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Biktarvy® (BIC/FTC/TAF) Comparison With DTG/3TC

This document is in response to your request for information regarding Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]) compared with dolutegravir/lamivudine (DTG/3TC) in people with HIV-1 (PWH). This response was developed according to principles of evidence-based medicine and contains data from clinical trials and real-world studies (N≥500).

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Summary

Clinical Studies: BIC/FTC/TAF vs DTG/3TC

Six prospective clinical studies evaluated outcomes in PWH who were VS or ARV-naive and were treated with BIC/FTC/FTC or DTG/3TC.[1-8]

- In three studies that reported virological outcomes, rates of VF were similar or noninferior between treatment groups.[1-6]
- Five studies reported weight-related outcomes.[1,3-5,7,9] In three studies, there was no significant difference between the BIC/FTC/TAF and DTG/3TC groups in the change in weight from baseline to Week 48, 96, or 144.[3-5] In two studies, increases in weight or trunk fat mass were significantly greater in the BIC/FTC/TAF group than in the DTG/3TC group ($P<0.05$).[1,7,9]
- In three studies that reported outcomes related to metabolic and laboratory parameters, changes from baseline to Week 48, 96, or 144 were not significantly different between groups.[3-5,7]
- In the DEBATE study, VS PWH who switched to BIC/FTC/TAF experienced increases in CD4+ T-cells and classical monocytes, whereas those who switched to DTG/3TC had increases in CD4+ cell subtypes, CD8+ T-cells with markers of exhaustion, and nonclassical monocytes.[8]

Real-World Data: BIC/FTC/TAF vs DTG/3TC

Real-world studies comparing outcomes of PWH who received BIC/FTC/TAF with those of PWH who received DTG/3TC are summarized below.[10-16]

Clinical Studies: BIC/FTC/TAF vs DTG/3TC

Open-Label, Multicenter Clinical Trial (PASO-DOBLE)

A phase 4, open-label, multicenter, randomized clinical trial was conducted to assess the efficacy of switching to DTG/3TC (n=277) compared with switching to BIC/FTC/TAF (n=276) in VS (VL <50 c/mL for ≥24 weeks) PWH with no prior exposure to DTG or BIC, no history of VF, and no resistance to study drugs. Prior regimens included TDF, EFV, or COBI-containing regimens. Randomization was stratified by baseline TAF use and sex at birth. The primary endpoint was the proportion of participants with plasma VL ≥50 c/mL at Week 48 by FDA Snapshot analysis (4% non-inferiority margin), and key secondary outcomes were weight change and the proportion of participants with >5% weight change at Week 48.[1]

In the ITT-E population at Week 48, switching to DTG/3TC was noninferior to switching to BIC/FTC/TAF, with 1% of participants (n=2) in the BIC/FTC/TAF group and 2% of participants (n=6) in the DTG/3TC group with VL ≥50 c/mL (difference, 1.4%; 95% CI: -0.5% to 3.4%; *P*=0.16). In these 8 participants, VLs were ≤282 c/mL, and adherence the week before VL testing was <95% in 5 participants; all participants stayed on study drugs and achieved VS at the next VL assessment. Through Week 48, 1 participant in the BIC/FTC/TAF group had CVF (ie, VL ≥50 c/mL with a second consecutive VL ≥200 c/mL 2–4 weeks later) and underwent resistance testing; no treatment-emergent resistance was detected.[1]

In the ITT-E population at Week 96, 0.4% of the DTG/3TC group and 1.1% of the BIC/FTC/TAF group had a VL ≥50 c/mL (difference, -0.7%; 95% CI: -2.1% to 0.7%). Through Week 96, an additional 2 participants in the BIC/FTC/TAF group and none in the DTG/3TC group had CVF; no treatment-emergent resistance was detected.[2]

