**Prescribe an alternative COVID-19 therapy for patients who are receiving any of the medications listed.**

- Amiodarone
- Apalutamide
- Bosentan
- Carbamazepine
- Cisapride
- Clopidogrel
- Clozapine
- Colchicine in patients with renal and/or hepatic impairment
- Disopyramide
- Dofetilide
- Dronedarone
- Eplerenone
- Ergot derivatives
- Flecainide
- Flibanserin
- Glecaprevir/pibrentasvir
- Ivabradine
- Lumateperone
- Lurasidone
- Mexiletine
- Phenobarbital
- Phenytoin
- Pimozide
- Propafenone
- Quinidine
- Ranolazine
- Rifampin
- Rifapentine
- Rivaroxaban
- Sildenafil for pulmonary hypertension
- St. John's wort
- Tadalafil for pulmonary hypertension
- Ticagrelor
- Vorapaxar

**Before prescribing ritonavir-boosted nirmatrelvir (Paxlovid), determine whether the patient is receiving any of the medications listed.**

- **If the patient is receiving any of these medications, withhold the medication if clinically appropriate.**
- **If withholding is not clinically appropriate, use an alternative concomitant medication or COVID-19 therapy.[a]**

- Alfuzosin
- Alprazolam
- Atorvastatin
- Avanafil
- Clonazepam
- Codeine
- Cyclosporine[b]
- Diazepam
- Everolimus[b]
- Fentanyl
- Hydrocodone
- Lomitapide
- Lovastatin
- Meperidine (pethidine)
- Midazolam (oral)
- Oxycodone
- Piroxicam
- Propoxyphene
- Rosuvastatin
- Salmeterol
- Sildenafil for erectile dysfunction
- Silodosin
- Simvastatin
- Sirolimus[b]
- Suvorexant
- Tacrolimus[b]
- Tadalafil for erectile dysfunction
- Tamsulosin
- Tramadol
- Triazolam
- Vardenafil

Paxlovid Drug Interactions

# FACT SHEET FOR HEALTHCARE PROVIDERS: EMERGENCY USE AUTHORIZATION FOR PAXLOVID™

**HIGHLIGHTS OF EMERGENCY USE AUTHORIZATION (EUA)**
**These highlights of the EUA do not include all the information needed to use PAXLOVID™ under the EUA. See the FULL FACT SHEET FOR HEALTHCARE PROVIDERS for PAXLOVID.**

**PAXLOVID (nirmatrelvir tablets; ritonavir tablets), co-packaged for oral use**
**Original EUA Authorized Date: 12/22/2021**

**---------- EUA FOR PAXLOVID ----------**

The U.S. Food and Drug Administration has issued an EUA for the emergency use of the unapproved PAXLOVID which includes nirmatrelvir, a SARS-CoV-2 main protease (Mpro: also referred to as 3CLpro or nsp5 protease) inhibitor, and ritonavir, an HIV-1 protease inhibitor and CYP3A inhibitor, for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

**LIMITATIONS OF AUTHORIZED USE**

- PAXLOVID is not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19.
- PAXLOVID is not authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19.
- PAXLOVID is not authorized for use longer than 5 consecutive days.

PAXLOVID may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which PAXLOVID belongs (i.e., anti-infectives).

PAXLOVID is not approved for any use, including for use as treatment of COVID-19. (1)

PAXLOVID is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of PAXLOVID under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

See Full Fact Sheet for Healthcare Providers for the justification for emergency use of drugs during the COVID-19 pandemic, information on available alternatives, and additional information on COVID-19.

**---------- DOSAGE AND ADMINISTRATION ----------**

PAXLOVID is nirmatrelvir tablets co-packaged with ritonavir tablets. (2.1)
Nirmatrelvir must be co-administered with ritonavir. (2.1)

- Initiate PAXLOVID treatment as soon as possible after diagnosis of COVID-19 and within 5 days of symptom onset. (2.1)
- Administer orally with or without food. (2.1)
- Dosage: 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together twice daily for 5 days. (2.1)
- **Dose reduction for moderate renal impairment (eGFR ≥30 to <60 mL/min)**: 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet), with both tablets taken together twice daily for 5 days. (2.2)
- PAXLOVID is not recommended in patients with severe renal impairment (eGFR <30 mL/min). (2.2, 8.6)
- PAXLOVID is not recommend in patients with severe hepatic impairment (Child-Pugh Class C). (2.3, 8.7)

