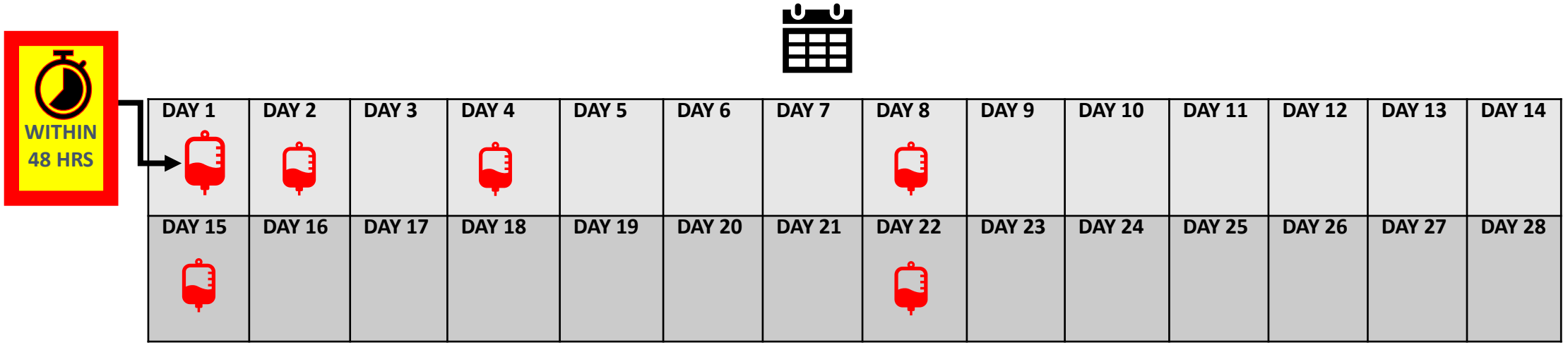
| | |
|---|---|
| **PREPARATION AND ADMINISTRATION continued** | **STORAGE OF DILUTED GOHIBIC:**<br>• **Diluted GOHIBIC must be used within 4 hours when stored at room temperature 20°C to 25°C (68°F to 77°F)**<br>• **Diluted GOHIBIC stored under refrigeration at 2°C to 8°C (36°F to 46°F) must be used within 24 hours.**<br>• **After removal of diluted GOHIBIC from the refrigerator stored at 2°C to 8°C (36°F to 46°F), it must be left to acclimatize to room temperature prior to administration.**<br>**ADMINISTRATION:**<br>• **Visually inspect for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if discoloration or visible particles are present.**<br>• **Administer diluted GOHIBIC via intravenous infusion over 30 - 60 minutes.**<br>**Avoid concomitant administration of GOHIBIC with other drugs in the same intravenous line.** |
| **DOSING AND STRENGTHS** | Injection: 200 mg/20 mL (10 mg/mL) in single-dose vials for further dilution. (3) |

Please visit GOHIBIC.com for more information

**References:** GOHIBIC Fact Sheet for Healthcare Providers, InflaRx Inc. April 2023.

# DOSING AND ADMINISTRATION (continued)

**Start treatment within 48 hours of intubation** (Day 1), followed by administration of GOHIBIC on Days 2, 4, 8, 15 and 22 as long as the patient is still hospitalized (even if discharged from ICU).




- Recommended dosage of GOHIBIC is 800 mg administered by intravenous infusion after dilution, **for a maximum of 6 (six) doses over the treatment period.**

Please visit GOHIBIC.com for more information

**References:** GOHIBIC Fact Sheet for Healthcare Providers, InflaRx Inc. April 2023.

# A CRITICAL UNMET NEED REMAINS IN SEVERE COVID-19

- Despite the availability of vaccines and the utilization of antivirals to help prevent COVID-19 hospitalizations, **there are still patients who become critically ill and progress to a septic disease state, develop acute respiratory distress syndrome (ARDS) and require invasive mechanical ventilation of ECMO.**[1]