In a substudy that assessed body composition changes in participants with paired body composition data and adjusted for sex, age, race, baseline weight, and baseline TAF use, a >5% weight gain was observed in 13.5% of participants in the DTG/3TC group and 22.1% in the BIC/FTC/TAF group at Week 48 (aOR, 2; 95% CI: 1.19–3.35) and in 19.7% and 34.8%, respectively, at Week 96 (aOR, 2.34; 95% CI: 1.49–3.67). In both treatment groups, from baseline to Week 96, lean mass decreased and fat mass increased, with greater gains in the BIC/FTC/TAF group in total mass (*P*=0.004), total fat mass (*P*=0.01), limb fat (*P*=0.009), and trunk fat (*P*=0.019) than in the DTG/3TC group. In a multivariable model of total fat mass change at Week 96, greater fat gain was associated with BIC/FTC/TAF use (*P*=0.038); female sex at birth (*P*=0.047); duration of previous ARV exposure (per +5 years; *P*=0.001); lower baseline total fat, per DXA assessment (per 5 kg lower; *P*<0.001); and lower diet quality (per 5 point decrease on the sDQS score; *P*=0.004).[9]

From baseline to Week 96, DRAEs were reported in 37 participants (13.4%) in the BIC/FTC/TAF group and in 21 (7.6%) in the DTG/3TC group (*P*=0.025); Grade 3 or 4 AEs were reported in 18 participants (6.5%) and 13 participants (4.7%), respectively (*P*=0.35).[2]

Open-Label Study (DYAD)

A phase 4, randomized, open-label study evaluated the efficacy and safety of switching to DTG/3TC (n=149) compared with staying on BIC/FTC/TAF (n=73) in VS PWH with no history of VF and no documented or suspected major INSTI or NRTI resistance. Eligible participants had undetectable VL for ≥3 months and had been receiving BIC/FTC/TAF for

≥3 months. The primary endpoint was the percentage of participants with VL ≥50 c/mL at Week 48 by FDA Snapshot analysis (6% non-inferiority margin) in the ITT-E population. Descriptive statistics were used to summarize the incidence and severity of AEs.[3]

At Week 48, 6 participants (4%) in the DTG/3TC group and 5 participants (7%) in the BIC/FTC/TAF group had HIV-1 RNA ≥50 c/mL (difference, -2.8%; 95% CI: -11.4% to 3.1%), which met the non-inferiority criteria. In the DTG/3TC and BIC/FTC/TAF groups, HIV-1 RNA <50 c/mL was achieved by 127 participants (85%) and 59 participants (81%), respectively (difference, 4.4%; 95% CI: -5.6% to 16%).[3]

After completing the randomized phase, 63 participants in the BIC/FTC/TAF group and 124 participants in the DTG/3TC group continued into the observational, open-label extension phase, and data were collected from electronic medical records. At Week 144, 3% of participants (5/149) in the DTG/3TC group and no participants in the BIC/FTC/TAF group had a VL ≥50 c/mL (adjusted treatment difference, 3.4%; 95% CI: -1.6% to 7.6%).[4]

Through Week 144, 16 participants (11%) in the DTG/3TC group and 6 participants (8%) in the BIC/FTC/TAF group had CVF (two consecutive VLs ≥50 c/mL); 2 participants (1%) and 1 participant (1%), respectively, developed resistance. Between Weeks 48 and 144, 4 participants in the DTG/3TC group experienced CVF, with no evidence of treatment-emergent resistance.[4]

Overall, DRAEs, DRAEs that led to withdrawal, and drug-related SAEs were reported more frequently in the DTG/3TC group than in the BIC/FTC/TAF group through Week 144 (Table 1).[4]

Table 1. DYAD Study: Safety Summary Through Week 144[4]

Safety Outcomes, n (%)		Weeks 0–144	
		BIC/FTC/TAF (n=73)	DTG/3TC (n=149)
DRAEs		8 (11)	49 (33)
DRAEs that occurred in ≥2% in either group	Insomnia	2 (3)	7 (4.7)
	Elevated SCr	1 (1)	3 (2)
	Nausea	1 (1)	8 (5.3)
	Weight gain	1 (1)	6 (4)
	Worsening depression	1 (1)	4 (3)
	Diarrhea	0	6 (4)
	Fatigue	0	6 (4)
	Headaches	0	5 (3)
	Light-headedness	0	3 (2)
DRAEs that led to withdrawal		0	11 (7)[a]
Drug-related SAE		0	1 (0.7)[b]

[a]Included neuropsychiatric complaints (n=7), weight gain (n=2), nausea (n=1), and pancreatitis (n=1).
[b]Pancreatitis.

