PDL NEW DRUG REVIEW

Proprietary Name: Vitekta®
Common Name: elvitegravir
PDL Category: Antiretrovirals

Comparable Products	Preferred Drug List Status
Isentress	Recommended
Tivicay	Non-Recommended

Summary

Indications and Usage: In combination with an HIV protease inhibitor coadministered with ritonavir and with other antiretroviral drug(s) for the treatment of HIV-1 infection in antiretroviral treatment-experienced adults. Limitations of use include the following: There are no comparative pharmacokinetic or clinical data assessing Vitekta® with cobicistat as single entities compared to Stribild®; Vitekta® coadministered with protease inhibitors and cobicistat is not recommended; and coadministration of Vitekta® with dosage regimens or HIV-1 protease inhibitors other than those presented in the table in the recommended dosage section is not recommended.

This is a pregnancy category B medication. The safety and efficacy of use in children have not been established.

Dosage Forms: Film-coated tablets: 85mg, 150mg

Recommended Dosage: Once daily with food in combination with a protease inhibitor (PI) coadministered with ritonavir and another antiretroviral drug. Please see the table below for the recommended regimens for use with Vitekta®.

Dosage of Vitekta®	Dosage of concomitant PI	Dosage of concomitant ritonavir
85mg PO QD	Atazanavir 300mg PO QD	100mg PO QD
	Lopinavir 400mg PO BID	100mg PO BID
150mg PO QD	Darunavir 600mg PO BID	100mg PO BID
	Fosamprenavir 700mg PO BID	100mg PO BID
	Tipranavir 500mg PO BID	200mg PO BID

Dose adjustments are not required for those with renal impairment or for those with mild or moderate hepatic impairment. As use has not been studied with severe hepatic impairment, it is not recommended in this population.

Drug Interactions*:* Elvitegravir is metabolized by CYP3A. Give didanosine 1 hour before or 2 hours after Vitekta®. Concomitant use with efavirenz, nevirapine, St. John's Wort, telaprevir, boceprevir rifampin, and rifapentine is not recommended. Vitekta® is not recommended in combination with Stribild® or in combination with a protease inhibitor and cobicistat. Other numerous potentially significant drug interactions are also documented. Please refer to the prescribing information specific information.

Common Adverse Drug Reactions: *Listed % incidence for adverse drug reactions= reported % incidence for drug (Vitekta®) minus reported % incidence for raltegravir. Please note that an incidence of 0% means the incidence was the same or that the active drug was less than its comparator.* The most frequently reported adverse events

included diarrhea (2%), nausea (1%), and headache (0%). Laboratory abnormalities included total bilirubin >2.5x ULN (0%), hematuria >75RBC/HPF (0%), serum amylase >2x ULN (0%), creatine kinase ≥10x ULN (2%), total cholesterol >300mg/dl (0%), total triglycerides >750mg/dl (1%), hyperglycemia >250mg/dl (2%), urine glucose 91%), GGT >5x ULN (0%), neutrophils <750/mm^3 (0%), ALT >5x ULN (0%), and AST >5x ULN (0%).

Contraindications: There are no contraindications with Vitekta®; however, as it is to be used with a protease inhibitor coadministered with ritonavir, the prescribing information of these latter products should be consulted.

Manufacturer: Gilead Sciences, Inc

Analysis: Elvitegravir, the active ingredient of Vitekta®, is an antiretroviral agent. It is an integrase strand transfer inhibitor (INSTI), where integrase is an HIV-1 enzyme that is needed for viral replication.

One randomized, double-blind, active-controlled study (N=702) was performed to assess the safety and efficacy of Vitekta® in treatment-experienced adult patients infected with HIV-1. Subjects were randomized to either Vitekta® or raltegravir, each given with a background regimen containing a protease inhibitor coadministered with ritonavir and a second antiretroviral agent. Included data for virologic outcomes was through 96 weeks of treatment. The mean increase from baseline in CD4+ cell count was 205cells/mm^3 with the Vitekta® vs 198cells/mm^3 in the raltegravir group. The table below includes additional results from the trial.

	Vitekta® (N=351)	Raltegravir (N=351)
HIV-1 RNA <50 copies/ml	52%	53%
HIV-1 RNA ≥50 copies/ml	36%	31%
No virologic data at week 96	12%	16%
Discontinued study drug due to AE or death	3%	7%
Discontinued study due to other reasons & last HIV-1 RNA <50 copies/ml	8%	9%
Missing data during window but on study drug	1%	1%

Place in Therapy: Vitekta® is an INSTI to be used in combination with an HIV protease inhibitor co-administered with ritonavir and other antiretroviral agents. It was found to be non-inferior to raltegravir.

There is no evidence at this time to support that Vitekta® is safer or more effective than the other currently available, more cost effective integrase inhibitors based on data reviewed from registration trials in the package insert. It is therefore recommended that Vitekta® be added to the Recommended Drug List as non-recommended.

PDL Placement:

- ☐ **Preferred**
- ☒ **Non-Recommended**
- ☐ **Preferred with Conditions**

References

[1] Vitekta [package insert]. Foster City, CA: Gilead Sciences, Inc; 2014.