**---------- DOSAGE FORMS AND STRENGTHS ----------**

- Tablets: nirmatrelvir 150 mg (3)
- Tablets: ritonavir 100 mg (3)

**----------CONTRAINDICATIONS----------**

- History of clinically significant hypersensitivity reactions to the active ingredients (nirmatrelvir or ritonavir) or any other components. (4)
- Co-administration with drugs highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions. (4, 7.3)
- Co-administration with potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance. (4)

**---------- WARNINGS AND PRECAUTIONS ----------**

- The concomitant use of PAXLOVID and certain other drugs may result in potentially significant drug interactions. Consult the full prescribing information prior to and during treatment for potential drug interactions. (5.1, 7)
- Hepatotoxicity: Hepatic transaminase elevations, clinical hepatitis, and jaundice have occurred in patients receiving ritonavir. (5.2)
- HIV-1 Drug Resistance: PAXLOVID use may lead to a risk of HIV-1 developing resistance to HIV protease inhibitors in individuals with uncontrolled or undiagnosed HIV-1 infection. (5.3)

**---------- ADVERSE REACTIONS ----------**

Adverse events (incidence ≥1% and ≥5 subject difference) were dysgeusia, diarrhea, hypertension, and myalgia. (6.1)

**You or your designee must report all SERIOUS ADVERSE EVENTS or MEDICATION ERRORS potentially related to PAXLOVID (1) by submitting FDA Form 3500 online, (2) by downloading this form and then submitting by mail or fax, or (3) contacting the FDA at 1-800-FDA-1088 to request this form. Please also provide a copy of this form to Pfizer Inc. at fax number: 1-866-635-8337. (6.4)**

**----------DRUG INTERACTIONS----------**

Co-administration of PAXLOVID can alter the plasma concentrations of other drugs and other drugs may alter the plasma concentrations of PAXLOVID. Consider the potential for drug interactions prior to and during PAXLOVID therapy and review concomitant medications during PAXLOVID therapy. (2.4, 4, 5.1, 7, 12.3)

**See FACT SHEET FOR PATIENTS, PARENTS, AND CAREGIVERS.**

# FACT SHEET FOR HEALTHCARE PROVIDERS: EMERGENCY USE AUTHORIZATION FOR EVUSHELD™ (tixagevimab co-packaged with cilgavimab)

**HIGHLIGHTS OF EMERGENCY USE AUTHORIZATION (EUA)**
**These highlights of the EUA do not include all the information needed to use EVUSHELD™ under the EUA. See the FULL FACT SHEET FOR HEALTHCARE PROVIDERS for EVUSHELD.**

**EVUSHELD (tixagevimab) injection; (cilgavimab) injection, co-packaged for intramuscular use**
**Original EUA Authorized Date: 12/2021**

**RECENT MAJOR CHANGES**

| | |
|---|---|
| Dosage and Administration (2.1, 17): modification of initial dosage and repeat dosing | 02/2022 |
| Adverse Reactions (6.1, 12.3): addition of TACKLE data | 02/2022 |
| Microbiology (12.4): updated neutralizing data | 02/2022 |

**EUA FOR EVUSHELD**

The U.S. Food and Drug Administration has issued an EUA for the emergency use of the unapproved product EVUSHELD (tixagevimab co-packaged with cilgavimab), SARS-CoV-2 spike protein-directed attachment inhibitor, for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 **and**
  - Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments **and** may not mount an adequate immune response to COVID-19 vaccination **or**
  - For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

EVUSHELD may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which EVUSHELD belongs (i.e., anti-infectives).

EVUSHELD has been authorized by FDA for the emergency use described above. EVUSHELD is not FDA-approved for any use, including use for pre-exposure prophylaxis of COVID-19. (1)

EVUSHELD is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of EVUSHELD under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

**LIMITATIONS OF AUTHORIZED USE**

- EVUSHELD is not authorized for use in individuals:
  - For treatment of COVID-19, or
  - For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.
- Pre-exposure prophylaxis with EVUSHELD is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate to severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination.
- In individuals who have received a COVID-19 vaccine, EVUSHELD should be administered at least two weeks after vaccination.

