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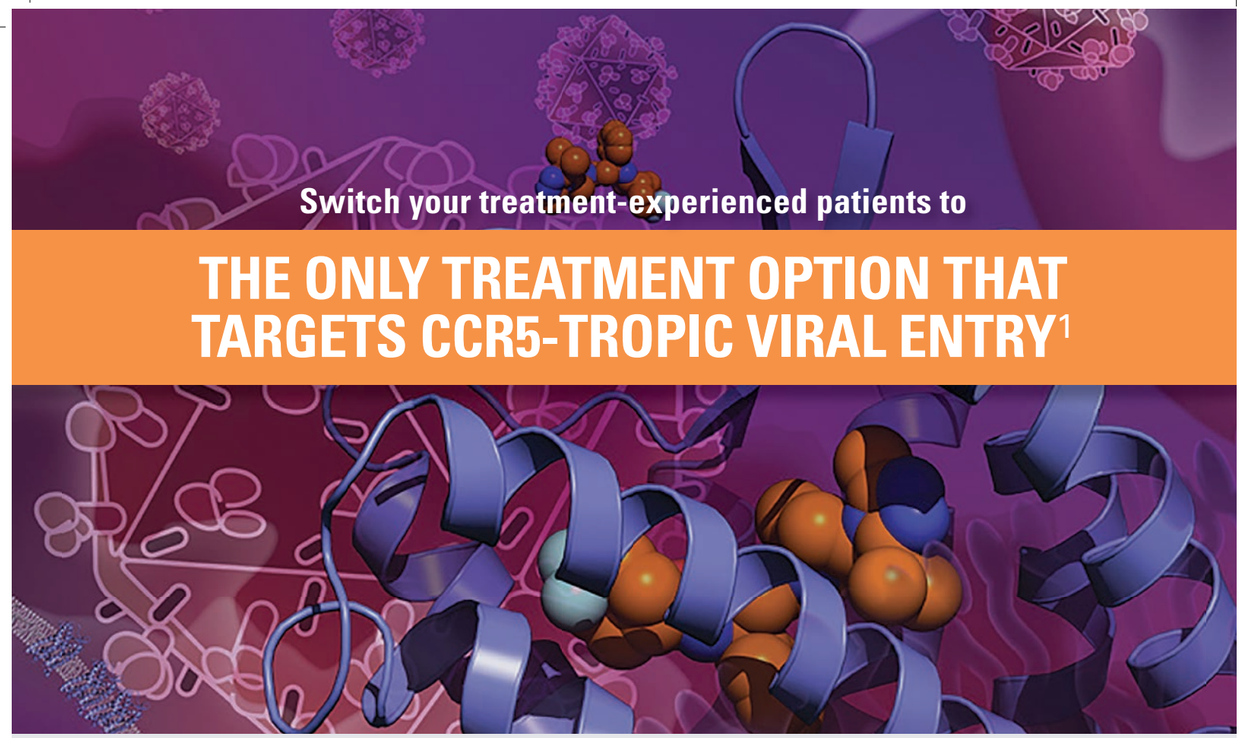

Switch your treatment-experienced patients to

THE ONLY TREATMENT OPTION THAT TARGETS CCR5-TROPIC VIRAL ENTRY[1]

Celsentri is indicated for your treatment-experienced adult patients with CCR5-tropic HIV-1 infection in combination with other ARVs.

Celsentri is a well-tolerated treatment option that has no cross-resistance to other ARV classes.[1,2]

CELSENTRI® (maraviroc) tablets

The image above shows the antiretroviral drug maraviroc (depicted in orange) binding to the CCR5 receptor. CCR5 with bound maraviroc is stabilized in an inactive conformation which prevents HIV from using the receptor for cell entry.[3,4]

Celsentri® maraviroc 150mg and 300mg tablets

Prescribing Information

See Summary of Product Characteristics (SPC) before prescribing.