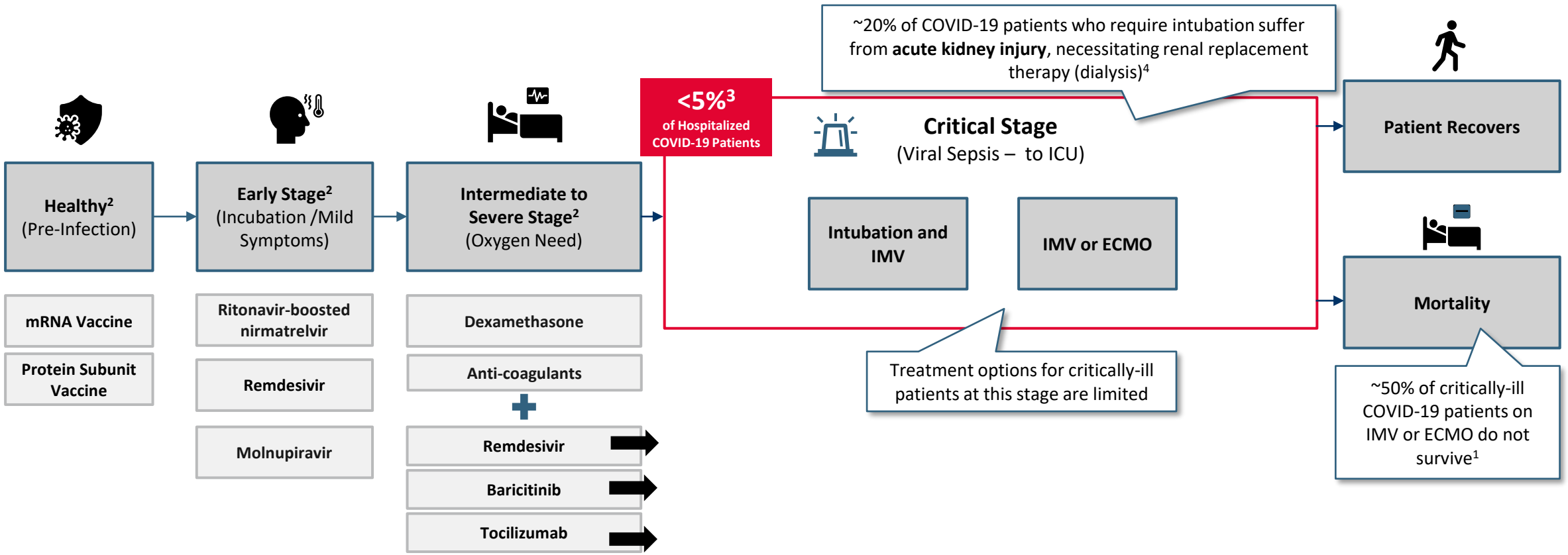
- The FDA cites the **mortality rate in patients who develop respiratory failure and require IMV or ECMO remains high**, ranging from **64–85% in certain age groups and 54 to 100%, respectively.**[1,2]


Please visit GOHIBIC.com for more information

**References**: [1]Nicholson, CJ, L Wooster, HH Sigurslid, RH Li, W Jiang, W Tian, CL Lino Cardenas, and R Malhotra, 2021, Estimating risk of mechanical ventilation and in-hospital mortality among adult COVID-19 patients admitted to Mass General Brigham: The VICE and DICE scores, EClinicalMedicine, 33:100765. [2]Emergency Use Authorization (EUA) for Vilobelimab (IFX-1) Center for Drug Evaluation and Research (CDER) Review; Page 22-30. April 2023. Gohibic Summary Review (fda.gov) . Emphasis added in **bold.**

# The Unmet Need: IMV and ECMO Patients have ≥50%[1] Mortality Rate

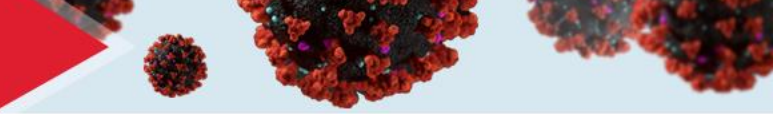
## Disease Progression and Treatment of COVID-19




Please visit GOHIBIC.com for more information

**References**: [1]Otto M, et al. Intern Med J. 2023;53(3):330-338; Havers FP, et al. JAMA Intern Med. 2022;182(10):1071-1081; Virk S, et al. Viruses. 2023;15:922. [2]U.S. Department of Health and Human Services, *Hospitalized adults: Therapeutic management*; Federal Drug Agency, *Coronavirus (COVID-19) Drugs.* [3] Centers for Disease Control and Prevention. COVID data tracker. Posted August 24, 2023. Accessed August 29, 2023. https://covid.cdc.gov/covid-data-tracker/#maps_percent-icu-beds-county. [4]Palevsky, P et al. UptoDate, *COVID-19: Issues related to acute kidney injury, glomerular disease, and hypertension*, (2023).

# IMMUNOMODULATOR TREATMENTS



| Drug(s) Evaluated | Study | Study Design | Total Patients | TOTAL IMV/ECMO Patients | Absolute 28-Day Mortality Difference, Total Patients Drug vs Placebo (%) | Absolute 28-Day Mortality Difference, IMV/ECMO Patients Drug vs Placebo (%) |
|---|---|---|---|---|---|---|
| BARI vs usual care | RECOVERY[1] | 1:1 randomized, controlled, open-label, platform trial | 8156 | 251 | 12 vs 14‡ | 29 vs 38† |
| BARI+REM+SoC vs PLC+REM+SoC | ACCT-2[2] | 1:1 randomized, double-blind, placebo controlled | 1033 | 111 | 5 vs 8 | 22 vs 21 |
| BARI+SoC vs PLC+SoC | COV-BARRIER[3] | 1:1 randomized, double-blind, placebo controlled | 1525 | Excluded | 8 vs 13‡ | Not Applicable |
| BARI+SoC vs PLC+SoC | Critically Ill COV-BARRIER[4] | 1:1 randomized, double-blind, placebo controlled | 101 | 101 | 39 vs 58†,‡ | 39 vs 58†,‡ |
| VILO+SoC vs PLC+SoC | PANAMO[5] | 1:1 randomized, double-blind, placebo controlled | 368 | 368 | 32 vs 42‡ | 32 vs 42‡ |