The mean change from baseline in eGFR in the BIC/FTC/TAF and DTG/3TC groups was +0.87 mL/min/1.73 m^2 and -3.37 mL/min/1.73 m^2 (*P*=0.03), respectively, at Week 48 and +0.51 mL/min/1.73m^2 and -3.84 mL/min/1.73m^2 (*P*=0.095) at Week 144. No differences were observed between groups in mean changes from baseline in Cr levels, lipid parameters (TC, LDL, HDL, TG, or TC:HDL ratio), weight, or BMI at Week 144.[3,4]

Open-Label Switch Study (INSTINCT)[5]

INSTINCT was a randomized, open-label, multicenter, phase 4 study that evaluated the effect of switching from DTG/3TC to BIC/FTC/TAF (n=70) vs staying on DTG/3TC (n=71) on metabolic parameters and systemic inflammation (levels of IL-6, sCD14, D-dimer, sCD163, hs-CRP, and KT ratio). Eligible participants were VS PWH (VL <50 c/mL) on stable ARV therapy with DTG/3TC for ≥48 weeks. Efficacy at Week 96 and changes from baseline to Week 96 in plasma inflammatory biomarkers, metabolic and renal parameters, CD4 and CD8 cell counts, and CD4/CD8 ratio were evaluated. Overall baseline demographics were as follows: median age was 45 years; 86.5% were male; 78% were Caucasian; and median duration of virologic suppression was 6.5 years.

No significant differences between groups were observed in changes in inflammatory biomarker levels from baseline to Week 96. At Week 96, 96.7% of the BIC/FTC/TAF group and 98.4% of the DTG/3TC group were VS; 3.3% and 1.6%, respectively, had a VL ≥50 c/mL; and 12.9% and 11.3% had no virologic data (ITT-E). There were no significant between-group differences in CD4 and CD8 counts and CD4/CD8 ratios. The mean annual percent change in body weight from baseline to Week 96 was +0.3% in the BIC/FTC/TAF group and +0.2% in the DTG/3TC group, and a similar proportion of participants in each group experienced a weight gain of >5% (23% and 17%, respectively; aOR, 0.65; 95% CI: 0.27–1.6). Changes in TC:HDL ratio, TG, $eGFR_{CKD\text{-}EPI}$, and glucose were minor, with no significant between-group differences.

AEs occurred at similar rates in both groups, and most were Grade 1 or 2 in severity and were considered unrelated to study drugs. Drug-related AEs occurred in 4.8% of the BIC/FTC/TAF group and 0.4% of the DTG/3TC group; all were Grade 1.
No treatment-related SAEs or study DCs were reported.

Open-Label, Non-Inferiority Study (VOGUE)[6]

A randomized, open-label, phase 3b, non-inferiority study compared the efficacy and safety of DTG/3TC (n=254) and BIC/FTC/TAF (n=255) in ARV-naive PWH. Randomization was stratified by baseline HIV-1 RNA (<100,000 c/mL vs ≥100,000 c/mL) and by CD4 count (<200 cells/mcL vs ≥200 cells/mcL). The primary endpoint was the proportion of participants at Week 48 with HIV-1 RNA <50 c/mL by FDA Snapshot algorithm (-10% non-inferiority margin). At baseline, the median age was 33 years, 16% were assigned female sex at birth, 83% were of White race, 39% were of Hispanic or Latinx ethnicity, 16% had HIV-1 RNA ≥500,000 c/mL, and 16% had a CD4 count <200 cells/mcL. The median (IQR) time from screening to treatment initiation was 10 (8–14) days.

At Week 48, 89% of participants in the DTG/3TC group and 92% of participants in the BIC/FTC/TAF group achieved HIV-1 RNA <50 c/mL (adjusted difference, -3; 95% CI: -8% to +2%), meeting the non-inferiority criteria. In the DTG/3TC and BIC/FTC/TAF groups, 16 participants (6%) and 8 participants (3%), respectively, had HIV-1 RNA ≥50 c/mL; of these participants, 9/12 participants and 2/3 participants with available data were virologically resuppressed at the next visit. Among participants with baseline HIV-1 RNA <100,000 c/mL, 93% (119/128) in the DTG/3TC group and 94% (134/142) in the BIC/FTC/TAF group achieved virologic suppression; among participants with baseline HIV-1 RNA ≥100,000 c/mL, 85% (107/126) and 89% (101/113), respectively, achieved virologic suppression. Among participants with baseline CD4 count <200 cells/mcL, 78% of participants (31/40) with DTG and 85% of participants (33/39) with BIC/FTC/TAF achieved virologic suppression, and 91% (195) and 94% (202/216), respectively, of participants with baseline CD4 ≥200 cells/mcL achieved virologic suppression.