Indication: HIV in >18 years as part of combination therapy for treatment-experienced adults with only CCR5-tropic HIV-1. **Dosage and administration:** CCR5 tropism status must be confirmed shortly before starting Celsentri. *Adults:* Orally: Celsentri 150 mg, 300 mg or 600 mg twice daily depending on interactions with co-administered antiretroviral therapy and other medicinal products (see SPC). Celsentri can be taken with or without food. *Elderly:* Limited data in 65+ yrs. *Renal impairment:* Caution and adjust Celsentri dosage interval in patients with creatinine clearance < 80ml/min taking potent CYP3A4 inhibitors (see SPC). *Hepatic impairment:* Caution due to lack of data. **Contraindications:** hypersensitivity to any ingredient (including peanut or soya). **Warnings and precautions:** Risk of severe skin & hypersensitivity reactions. Discontinue Celsentri and other suspect agents immediately if suspected. Not recommended in treatment naïve patients. Adjust Celsentri dose and/or dose interval when co-administered with interacting medication. Risk of dose-related dizziness: caution patients with a history of postural hypotension or receiving medicines known to lower blood pressure. Risks of osteonecrosis, immune reactivation syndrome, potential effect on immunity. Use Celsentri with caution in patients with severe cardiovascular disease, severe renal insufficiency, reduced hepatic function, significant underlying liver disorders, hepatitis B/C co-infection or renal impairment due to lack of data. Consider discontinuation of Celsentri in any patient with signs or symptoms of acute hepatitis. Celsentri contains soya lecithin. **Interactions:** Celsentri is a substrate of (but does not inhibit or induce) CYP3A4. See SPC for dose adjustment guidance when co-administering Celsentri with CYP3A4 inhibitors and/or inducers. Use with fosamprenavir/ritonavir, St John's Wort or two inducers (e.g. rifampicin + efavirenz) not recommended. Caution with dabigatran etexilate. **Pregnancy and lactation:** Not recommended. Avoid breast-feeding. **Side effects:** See SPC for full details. Nausea, diarrhoea, fatigue, headache, abdominal pain, flatulence, rash, asthenia, insomnia, depression, anorexia, anaemia and increased levels of alanine aminotransferase and aspartate. Rarely, neoplasms, blood disorders, cardiac disorders, hepatotoxicity, Stevens Johnson syndrome, toxic epidermal necrolysis, muscle atrophy. **Basic NHS cost:** 150mg: 60 tablets £519.14 EU/1/07/418/003; 300mg : 60 tablets £519.14 EU/1/07/418/008. MA holder: ViiV Healthcare UK Ltd, 980 Great West Road, Brentford, Middlesex TW8 9GS. Further information available from Customer Contact Centre, GlaxoSmithKline UK Ltd, Stockley Park West, Uxbridge, Middlesex UB11 1BT.

POM | S1A

Celsentri is a registered trademark of the ViiV Healthcare Group of Companies.

Date of Approval: October 2016

Zinc code: UK/MVC/0007/13(3)

Adverse events should be reported. For the UK, reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.

Adverse events should be reported. For Ireland, adverse events should be reported directly to the HPRA; Freepost, Pharmacovigilance Section, Health Products Regulatory Authority, Earlsfort Terrace, Dublin 2, Tel: +353 1 676 4971, medsafety@hpra.ie. Adverse events should also be reported to GlaxoSmithKline on 1800 244 255.

References: 1. Gulick RM, Lalezari J, Goodrich J, et al. Maraviroc for previously treated patients with R5 HIV-1 infection. *N Engl J Med.* 2008;359(14):1429-1441. **2.** Dorr P, Westby M, Dobbs S, et al. Maraviroc (UK-427,857), a potent, orally bioavailable, and selective small molecule inhibitor of chemokine receptor CCR5 with broad-spectrum antihuman immunodeficiency virus type 1 activity. *Antimicrob Agents Chemother.* 2005;49(11):4721-4732. **3.** Tan Q, Zhu Y, Li J, et al. Structure of the CCR5 chemokine receptor—HIV entry inhibitor maraviroc complex. *Science.* 2013;341:1387-1390. **4.** The Scripps Research Institute. Molecular structure reveals how HIV infects cells. http://www.scripps.edu/news/press/2013/20130912stevens.html. Published September 12, 2013. Accessed January 9, 2017.