BARI = baricitinib; NA = not applicable; NP = not performed; PLC = placebo; REM = remdesivir; SoC = standard-of-care; VILO = vilobelimab * Analysis of the overall patient population, † Not powered to show 28-day all-cause mortality, ‡ Significant

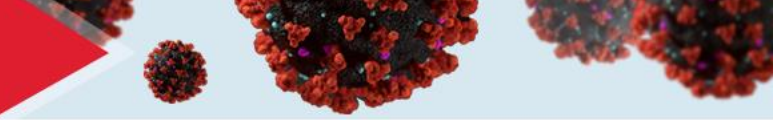
GOHIBIC was not evaluated in comparison to other treatments in a head-to-head clinical study.[5]

Please visit GOHIBIC.com for more information

**References** [1.] RECOVERY Collaborative Group, Lancet 2022;400: 359–68, [2.] Kalil et al. N Engl J Med. 2021;384(9):795-807, [3]. Marconi et al. Lancet Respir Med 2021;9:1407–18, [4]. Ely et al. Lancet Respir Med 2022;10:327–36, [5] Vlaar et al. Lancet Respir Med 2022;10:1137–46.

Gohibic (vilobelimab) Injection 200 mg/20 mL

# IMMUNOMODULATOR TREATMENTS



| Drug(s) Evaluated | Study | Study Design | Total Patients | TOTAL IMV/ECMO Patients | Absolute 28-Day Mortality Difference, Total Patients Drug vs Placebo (%) | Absolute 28-Day Mortality Difference, IMV/ECMO Patients Drug vs Placebo (%) |
|---|---|---|---|---|---|---|
| TCZ vs usual care | RECOVERY[1] | 1:1 randomized, controlled, open-label, platform trial | 4116 | 562 | 31 vs 35‡ | 49 vs 51 |
| TCZ+SoC vs PLC+SoC | COVACTA[2] | 2:1 randomized, double-blind, placebo controlled | 452 | 165 | 20 vs 19† | 28 vs 24 |
| TCZ+SoC vs PLC+SoC | EMPACTA[3] | 2:1 randomized, double-blind, placebo controlled | 388 | Excluded | 10 vs 9 | Not Applicable |
| TCZ+REM+SoC vs PLC+REM+SoC | REMDACTA[4] | 2:1 randomized, double-blind, placebo controlled | 649 | 81 | 18 vs 20 | 34 vs 45† |
| TCZ+SoC vs SoC | REMAP-CAP[5] | 1:1 randomized, controlled, open-label, platform trial | 755 | 225 | 28 vs 35 | No Analysis |
| VILO+SoC vs PLC+SoC | PANAMO[6] | 1:1 randomized, double-blind, placebo controlled | 368 | 368 | 32 vs 42‡ | 32 vs 42‡ |

NA = not applicable; NP = not performed; PLC = placebo; REM = remdesivir; SoC = standard-of-care; TCZ = tocilizumab; VILO = vilobelimab * Analysis of the overall patient population, † Not powered to show 28-day all-cause mortality, ‡ Significant

GOHIBIC was not evaluated in comparison to other treatments in a head-to-head clinical study.[6]

Please visit GOHIBIC.com for more information

**References** [1]RECOVERY Collaborative Group, Lancet 2021; 397: 1637–45, [2] Rosas et al. N Engl J Med 2021 384:1503–1516, [3] Salama et al. N Engl J Med 2021;384:20–30, [4] Rosas et al. Intensive Care Med 2021;47:1258–1270, [5] REMAP-CAP Investigators, N Engl J Med. 2021;384(16):1491-1502, [6] Vlaar et al. Lancet Respir Med 2022;10:1137–46.

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# SAFETY PROFILE

- **GOHIBIC showed a similar safety profile compared to placebo for treatment emergent adverse events.[1,2]**
- **GOHIBIC was not evaluated in comparison to other treatments in a head-to-head clinical study.[2]**

**The most common side effects of GOHIBIC include[1]**

Lung infection, sepsis, sudden confusion, sudden lung artery blockage, high blood pressure, collapsed lung, venous blood clotting (usually in the leg), herpes infection, certain infections caused by enterococci, urinary tract infection, low blood oxygenation, low platelets, the presence of air in the space in the chest between the two lungs, infection of the respiratory tract, heart arrythmia, constipation, and rash.