At Week 48, 7 participants in the DTG/3TC group and 6 participants in the BIC/FTC/TAF group had virologic rebound (HIV-1 RNA ≥200 c/mL), and 1 participant in the BIC/FTC/TAF group had virologic nonresponse; no cases of treatment-emergent resistance were detected in either treatment group.

Overall, the incidences of AEs were similar between treatment groups. TRAEs were reported in 44 participants (17%) in the DTG/3TC group and in 49 participants (19%) in the BIC/FTC/TAF group; Grade 3 or 4 drug-related TRAEs were reported in 1 participant (<1%) in each group. SAEs were reported in 23 participants (9%) in the DTG/3TC group and in 20 (8%) in the BIC/FTC/TAF group. No TRAEs with DTG/3TC and 2 TRAEs (<1%) with BIC/FTC/TAF (alopecia and increased weight; each, n=1) led to study DC.

Single-Center Study[7]

A single-center, randomized, open-label, controlled trial compared metabolic outcomes between PWH who switched to or stayed on BIC/FTC/TAF (n=43) and those who switched to DTG/3TC (n=87). Week 48 secondary outcomes included weight, BMI, waist circumference, lipids, insulin resistance, DXA scan, and FibroScan.

At baseline, there were significant differences between groups in weight (*P*=0.013), waist circumference (*P*=0.006), and BMI (*P*=0.024). Virologic suppression was maintained through Week 48, with no differences between groups. Analyses using linear mixed models adjusted for baseline BMI demonstrated significant differences between groups in mean changes from baseline to Week 48 in several parameters (Table 2), and changes in lean body mass, TC, LDL, TG, glucose, insulin, HOMA-IR, liver fibrosis, and FibroScan results were not significantly different between groups. From baseline to Week 48, greater treatment-mediated changes in trunk fat mass were seen in participants with a BMI >30 kg/m^2 (BIC/FTC/TAF, +1.4 kg; DTG/3TC, -1.1 kg) than in participants with a BMI <30 kg/m^2 (BIC/FTC/TAF, +0.6 kg; DTG/3TC, +0.2 kg). Safety data were not reported.

Table 2. Metabolic Parameters With Significant Between-Group Differences From Baseline to Week 48 (Degroote et al)[7]

Parameter	BIC/FTC/TAF (n=43)	DTG/3TC (n=87)	*P*-Value
ALT, U/L	+4.55	-0.73	0.04
HDL, mg/L	-2.84	-0.043	0.043
Lean trunk mass, g	-474	+112	0.032
Trunk fat mass, g	+719	+41	0.043
Fat, %	+1.32	-0.04	0.003

Prospective, Open-Label Switch Study (DEBATE)[8]

The randomized, open-label, prospective DEBATE study compared immunological outcomes between PWH who switched from their ARV regimen to BIC/FTC/TAF (n=33) or DTG/3TC (n=33). Eligible participants were taking a triple-drug ARV regimen and had undetectable HIV VL for >12 months. Blood samples were collected at baseline and at 6 and 12 months.

Although the absolute numbers of T cells and monocytes were similar between groups at 12 months, there were differences between the groups in the changes in a number of cell subtypes. Classical monocytes (CD14++CD16-) increased in participants in the BIC/FTC/TAF group from baseline to 6 months (*P*=0.009; between groups at 6 months, *P*=0.0028). From baseline to 12 months, activated CD4+ T cells significantly increased among participants in the BIC/FTC/TAF group (*P*=0.0367). Participants who switched to

DTG/3TC had significantly greater increases from baseline to 12 months in additional subtypes of CD4+ T cells (terminally differentiated T [*P*=0.0007] and exhausted cells [*P*=0.0004]), transitional memory lymphocytes (*P*<0.0001) and T memory stem cells (*P*=0.0019), nonclassical monocytes (CD14+CD16++; *P*=0.0195), and CD8+ markers of exhaustion (*P*=0.0426; between groups at 12 months, *P*=0.026) than participants in the BIC/FTC/TAF group. No significant changes from baseline in CD19+ B cells were observed in either group.