ViiV Healthcare

Date of preparation: January 2017 VIIV/MVC/0004/16

PRESCRIBING INFORMATION: Consult the Summary of Product Characteristics (SPC) before prescribing.
Descovy®▼ emtricitabine 200mg/ tenofovir alafenamide 10mg or 25mg film coated tablets.
Indication: In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults & adolescents (aged 12 years & older weighing at least 35 kg). **Dosage:** Adults & adolescents (aged ≥ 12 years, weighing at least 35 kg): One tablet, once daily, orally with or without food. The dose of Descovy should be administered according to the third agent in the HIV treatment regimen. Please consult the SPC for further information. Children (< 12 years or weighing < 35 kg): Safety & efficacy has not been established. Elderly: No dose adjustment is required. Renal: No dose adjustment is required in adult or adolescent patients (aged ≥ 12 years, weighing at least 35 kg) with estimated creatinine clearance (CrCl) ≥ 30 mL/min. In patients with CrCl < 30 mL/min: not recommended. Should be discontinued in patients whose CrCl declines to < 30 mL/min during treatment. Hepatic: Mild/moderate hepatic impairment: no dose adjustment required. Severe hepatic impairment: not recommended. **Contraindications:** Hypersensitivity to the active substances or to any excipients. **Warnings & Precautions:** Safety & efficacy in HBV/HCV co-infection has not been established. Co-infected HIV/HBV patients should be closely monitored for at least several months following discontinuation for symptoms of severe acute exacerbations of hepatitis. Descovy should be avoided in antiretroviral patients with HIV-1 harbouring the K65R mutation. Risks of mitochondrial dysfunction, immune reactivation syndrome, opportunistic infections, osteonecrosis with CART therapy. **Interactions:** Co-administration with certain anticonvulsants (e.g. carbamazepine, oxcarbazepine, phenobarbital & phenytoin), antimycobacterials (e.g. rifampicin, rifabutin & rifapentine), boceprevir, telaprevir, St. John's wort and HIV PIs other than atazanavir, lopinavir and darunavir is not recommended. Should not be administered concomitantly with medicines containing tenofovir disoproxil (as fumarate), lamivudine or adefovir dipivoxil. Co-administration of emtricitabine with medicinal products that are eliminated by active tubular secretion may increase concentrations of emtricitabine. Medicinal products that decrease renal function may increase concentrations of emtricitabine. Medicinal products that induce P-glycoprotein (P-gp) are expected to decrease the absorption of tenofovir alafenamide, resulting in decreased plasma concentration of tenofovir alafenamide, which may lead to loss of therapeutic effect of Descovy and development of resistance. Co-administration with medicinal products that inhibit P-gp are expected to increase the absorption and plasma concentration of tenofovir alafenamide. Tenofovir alafenamide is a substrate of OATP1B1 and OATP1B3 *in vitro*. The distribution of tenofovir alafenamide in the body may be affected by the activity of OATP1B1 and OATP1B3. **Pregnancy & lactation:** Use in pregnancy only if potential benefit justifies the potential risk to the foetus. Breast-feeding: not recommended. **Side effects:** Refer to SPC for full information regarding side effects. Very common (≥1/10): Nausea. Common (≥1/100 to <1/10): Headache, dizziness, diarrhoea, vomiting, abdominal pain, flatulence, abnormal dreams, rash & fatigue. Uncommon (≥1/1000 to <1/100): anaemia, arthralgia, dyspepsia, angioedema & pruritus. **Legal Category:** POM. **Pack:** Bottle of 30 film-coated tablets. **Price:** UK NHS List Price – £355.73; Eire/Ireland – €587.98. **Marketing Authorisation Number:** EU/1/16/1099/001; EU/1/16/1099/003. Further information is available from Gilead Sciences Ltd, 280 High Holborn, London, WC1V 7EE, UK; Telephone: +44 (0) 8000 113700, For Ireland: +353 214 825 999. E-mail: ukmedinfo@gilead.com. Descovy is a trademark. **Date of approval:** June 2016; FTAF/UK/16-03/MM/1052(1).

▼ This medicinal product is currently subject to additional monitoring. Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse reactions to Descovy should be reported to Gilead via email to Safety_FC@gilead.com or by telephone +44 (0) 1223 897500.