**Report side effects to FDA MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to InflaRx by calling 1-888-254-0602**

Please visit GOHIBIC.com for more information

References: [1]GOHIBIC Fact Sheet for Healthcare Providers, InflaRx Inc. April 2023; [2]Vlaar et al. Lancet Resp Med. 2022;10(12):1137-1146

# ADVERSE REACTIONS PROFILE

**Adverse Reactions that Occurred in ≥3% of Patients Treated with GOHIBIC and at least 1% More Frequently than Observed in the Placebo Arm through Day 60**

| Adverse Reactions | GOHIBIC + SoC (N=175) | | Placebo + SoC (N=189) | |
|---|---|---|---|---|
| | n | (%) | n | (%) |
| Pneumonia[1] | 55 | (31.4%) | 44 | (23.3%) |
| Sepsis[2] | 38 | (21.7%) | 30 | (15.9%) |
| Delirium[3] | 22 | (12.6%) | 20 | 10.6%) |
| Pulmonary embolism | 19 | (10.9%) | 17 | (9.0%) |
| Hypertension | 16 | (9.1%) | 13 | (6.9%) |
| Pneumothorax | 14 | (8.0%) | 11 | (5.8%) |
| Deep vein thrombosis | 11 | (6.3%) | 9 | (4.8%) |
| Herpes simplex | 11 | (6.3%) | 5 | (2.6%) |
| Enterococcal infection | 10 | (5.7%) | 8 | (4.2%) |
| Bronchopulmonary aspergillosis | 10 | (5.7%) | 7 | (3.7%) |
| Hepatic enzyme increased | 9 | (5.1%) | 7 | (3.7%) |
| Urinary tract infection | 9 | (5.1%) | 6 | (3.2%) |
| Hypoxia | 8 | (4.6%) | 6 | (3.2%) |
| Thrombocytopenia | 8 | (4.6%) | 2 | (1.1%) |
| Pneumomediastinum | 8 | (4.6%) | 0 | (0.0%) |
| Respiratory tract infection | 7 | (4.0%) | 5 | (2.6%) |
| Supraventricular tachycardia | 7 | (4.0%) | 1 | (0.5%) |
| Constipation | 6 | (3.4%) | 3 | (1.6%) |
| Rash | 6 | (3.4%) | 0 | (0.0%) |

**FOR GUIDANCE ON REPORTING ADVERSE EVENTS PLEASE SEE PAGE 29.**

SoC = standard of care.

[1] "Pneumonia" includes preferred terms containing the term "pneumonia"; does not include "COVID-19 pneumonia"

[2] "Sepsis" includes preferred terms containing the term "sepsis".

[3] "Delirium includes the following preferred terms: Delirium, Intensive care unit delirium A patient is only listed once (regardless of event numbers) but one patient can be listed in different categories with one or additional reactions.

References: GOHIBIC Fact Sheet for Healthcare Providers, InflaRx Inc. April 2023;

# CLINICAL OVERVIEW

- Clinical data supporting this EUA are based on PANAMO (NCT04333420), a Phase 3, double-blind, randomized, placebo-controlled multicenter trial evaluating GOHIBIC for the treatment of COVID-19 in adult (≥ 18 years) patients requiring IMV or ECMO. The multinational trial was conducted in Europe, Latin America, Russia, and South Africa.