See Full Fact Sheet for Healthcare Providers for examples of medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination, the justification for emergency use of drugs during the COVID-19 pandemic, information on available alternatives, and additional information on COVID-19. (1)

**DOSAGE AND ADMINISTRATION**

The dosage of EVUSHELD for emergency use is:

- Initial dose: 300 mg of tixagevimab and 300 mg of cilgavimab administered as two separate consecutive intramuscular injections.
- Repeat dose: The SARS-CoV-2 variants that will be circulating in the United States when EVUSHELD may need to be redosed are not known at this time and therefore repeat dosing recommendations cannot be made; the Fact Sheets will be revised with repeat dosing recommendations in the future when more data are available. (2.1)

See Full Fact Sheet for Healthcare Providers for detail on preparation and administration. (2)

**DOSAGE FORMS AND STRENGTHS**

Injection:

- tixagevimab 150 mg/1.5 mL (100 mg/mL) in a single-dose vial. (3)
- cilgavimab 150 mg/1.5 mL (100 mg/mL) in a single-dose vial. (3)

**CONTRAINDICATIONS**

EVUSHELD is contraindicated in individuals with previous severe hypersensitivity reactions, including anaphylaxis, to any component of EVUSHELD. (4)

**WARNINGS AND PRECAUTIONS**

- Hypersensitivity Including Anaphylaxis: Serious hypersensitivity reactions, including anaphylaxis, have been observed with IgG1 monoclonal antibodies like EVUSHELD. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive therapy. Clinically monitor individuals after injections and observe for at least 1 hour. (5.1)
- Clinically Significant Bleeding Disorders: As with any other intramuscular injection, EVUSHELD should be given with caution to individuals with thrombocytopenia or any coagulation disorder. (5.2)
- Cardiovascular Events: A higher proportion of subjects who received EVUSHELD versus placebo reported myocardial infarction and cardiac failure serious adverse events. All of the subjects with events had cardiac risk factors and/or a prior history of cardiovascular disease, and there was no clear temporal pattern. A causal relationship between EVUSHELD and these events has not been established. Consider the risks and benefits prior to initiating EVUSHELD in individuals at high risk for cardiovascular events, and advise individuals to seek immediate medical attention if they experience any signs or symptoms suggestive of a cardiovascular event. (5.3)

**ADVERSE REACTIONS**

Most common adverse events (all grades, incidence ≥3%) are headache, fatigue, and cough. (6.1)

**You or your designee must report all SERIOUS ADVERSE EVENTS or MEDICATION ERRORS potentially related to EVUSHELD (1) by submitting FDA Form 3500 online, (2) by downloading this form and then submitting by mail or fax, or (3) contacting the FDA at 1-800-FDA-1088 to request this form. Please also provide a copy of this form to *AstraZeneca* by Fax at 1-866-742-7984 or call 1-800-236-9933. (6.4)**

**See PATIENT AND PARENTS/CAREGIVER FACT SHEET.**

**Revised 02/2022**

# FACT SHEET FOR HEALTHCARE PROVIDERS: EMERGENCY USE AUTHORIZATION FOR MOLNUPIRAVIR

**HIGHLIGHTS OF EMERGENCY USE AUTHORIZATION (EUA)**
**These highlights of the EUA do not include all the information needed to use molnupiravir under the EUA. See the FULL FACT SHEET FOR HEALTHCARE PROVIDERS for molnupiravir.**

**MOLNUPIRAVIR capsules, for oral use**
**Original EUA Authorized Date: 12/23/2021**

**MANDATORY REQUIREMENTS FOR ADMINISTRATION OF MOLNUPIRAVIR UNDER EMERGENCY USE AUTHORIZATION**

Refer to FULL FACTSHEET for details.