PRESCRIBING INFORMATION: Consult the Summary of Product Characteristics before prescribing.
GENVOYA®▼ elvitegravir 150mg/cobicistat 150mg/emtricitabine 200mg/ tenofovir alafenamide 10mg film coated tablets.
Indication: Treatment of HIV-1 infection in adults & adolescents (aged 12 years & older weighing at least 35 kg) without any known mutations associated with resistance to the integrase inhibitor class, emtricitabine or tenofovir. **Dosage:** Adults & adolescents (aged ≥ 12 years, weighing at least 35 kg): One tablet, once daily, orally & whole with food. Children (< 12 years or weighing < 35 kg): Safety & efficacy has not been established. Elderly: No dose adjustment is required. Renal: No dose adjustment is required in adult or adolescent patients (aged ≥ 12 years, weighing at least 35 kg) with estimated creatinine clearance (CrCl) ≥ 30 mL/min. In patients with CrCl < 30 mL/min: not recommended. Should be discontinued in patients whose CrCl declines to < 30 mL/min during treatment. Hepatic: Mild/moderate hepatic impairment: no dose adjustment required. Severe hepatic impairment: not recommended. **Contraindications:** Hypersensitivity to the active substances or to any excipients. Co-administration with alfuzosin, amiodarone, quinidine, carbamazepine, phenobarbital, phenytoin, rifampicin, dihydroergotamine, ergometrine, ergotamine, cisapride, St. John's wort, lovastatin, simvastatin, pimozide, sildenafil for treatment of pulmonary arterial hypertension & oral midazolam & triazolam. **Warnings & Precautions:** Should not be co-administered with other antiretroviral products. Safety & efficacy in HBV/HCV co-infection has not been established. Co-infected HIV/HBV patients should be closely monitored for at least several months following discontinuation for symptoms of severe acute exacerbations of hepatitis. Should not be administered concomitantly with medicines containing tenofovir disoproxil (as fumarate), lamivudine or adefovir for treatment of HBV infection. Patients with galactose intolerance, Lapp lactase deficiency & glucose-galactose malabsorption should not take Genvoya. Women of childbearing potential should use either a hormonal contraceptive containing at least 30 µg ethinylestradiol & norgestimate as the progestagen or an alternative reliable method of contraception. Risks of mitochondrial dysfunction, immune reactivation syndrome, opportunistic infections, osteonecrosis with nucleoside analogues & CART therapy. **Interactions:** Co-administration with medicines that induce/inhibit CYP3A may affect the exposure of elvitegravir by decreasing its plasma concentrations leading to a reduced therapeutic effect of Genvoya. Cobicistat is an inhibitor of CYP3A & is a CYP3A substrate. Medicines highly dependent on CYP3A metabolism & have high first pass metabolism are most susceptible to large increases in exposure when co-administered with cobicistat. Medicines that inhibit CYP3A may decrease the clearance of cobicistat, resulting in increased plasma concentrations of cobicistat. Co-administration with medicines that are substrates of P-gp, BCRP, OATP1B1 & OATP1B3 may result in increased plasma concentrations of these products. Medicines that decrease renal function may increase concentrations of emtricitabine. **Pregnancy & lactation:** Should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. It should not be used during breast-feeding. **Side effects:** Refer to SPC for full information regarding side effects. Very common (≥1/10): Nausea. Common (≥1/100 to <1/10): Headache, dizziness, diarrhoea, vomiting, abdominal pain, flatulence, abnormal dreams, rash & fatigue. Uncommon (≥1/1000 to <1/100): anaemia, depression, dyspepsia, angioedema & pruritus. **Legal Category:** POM. **Pack:** Bottle of 30 film-coated tablets. **Price:** UK NHS List Price - £879.51; Eire/Ireland – €1266.00. **Marketing Authorisation Number:** EU/1/15/1061/001 Further information is available from Gilead Sciences Ltd, 280 High Holborn, London, WC1V 7EE, UK; Telephone: +44 (0) 8000 113700. E-mail: ukmedinfo gilead.com. Genvoya is a trademark. **Date of approval:** July 2016. Job Bag No: TAF/UK/15-09/MM/1098(1).

▼ This medicinal product is currently subject to additional monitoring. Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse reactions to Genvoya should be reported to Gilead via email to Safety_FC@gilead.com or by telephone +44 (0) 1223 897500.