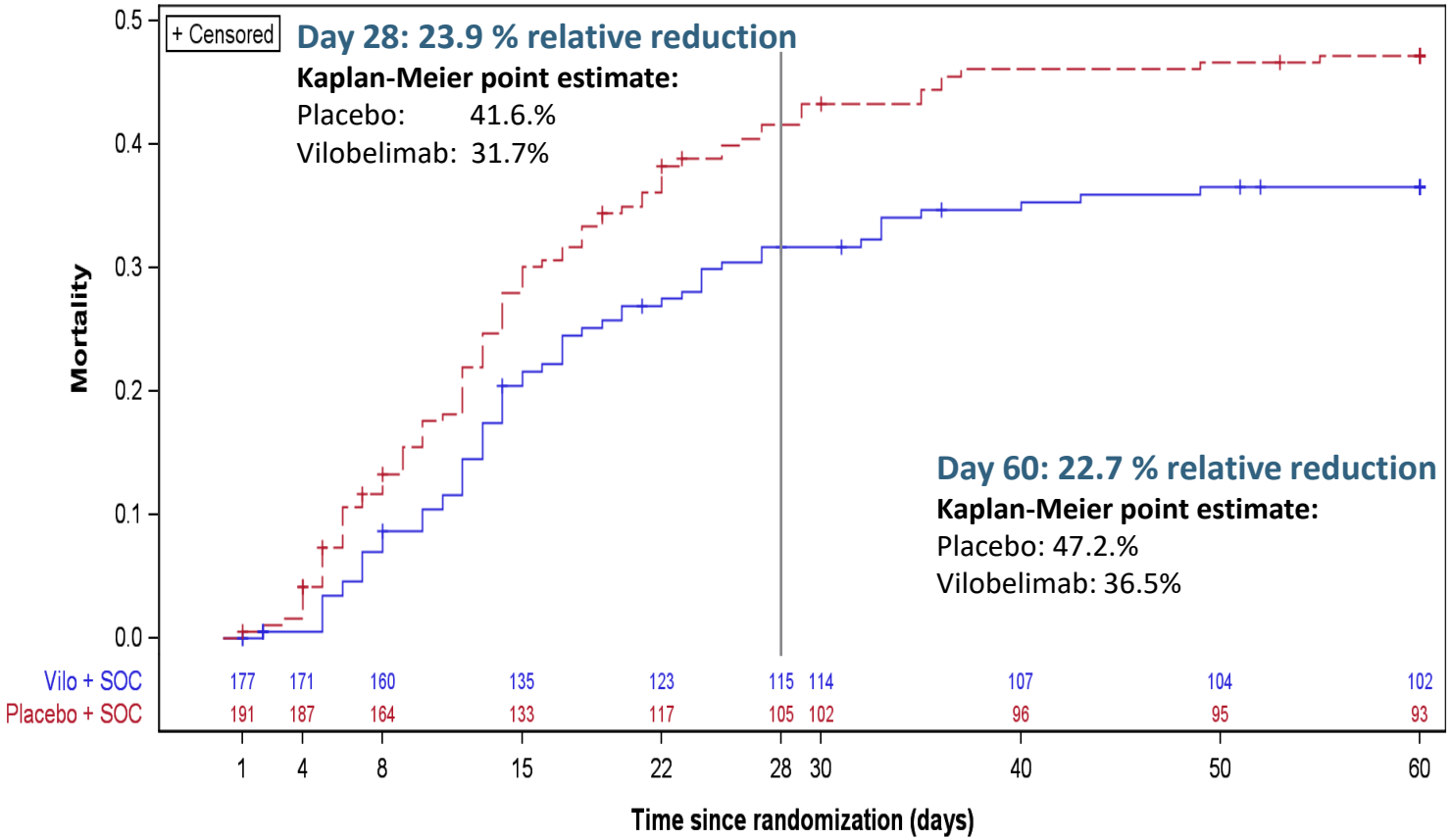
- Efficacy analyses were based on 368 patients, 177 in the GOHIBIC group and 191 in the placebo group. The mean age of participation was 56 years [range: 22 to 81 years] and 68.5% were male. [3] Standard-of-Care on top of GOHIBIC and placebo was corticosteroids (97%) and anticoagulants (98%) with 20% receiving prior or concomitant immunomodulatory therapies (tocilizumab > baricitinib).

- The primary endpoint in the study was time to death through Day 28. The Kaplan-Meier estimated 28- Day mortality rate in the GOHIBIC group was 31.7% and the estimated rate in the placebo group was 41.6%, resulting in a hazard ratio of 0.67 (95% CI [0.48, 0.96], p<0.05%.

References: [6]Vlaar et al. Lancet Resp Med. 2022;10(12):1137-1146

# CLINICAL OVERVIEW

## All-cause mortality: Overall




Placebo + SOC

Vilobelimab + SOC

**SOC included concomitant use:**

- Corticosteroid use: 97%
- Anti-coagulant use: 98%
- Immunomodulators 20%

(tocilizumab > baricitinib, prior or concomitant)

**References:** Vlaar et al. Lancet Resp Med. 2022;10(12):1137-1146

# IMPORTANT CLARIFICATION REGARDING PANAMO TRIAL PRIMARY ENDPOINT ANALYSIS & RESULTS

As part of its authorization process for GOHIBIC, FDA's Center for Drug Evaluation and Research (CDER) conducted a thorough analysis of the data provided by InflaRx and issued a detailed report. One section addressed why FDA/CDER found the relative reduction in 28-day all-cause mortality of 23.9% to be statistically significant. Below is CDER's explanation as to how it reached that conclusion. The CDER report said:

**"This is a rare instance of the Agency relying on a non-prespecified analysis as the primary analysis to support efficacy; however, in this particular case, the non-prespecified analysis is the more reliable method.**

**"Similar results were obtained in *post-hoc* supplementary analyses that used other methods to adjust for potential differences across countries or regions."**

**– FDA STATEMENT FROM: Emergency Use Authorization (EUA) for Vilobelimab (IFX-1) Center for Drug Evaluation and Research (CDER Review) (Section 7.2.5.3, page 28)**

References: Emergency Use Authorization (EUA) for Vilobelimab (IFX-1) Center for Drug Evaluation and Research (CDER) Review, Pg 22-29 Sections 7.2.3 and 7.2.5.3, April 2023

# IMPORTANT CLARIFICATION REGARDING PANAMO TRIAL PRIMARY ENDPOINT ANALYSIS & RESULTS

"The Kaplan-Meier estimates of the mortality rate within 28 days were 31.7% in the VILO group and 41.6% in the placebo group. The Cox proportional hazards model stratifying by site produced an estimated HR of 0.728 (95% CI = 0.502, 1.056), indicating that VILO reduced the risk of death by 27.2%.