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Real-World Data: BIC/FTC/TAF vs DTG/3TC

Table 3 summarizes real-world studies that compare outcomes of PWH who received BIC/FTC/TAF with those of PWH who received DTG/3TC (N≥500).

Table 3. Real-World Data Comparing BIC/FTC/TAF With DTG/3TC[10-16]

Study Design and Population	Outcomes	Safety Results
Prospective Studies		
OPERA, a longitudinal cohort study in VS PWH who switched to BIC/FTC/TAF (n=3527) or DTG/3TC (n=2213) and were followed for a median of 16 mo and 15 mo, respectively[10]	• There were no significant differences between groups in VF (VL ≥200 c/mL), with 84 (2%) with BIC/FTC/TAF and 59 (3%) with DTG/3TC (HR, 0.84; 95% CI: 0.59–1.18). • DTG/3TC was associated with a greater risk of regimen DC than BIC/FTC/TAF (n=425 [19%] and n=599 [17%], respectively; HR, 0.83; 95% CI: 0.73–0.94).	DCs were reported in 17% with BIC/FTC/TAF and 19% with DTG/3TC, with treatment-related reasons for DC reported in 6% and 9%, respectively.
BicDol, a study in the French Dat'AIDS Cohort that compared the effectiveness of BIC/FTC/TAF (n=1826) and DTG + ABC/3TC or TDF/FTC (n=703) in ARV-naive PWH with high baseline viremia (HIV-1 RNA ≥5 $\log_{10}$ c/mL)[11]	• A DTG-based regimen was associated with achieving virologic suppression (HIV-1 RNA <50 c/mL) faster among PWH with baseline HIV-1 RNA ≥5 $\log_{10}$ c/mL (*P*=0.037), PWH with acute HIV-1 infection (*P*=0.025), and PWH with baseline HIV-1 RNA ≥5.7 $\log_{10}$ c/mL (*P*=0.005) than with BIC/FTC/TAF. • In a Cox model that used propensity scores estimated from age, sex, acute HIV infection, CD4 count, and baseline VL, patients who received a DTG-based regimen achieved virologic suppression faster than patients who received BIC/FTC/TAF (aHR >1 for all subgroups).	Safety data were not reported.

Study Design and Population	Outcomes	Safety Results
Prospective, longitudinal cohort study in VS PWH who switched to BIC/FTC/TAF (n=673) or a DTG-based regimen, including DTG/3TC (n=36)[12]	• At Week 144, BIC/FTC/TAF was associated with a significantly lower annualized mean weight gain post-switch compared with pre-switch trajectories than treatment with DTG/3TC (+0.23 kg/year vs +1.08 kg/year, respectively; *P*<0.05). • From baseline to Week 144, DTG-based regimens were associated with higher rates of newly diagnosed HTN, metabolic dysfunction-associated steatotic liver disease, and hyperlipidemia.	Safety data were not reported.
CoRIS multicenter, prospective, PS-matched cohort study in ARV-naive PWH who received BIC/FTC/TAF (n=340) or DTG/3TC (n=340)[13]	• At Week 96, there were no significant differences between groups in the incidences of new onset overweight, obesity, DM, HTN, dyslipidemia, or liver steatosis or in levels of TC, LDL, HDL, TG, TC:HDL ratio, or HSI (each, *P*>0.3).	Safety data were not reported.
Retrospective Studies		
Retrospective study of REGAL global cohort in PWH aged ≥50 years who switched to BIC/FTC/TAF (n=551) or DTG/3TC (n=593)[14]	• At 48 weeks, the incidence rate of VF per 100 person-years was 0.2 (95% CI: 0–0.46) with BIC/FTC/TAF and 0.18 (95% CI: 0–0.42) with DTG/3TC • Up to 288 weeks, VF was reported in 1 patient (0.2%) in each treatment group; no resistance was reported. • From baseline to Week 96, median CD4 cell counts increased slightly, and CD4/CD8 ratios remained stable, with no significant between-group differences in either outcome. • Biomarkers of hepatic function remained stable through Week 96, with no significant between-group differences.	Safety data were not reported.

