

Prior Authorization DRUG Guidelines

INVIRASE (Saquinavir)

Effective Date: 1/28/14

Date Developed: 1/28/14 by Catherine Sanders, MD

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Invirase is an Antiretroviral Agent, Protease Inhibitor used in the treatment of HIV-1 infections. Invirase binds to the site of HIV-1 protease activity and inhibits cleavage of viral Gag-Pol polyprotein precursors into individual functional proteins required for infectious HIV. This results in the formation of immature, noninfectious viral particles.

Pre-Authorization Criteria:

Invirase is used for treatment of HIV-1 infections and must be used in combination with ritonavir.

Invirase may also be used with other antiretroviral agents.

Pretreatment EKG should be done and therapy is not to be initiated if pretreatment QT interval is >450 msec.

VCHCP requires that Invirase be prescribed by an Immunology Clinic physician with current American Academy of HIV Medicine (AAHIVM) certification or a physician boarded in Infectious Disease.

Medication Guide:

An FDA-approved patient medication guide, which is available with the product information and at <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM229206.pdf>, must be dispensed with this medication.

Dosing: Adult:

Saquinavir should always be used with concomitant ritonavir.

HIV infection: Oral: 1000 mg twice daily given in combination with ritonavir 100 mg twice daily. This combination should be given together and within 2 hours after a full meal in combination with a nucleoside analog.

Dosage adjustments when administered in combination therapy: Saquinavir: 1000 mg twice daily administered with lopinavir 400 mg/ritonavir 100 mg (Kaletra™) twice daily; no additional ritonavir is necessary

Dosing: Pediatric:

HIV infection: Oral: Children >16 years: Refer to adult dosing.

Administration:

Administer saquinavir and ritonavir at the same time and within 2 hours after a full meal. Patients unable to swallow capsules may open capsules and mix contents with 15 mL of syrup (or sorbitol if diabetic or glucose intolerant) or with 3 teaspoons of jam. Mixture should be stirred for 30-60 seconds and then administered entirely. Suspension should be at room temperature prior to administration.

Dosing: Geriatric:

Clinical studies did not include sufficient numbers of patients ≥ 65 years of age. Use caution due to increased frequency of organ dysfunction.

Dosing: Renal Impairment:

No dosage adjustment necessary. However, has not been studied in severe renal impairment or ESRD.

Dosing: Hepatic Impairment:

Mild to moderate impairment (Child-Pugh classes A and B): No dosage adjustment necessary.

Severe impairment (Child-Pugh class C): Use is contraindicated when coadministered with ritonavir.

Dosage Forms: U.S.:

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Capsule, Oral:

Invirase: 200 mg

Tablet, Oral:

Invirase: 500 mg

Generic Equivalent Available: U.S.-No

Exclusions:

Invirase is not to be used if not concomitantly used with ritonavir.

Do not use if pretreatment EKG reveals QT interval >450 msec.

Therapy is to be discontinued promptly if viral suppression response is lost, as continuation may increase the likelihood of cross-resistance to other protease inhibitors.

Contraindications:

Hypersensitivity to saquinavir or any component of the formulation; congenital or acquired QT prolongation, refractory hypokalemia or hypomagnesemia, concomitant use of other medications that both increase saquinavir plasma concentrations and prolong the QT interval; complete AV block (without implanted ventricular pacemaker) or patients at high risk of complete AV block; severe hepatic impairment; coadministration of saquinavir/ritonavir with alfuzosin, amiodarone, bepridil, cisapride, dofetilide, ergot derivatives, flecainide, lidocaine (systemic), lovastatin, midazolam (oral), pimozone, propafenone, quinidine, rifampin, sildenafil (when used for pulmonary artery hypertension [eg, Revatio[®]]), simvastatin, trazodone, or triazolam

Adverse Reactions:

$>10\%$: nausea

Other severe less common adverse reactions: altered cardiac conduction including prolongation of QT interval, potentially leading to torsade de pointes and prolongation of PR interval, potentially leading to heart block, fat redistribution, immune reconstitution syndrome, increased cholesterol, hyperglycemia, diabetes mellitus, hypertriglyceridemia, pancreatitis, hepatotoxicity, hypersensitivity reactions, Stevens-Johnson syndrome, hemolytic anemia, thrombocytopenia, pancytopenia, autoimmune disorders.

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18. www.epocrates.com: Invirase Drug Information

REVISION HISTORY:

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