"However, the result was not statistically significant ($p$ = 0.0941). The analysis stratifying by site effectively excluded the 61 (16.6%) subjects from sites with no deaths and/or enrollment in only one treatment group. When considering a *post-hoc* analysis that used a Cox proportional hazards model without stratifying by site, the estimated HR was a statistically significant 0.674 (95% CI = 0.476, 0.955; $p$ = 0.0266).

"Ultimately the Agency used the *post-hoc* analysis (non-prespecified), which included all randomized subjects, as the primary basis of efficacy.

**"The Requester originally proposed this non-site stratified method as the preferred analysis prior to study initiation, but subsequently changed to a site-stratified analysis based on comments from the Agency.**

"However, the Agency would have recommended a non-site stratified approach if the possibility of site dependent low enrollment had been more apparent. Because low enrollment at some sites leads to the exclusion of subjects in the prespecified site-stratified analysis, **the non-site stratified analysis is a more reliable and appropriate method to avoid the loss of statistical power.**"

**– FDA STATEMENT FROM: Emergency Use Authorization (EUA) for Vilobelimab (IFX-1) Center for Drug Evaluation and Research (CDER Review)[4]**
(Section 7.2.5.3, page 28)

**Access the full 'Emergency Use Authorization (EUA) for Vilobelimab (IFX-1) Center for Drug Evaluation and Research (CDER) Review' via the following link: GOHIBIC SUMMARY REVIEW (fda.gov)**

References: Emergency Use Authorization (EUA) for Vilobelimab (IFX-1) Center for Drug Evaluation and Research (CDER) Review, Pg 22-29 Sections 7.2.3 and 7.2.5.3, April 2023

# HOW TO ORDER

| VERIFY ACCOUNT/ACCOUNT SET UP<br>Verify that your facility has an active account by contacting: | |
|---|---|
| **EMAIL:** | **PHONE:** |
| ASDAAccountsetup@amerisourcebergen.com | 1-800-746-6273 |

| HOW TO PLACE AN ORDER:<br>When placing an order by EMAIL, PHONE or the ORDERING PORTAL: inpatient hospitals please have your account ready. | | |
|---|---|---|
| **EMAIL:** | **PHONE:** | **PORTAL:** |
| Service@asdhealthcare.com | 1-800-746-6273 | ABC Order \| AmerisourceBergen |

| ORDERING FROM ASD HEALTHCARE/Amerisource Bergen | | | |
|---|---|---|---|
| **IMPORTANT ORDERING INFORMATION:**<br>CONSIDER STOCKING THE FIRST FOUR DOSES OF GOHIBIC | | | |
| **GOHIBIC NDC CODE** | **LABEL NAME** | **GENERIC NAME** | **PRODUCT DESCRIPTION** |
| 83000-0110-04* | Gohibic (vilobelimab) Injection | vilobelimab | GOHIBIC 200 mg/20 mL (10 mg/mL) is a clear to slightly opalescent, colorless solution that is supplied in a single-dose vial for intravenous administration after dilution |

*NDC=National Drug Code; NDCs are listed as 11-digit codes for hospital institutional ordering and billing.

# SHIPPING AND DELIVERY

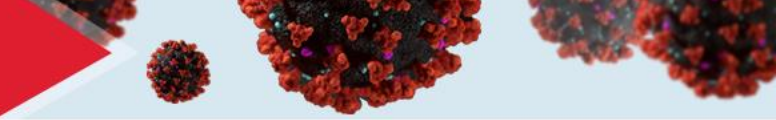
| SHIPPING AND DELIVERY (NEXT DAY DELIVERY AVAILABLE*) | |
|---|---|
| **PREPAID DELIVERY (ON STANDARD ORDER).** | The specialty distributor will ship GOHIBIC via cold chain distribution in a freight prepaid standard delivery |
| **SHIPPING SCHEDULE** | ***OVERNIGHT DELIVERY:**<br>GOHIBIC can be obtained by drop shipment for overnight delivery Monday through Thursday.<br><br>**IMPORTANT TO NOTE:**<br>- Orders received on **FRIDAY** will be processed on **SUNDAY for MONDAY delivery.**<br>- Orders received on **SATURDAY or SUNDAY** will be processed on **MONDAY for TUESDAY delivery.** |