**----------EUA FOR MOLNUPIRAVIR----------**

The U.S. Food and Drug Administration (FDA) has issued an EUA for the emergency use of the unapproved molnupiravir, a nucleoside analogue that inhibits SARS-CoV-2 replication by viral mutagenesis for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate. Molnupiravir is not FDA-approved for any use including for use for the treatment of COVID-19. Prior to initiating treatment with molnupiravir, carefully consider the known and potential risks and benefits. (1)

**LIMITATIONS OF AUTHORIZED USE (1)**

- Molnupiravir is not authorized
  - for use in patients less than 18 years of age (5.2)
  - for initiation of treatment in patients requiring hospitalization due to COVID-19. Benefit of treatment with molnupiravir has not been observed in subjects when treatment was initiated after hospitalization due to COVID-19. (2.1)
  - for use for longer than 5 consecutive days.
  - for pre-exposure or post-exposure prophylaxis for prevention of COVID-19.

Molnupiravir may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which molnupiravir belongs (i.e., anti-infectives).

Molnupiravir is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of molnupiravir under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

See the box in the beginning of the Full Fact Sheet for details on mandatory requirements for administration of molnupiravir under emergency use authorization.

See Full Fact Sheet for Healthcare Providers for the justification for emergency use of drugs during the COVID-19 pandemic, information on available alternatives, and additional information on COVID-19.

**----------DOSAGE AND ADMINISTRATION----------**

- 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days, with or without food. (2.1)
- Take molnupiravir as soon as possible after a diagnosis of COVID-19 has been made, and within 5 days of symptom onset. (2.1)
- Completion of the full 5-day treatment course and continued isolation in accordance with public health recommendations are important to maximize viral clearance and minimize transmission of SARS-CoV-2. (2.1)
- Molnupiravir is not authorized for use for longer than 5 consecutive days because the safety and efficacy have not been established. (2.1)

**----------DOSAGE FORMS AND STRENGTHS----------**

Capsules: 200 mg (3)

**----------CONTRAINDICATIONS----------**

No contraindications have been identified based on the limited available data on the emergency use of molnupiravir authorized under this EUA. (4)

**----------WARNINGS AND PRECAUTIONS----------**

- Embryo-Fetal Toxicity: Molnupiravir is not recommended for use during pregnancy. (5.1, 8.1, 8.3)
- Bone and Cartilage Toxicity: Molnupiravir is not authorized for use in patients less than 18 years of age because it may affect bone and cartilage growth. (5.2, 8.4, 13.2)

**----------ADVERSE REACTIONS----------**

Most common adverse reactions (incidence ≥ 1%) are diarrhea, nausea, and dizziness. (6.1)

**You or your designee must report all SERIOUS ADVERSE EVENTS or MEDICATION ERRORS potentially related to molnupiravir (1) by submitting FDA Form 3500 online, (2) by downloading this form and then submitting by mail or fax, or (3) contacting the FDA at 1-800-FDA-1088 to request this form. Please also provide a copy of this form to Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ USA at 1-800-672-6372 or Fax 215-616-5677 (6.4)**

**----------DRUG INTERACTIONS----------**

No drug interactions have been identified based on the limited available data on the emergency use of molnupiravir authorized under this EUA. (7)

**----------USE IN SPECIFIC POPULATIONS----------**

- Pregnancy: The use of molnupiravir is not recommended during pregnancy. Advise individuals of childbearing potential to use effective contraception correctly and consistently, as applicable, for the duration of treatment and for 4 days after the last dose of molnupiravir. (8.1, 8.3)
- Lactation: Breastfeeding is not recommended during treatment and for 4 days after the last dose of molnupiravir. A lactating individual may consider interrupting breastfeeding and may consider pumping and discarding breast milk during treatment and for 4 days after the last dose of molnupiravir. (8.2)

**See FACT SHEET FOR PATIENTS AND CAREGIVERS.**

# FACT SHEET FOR HEALTHCARE PROVIDERS: EMERGENCY USE AUTHORIZATION FOR EVUSHELD™ (tixagevimab co-packaged with cilgavimab)

**HIGHLIGHTS OF EMERGENCY USE AUTHORIZATION (EUA)**
**These highlights of the EUA do not include all the information needed to use EVUSHELD™ under the EUA. See the FULL FACT SHEET FOR HEALTHCARE PROVIDERS for EVUSHELD.**

**EVUSHELD (tixagevimab) injection; (cilgavimab) injection, co-packaged for intramuscular use**
**Original EUA Authorized Date: 12/2021**