Study Design and Population	Outcomes	Safety Results

DRAGON, a retrospective, observational cohort study that assessed factors associated with weight gain after initiating BIC/FTC/TAF (n=681) or DTG/3TC (n=406) in ARV-naive PWH of Asian origin[15]	• At Week 96, the overall rate of virologic suppression (VL <200 c/mL) was 98% in each treatment group.
	  • Among PWH with baseline CD4 <200 cells/mcL, the rate of virologic suppression was 97% with BIC/FTC/TAF and 100% with DTG/3TC.
	  • Among PWH with baseline VL >500,000 c/mL, the rate of virologic suppression was 98% and 100%, respectively.
	• From baseline to Week 96, the mean weight change was +5.1 kg with BIC/FTC/TAF and +2.8 kg with DTG/3TC; 36% and 18%, respectively, had a weight gain of >10% (aOR, 2.09; 95% CI: 1.26–3.48; *P*<0.01).
		Safety data were not reported.

Retrospective study in Spain in PWH who were VS at time of switch to BIC/FTC/TAF (n=332) or DTG/3TC (n=358)[16]	• In the BIC/FTC/TAF and DTG/3TC groups, similar percentages of patients had virological suppression (VL <50 c/mL; 96.1% vs 96.4%), low-level viremia (VL 51–500 c/mL; 3% vs 2.5%), and VF (VL >200 c/mL; 0.9% vs 1.1%). No resistance mutations were observed in patients with VF in the BIC/FTC/TAF group. • The risk of DC was not significantly different between the BIC/FTC/TAF (15.4%) and DTG/3TC groups (8.7%; aHR, 1.2; 95% CI: 0.71–2; *P*=0.494). • No between-group differences in weight gain were observed.	Reasons for treatment DC in the BIC/FTC/TAF and DTG/3TC groups included AEs (2.1% vs 1.9%, respectively), death (2.1% vs 1.1%), and drug-drug interaction (0.6% vs 0%). AEs that resulted in treatment DC in the BIC/FTC/TAF group were weight gain (n=4), dyslipidemia (n=2), and arthralgia (n=1); AEs that resulted in treatment DC in the DTG/3TC group were anxiety and/or insomnia (n=3), subjective lipoatrophy (n=1), cavum cancer and difficulty swallowing the pill (n=1), abdominal pain (n=1), and weight gain (n=1).

Abbreviations: ABC=abacavir; aHR=adjusted hazard ratio; DM=diabetes mellitus; HSI=hepatic steatosis index; HTN=hypertension; PS=propensity score.

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Abbreviations

3TC=lamivudine
AE=adverse event
aOR=adjusted odds ratio
ARV=antiretroviral
BIC=bictegravir
c/mL=copies per mL
CD=cluster of differentiation
CKD-EPI=Chronic Kidney Disease Epidemiology Collaboration
COBI=cobicistat
CVF=confirmed virologic failure
DC=discontinuation
DRAE=drug-related adverse event
DTG=dolutegravir
DXA=dual-energy X-ray absorptiometry
EFV=efavirenz
FTC=emtricitabine
HOMA-IR=Homeostatic Model Assessment for Insulin Resistance
HR=hazard ratio
hs-CRP=high-sensitivity C-reactive protein
IL-6=interleukin-6
INSTI=integrase strand transfer inhibitor
ITT-E=intent-to-treat exposed
KT=kynurenine/tryptophan
NRTI=nucleos(t)ide reverse transcriptase inhibitor
OPERA=Observational Pharmaco-Epidemiology Research and Analysis
PWH=people with HIV
SAE=serious adverse event
sDQS=Short Diet Quality Screener
TAF=tenofovir alafenamide
TC=total cholesterol
TDF=tenofovir disoproxil fumarate
TG=triglycerides
TRAE=treatment-related adverse event
VF=virologic failure
VL=viral load
VS=virologically suppressed

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Biktarvy US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

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🖱 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🖱 www.accessdata.fda.gov/scripts/medwatch

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