# RETURN POLICY

| GOHIBIC PRODUCT RETURN POLICY | |
|---|---|
| **SHORT DATED AND EXPIRED PRODUCT** | Product in original, sealed, unopened cartons within (3) months prior to the expiration date and up to (12) twelve months after expiration date. |
| **VALUATION OF SHORT DATED AND EXPIRED RETURN** | Credit for return goods is issued based upon the lower of the current published price at the time the returned merchandise is received OR the lowest price paid by customer for that particular lot. |
| **PROCEDURE FOR RETURNING SHORT-DATED OR EXPIRED PRODUCT** | Customers (hospitals) must obtain a return goods authorization (RGA) number for return of GOHIBIC through mailto:InflaRxReturns@icsconnect.com or by calling **866-916-0571.** |
| **RETURN GOODS ADDRESS** | InflaRx Pharmaceuticals Inc.<br>ATTN: Returned Goods Department<br>420 International Blvd<br>Brooks, KY 40109<br><br>**Product returns are subject to the current Return Goods Policy.**<br>**For return questions, contact ICS at 866-916-0571.** |

***Additional terms and conditions may apply. If you have questions, contact ICS Customer Service at 1-866-916-0571**

# BILLING AND CODING



## NATIONAL DRUG CODES (NDC)

**Drug products are identified and reported using a unique 3 segment number called a National Drug Code, which is a universal product identifier. The NDC should be reported on a claim in the format required by each's patient's health plan.**

| GOHIBIC NDC | DISCRIPTION |
|---|---|
| 83000-110-04 | **GOHIBIC 10-digit Format** |
| 83000-0110-04 | **GOHIBIC 11-digit Format dose*** |

* NDCs are listed as 11-digit codes for hospital institutional ordering billing.

## ICD-10-CM DIAGNOSIS CODE

**All claims should include an accurate and appropriately documented diagnosis code.**

| ICD-10-CM CODE | DESCRIPTION |
|---|---|
| J12.82 | **Pneumonia due to COVID-19** |
| U07.1 | **COVID-19** |

# RESOURCES

**Letter of Authorization (LOA):**

- EUA 118 InflaRX Gohibic LOA (04122023).docx (fda.gov)

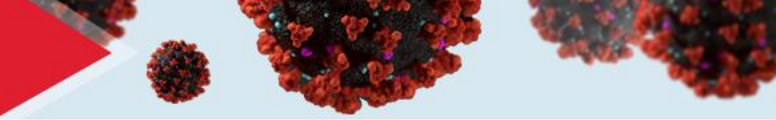
**GOHIBIC FACT SHEETS**

- Fact Sheet for Patients and Caregivers (fda.gov)
- Fact Sheet for Healthcare Providers: Emergency Use Authorization for Gohibic (fda.gov)

To receive copies of the GOHIBIC Frequently Asked Questions and AMCP Dossier, email your name, NPI number and state of licensure to info.gohibic@inflarx.com

Gohibic (vilobelimab) Injection 200 mg/20 mL

# IMPORTANT SAFETY INFORMATION



**Contraindications:** No contraindications have been identified based on limited available data on emergency use of GOHIBIC authorized under this EUA.

**Warnings and Precautions:** There are limited clinical data available for GOHIBIC. Serious and unexpected adverse events (AEs) may occur that have not been previously reported with GOHIBIC use.

**Serious Infections:** Serious infections due to bacterial, fungal, and viral pathogens have been reported in patients with COVID-19 receiving GOHIBIC. In patients with COVID-19, monitor for signs and symptoms of new infections during and after treatment with GOHIBIC. There is limited information regarding the use of GOHIBIC in patients with COVID-19 and concomitant active serious infections. The risks and benefits of treatment with GOHIBIC in COVID-19 patients with other concurrent infections should be considered.

**Hypersensitivity Reactions**: Hypersensitivity reactions have been observed with GOHIBIC. If a severe hypersensitivity reaction occurs, administration of GOHIBIC should be discontinued and appropriate therapy initiated.

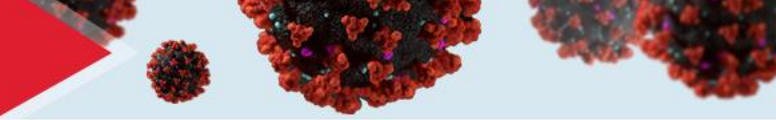
**Adverse Reactions** The most common adverse reactions (adverse events reported with incidence ≥3% and >1% more commonly observed than in the placebo arm) are pneumonia, sepsis, delirium, pulmonary embolism, hypertension, pneumothorax, deep vein thrombosis, herpes simplex, enterococcal infection, bronchopulmonary aspergillosis, hepatic enzyme increased, urinary tract infection, hypoxia, thrombocytopenia, pneumomediastinum, respiratory tract infection, supraventricular tachycardia, constipation, and rash.