**----------RECENT MAJOR CHANGES----------**

| | |
|---|---|
| Dosage and Administration (2.1, 17): modification of initial dosage and repeat dosing | 02/2022 |
| Adverse Reactions (6.1, 12.3): addition of TACKLE data | 02/2022 |
| Microbiology (12.4): updated neutralizing data | 02/2022 |

**----------EUA FOR EVUSHELD----------**

The U.S. Food and Drug Administration has issued an EUA for the emergency use of the unapproved product EVUSHELD (tixagevimab co-packaged with cilgavimab), SARS-CoV-2 spike protein-directed attachment inhibitor, for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 **and**
  - Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments **and** may not mount an adequate immune response to COVID-19 vaccination **or**
- For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

EVUSHELD may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which EVUSHELD belongs (i.e., anti-infectives).

EVUSHELD has been authorized by FDA for the emergency use described above. EVUSHELD is not FDA-approved for any use, including use for pre-exposure prophylaxis of COVID-19. (1)

EVUSHELD is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of EVUSHELD under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

**LIMITATIONS OF AUTHORIZED USE**

- EVUSHELD is not authorized for use in individuals:
  - For treatment of COVID-19, or
  - For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.
- Pre-exposure prophylaxis with EVUSHELD is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate to severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination.
- In individuals who have received a COVID-19 vaccine, EVUSHELD should be administered at least two weeks after vaccination.

See Full Fact Sheet for Healthcare Providers for examples of medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination, the justification for emergency use of drugs during the COVID-19 pandemic, information on available alternatives, and additional information on COVID-19. (1)

**----------DOSAGE AND ADMINISTRATION----------**

The dosage of EVUSHELD for emergency use is:

- Initial dose: 300 mg of tixagevimab and 300 mg of cilgavimab administered as two separate consecutive intramuscular injections.
- Repeat dose: The SARS-CoV-2 variants that will be circulating in the United States when EVUSHELD may need to be redosed are not known at this time and therefore repeat dosing recommendations cannot be made; the Fact Sheets will be revised with repeat dosing recommendations in the future when more data are available. (2.1)

See Full Fact Sheet for Healthcare Providers for detail on preparation and administration. (2)

**----------DOSAGE FORMS AND STRENGTHS----------**

Injection:

- tixagevimab 150 mg/1.5 mL (100 mg/mL) in a single-dose vial. (3)
- cilgavimab 150 mg/1.5 mL (100 mg/mL) in a single-dose vial. (3)

**----------CONTRAINDICATIONS----------**

EVUSHELD is contraindicated in individuals with previous severe hypersensitivity reactions, including anaphylaxis, to any component of EVUSHELD. (4)

**----------WARNINGS AND PRECAUTIONS----------**

- Hypersensitivity Including Anaphylaxis: Serious hypersensitivity reactions, including anaphylaxis, have been observed with IgG1 monoclonal antibodies like EVUSHELD. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive therapy. Clinically monitor individuals after injections and observe for at least 1 hour. (5.1)
- Clinically Significant Bleeding Disorders: As with any other intramuscular injection, EVUSHELD should be given with caution to individuals with thrombocytopenia or any coagulation disorder. (5.2)
- Cardiovascular Events: A higher proportion of subjects who received EVUSHELD versus placebo reported myocardial infarction and cardiac failure serious adverse events. All of the subjects with events had cardiac risk factors and/or a prior history of cardiovascular disease, and there was no clear temporal pattern. A causal relationship between EVUSHELD and these events has not been established. Consider the risks and benefits prior to initiating EVUSHELD in individuals at high risk for cardiovascular events, and advise individuals to seek immediate medical attention if they experience any signs or symptoms suggestive of a cardiovascular event. (5.3)

**----------ADVERSE REACTIONS----------**

Most common adverse events (all grades, incidence ≥3%) are headache, fatigue, and cough. (6.1)

**You or your designee must report all SERIOUS ADVERSE EVENTS or MEDICATION ERRORS potentially related to EVUSHELD (1) by submitting FDA Form 3500 online, (2) by downloading this form and then submitting by mail or fax, or (3) contacting the FDA at 1-800-FDA-1088 to request this form. Please also provide a copy of this form to *AstraZeneca* by Fax at 1-866-742-7984 or call 1-800-236-9933. (6.4)**

**See PATIENT AND PARENTS/CAREGIVER FACT SHEET.**

**Revised 02/2022**