Please visit GOHIBIC.com for more information

References: GOHIBIC Fact Sheet for Healthcare Providers, InflaRx Inc. April 2023;

inflaRx

# IMPORTANT SAFETY INFORMATION



## Use in Specific Populations

### Pregnancy

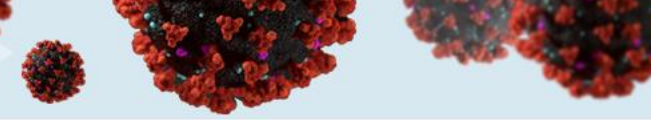
There are no available data on GOHIBIC use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. Placental transfer of monoclonal antibodies such as GOHIBIC is greater during the third trimester of pregnancy; therefore, potential effects on a fetus are likely to be greater during the third trimester of pregnancy. In an enhanced pre- and post-natal (ePPND) study conducted in cynomolgus monkeys, placental transport of GOHIBIC was observed but there was no evidence of fetal harm following intravenous administration of GOHIBIC throughout pregnancy at doses 2.5 times the maximum recommended human dose (MRHD) of 800 mg on a mg/kg basis (see Data). The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk for major birth defects and miscarriage in clinical recognized pregnancies is 2% - 4% and 15% - 20%, respectively.

### Pediatric Use

GOHIBIC is not authorized or approved for the emergency use in pediatric patients for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized patients when initiated within 48 hours of receiving invasive mechanical ventilation (IMV), or extracorporeal membrane oxygenation (ECMO).



References: GOHIBIC Fact Sheet for Healthcare Providers, InflaRx Inc. April 2023;



## Use in Specific Populations (continued)

### Geriatric Use

Of the total number of GOHIBIC-treated patients in clinical studies for COVID-19 receiving invasive mechanical ventilation (IMV), or extracorporeal membrane oxygenation (ECMO), 53 (30%) were >65 years. No overall differences in effectiveness or safety of GOHIBIC have been observed between patients 65 years of age and older and younger adult patients.

For additional information, please see:

- Fact Sheet for Healthcare Providers: Emergency Use Authorization for Gohibic (fda.gov)
- Fact Sheet for Patients and Caregivers (fda.gov)



References: GOHIBIC Fact Sheet for Healthcare Providers, InflaRx Inc. April 2023;

# ADVERSE EVENT REPORTING

## Required Reporting for Serious Adverse Events and Medication Errors

The prescribing healthcare provider and/or the provider's designee is/are responsible for mandatory reporting of all serious adverse events (SAEs) and medication errors potentially related to GOHIBIC within 7 calendar days from the healthcare provider's awareness of the event.

To report adverse events and medication errors, complete and submit FDA form 3500 to MedWatch online http://www.fda.gov/medwatch/report.htm or download FDA Form 3500 at https://www.fda.gov/media/76299/download and mail the completed form to MedWatch at 5600 Fisher's Lane, Rockville, MD 20852-9787 or fax it to **1-800-FDA-0178.** You may also request a reporting form by calling **1-800-FDA-1088.**

**In addition, please provide a copy of all FDA MedWatch forms to:**

InflaRx GmbH Fax: 1-866-728-2630

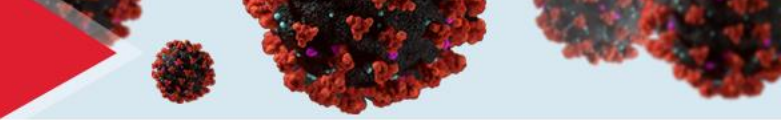
E-mail: pvusa@inflarx.de or call InflaRx GmbH at 1-888-254-0602 to report AEs.

**IMPORTANT TO NOTE:** Submitted reports must state, "GOHIBIC use for COVID-19 under Emergency Use Authorization" at the beginning of the question "Describe Event" for further analysis. A copy of the completed FDA Form 3500 must also be provided to InflaRx per the instructions in the authorized labeling.

Please visit GOHIBIC.com for more information

References: GOHIBIC Fact Sheet for Healthcare Providers, InflaRx Inc. April 2023;

# MEDICAL INFORMATION AND PRODUCT COMPLAINTS



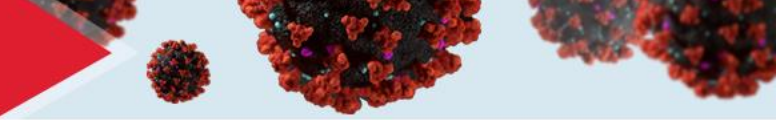
## FOR MEDICAL INFORMATION REQUEST

Please send your questions to: medical.affairs@inflarx.de

## FOR PRODUCT COMPLAINTS

Please contact: info.gohibic@inflarx.com

# DISCLAIMER



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**You are ultimately responsible for determining the appropriate reimbursement and billing codes.**

Please visit GOHIBIC.com for more information

GOHIBIC has not been approved but has been authorized for emergency use by FDA under an EUA, for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO).

The emergency use of GOHIBIC is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization revoked sooner.