PRESCRIBING INFORMATION: Consult the Summary of Product Characteristics (SPC) before prescribing.
Odefsey®▼ emtricitabine 200mg/ rilpivirine 25mg/ tenofovir alafenamide 25mg film coated tablets.
Indication: Treatment of HIV-1 infection in adults & adolescents (aged 12 years & older weighing at least 35 kg) without any known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor class, tenofovir or emtricitabine and with a viral load ≤ 100,000 HIV-1 RNA copies/mL. **Dosage:** Adults & adolescents (aged ≥ 12 years, weighing at least 35 kg): One tablet, once daily, orally with food. Children (< 12 years or weighing < 35 kg): Safety & efficacy has not been established. Elderly: No dose adjustment is required. Renal: No dose adjustment is required in adult or adolescent patients (aged ≥ 12 years, weighing at least 35 kg) with estimated creatinine clearance (CrCl) ≥ 30 mL/min. In patients with CrCl < 30 mL/min: not recommended. Should be discontinued in patients whose CrCl declines to < 30 mL/min during treatment. Hepatic: Mild/moderate hepatic impairment: no dose adjustment required. Use with caution in patients with moderate hepatic impairment. Severe hepatic impairment: not recommended. **Contraindications:** Hypersensitivity to the active substances or to any excipients. Use with medicines that can result in significant decreases in rilpivirine plasma concentrations (due to cytochrome P450 [CYP]3A enzyme induction or gastric pH increase), which may result in loss of therapeutic effect of Odefsey including: carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampicin, rifapentine, omeprazole, esomeprazole, dexlansoprazole, lansoprazole, pantoprazole, rabeprazole, dexamethasone (oral and parenteral doses), except as a single dose treatment, St. John's wort. **Warnings & Precautions:** There are insufficient data to justify the use in patients with prior NNRTI failure. Resistance testing and/or historical resistance data should guide the use of Odefsey. At supratherapeutic doses (75 mg once daily and 300 mg once daily), rilpivirine has been associated with prolongation of the QTc interval of the electrocardiogram (ECG). Should be used with caution when co-administered with medicines with a known risk of Torsade de Pointes. Safety & efficacy in HBV or HCV co-infection has not been established. Co-infected HIV/HBV patients should be closely monitored with both clinical and laboratory follow up for at least several months following discontinuation for symptoms of severe acute exacerbations of hepatitis. The safety and efficacy of Odefsey in patients with significant underlying liver disorders have not been established. Risks of mitochondrial dysfunction, immune reactivation syndrome, opportunistic infections, osteonecrosis with CART therapy. Should not be co-administered with other antiretroviral medicines or with other medicines containing tenofovir alafenamide, lamivudine, tenofovir disoproxil (as fumarate) or adefovir dipivoxil. **Interactions:** Co-administration of emtricitabine with medicines that are eliminated by active tubular secretion may increase concentrations of emtricitabine and/or the co-administered medicines. Medicines that decrease renal function may increase concentrations of emtricitabine. Rilpivirine is primarily metabolised by CYP3A. Medicines that induce or inhibit CYP3A may thus affect the clearance of rilpivirine. Medicines that induce P-glycoprotein (P-gp) are expected to decrease the absorption of tenofovir alafenamide, resulting in decreased plasma concentration of tenofovir alafenamide, which may lead to loss of therapeutic effect of Odefsey and development of resistance. Co-administration with medicines that inhibit P-gp are expected to increase the absorption and plasma concentration of tenofovir alafenamide. Tenofovir alafenamide is a substrate of OATP1B1 and OATP1B3 *in vitro*. The distribution of tenofovir alafenamide in the body may be affected by the activity of OATP1B1 and OATP1B3. **Pregnancy & lactation:** Use in pregnancy only if potential benefit justifies the potential risk to the foetus. Breast-feeding; not recommended. **Side effects:** Refer to SPC for full information regarding side effects. Very common (≥1/10): increased total cholesterol (fasted), increased LDL cholesterol (fasted), insomnia, headache, dizziness, nausea, increased pancreatic amalyse, increased transaminases (AST and/or ALT). Common (≥1/100 to <1/10): decreased white blood cell count, decreased haemoglobin, decreased platelet count, decreased appetite, increased triglycerides (fasted), depression, abnormal dreams, sleep disorders, depressed mood, somnolence, abdominal pain, vomiting, increased lipase, abdominal discomfort, dry mouth, flatulence, diarrhoea, increased bilirubin, rash, fatigue. Uncommon (≥1/1000 to <1/100): anaemia, immune reactivation syndrome, dyspepsia, severe skin reactions with systemic symptoms, angioedema, pruritus, arthralgia. **Legal Category:** POM. **Pack:** Bottle of 30 film-coated tablets. **Price:** UK NHS List Price – £525.95; Eire/Ireland – TBC. **Marketing Authorisation Number:** EU/1/16/1112/001; EU/1/16/1112/002. Further information is available from Gilead Sciences Ltd, 280 High Holborn, London, WC1V 7EE, UK; Telephone: +44 (0) 8000 113700, For Ireland: +353 214 825 999. E-mail: ukmedinfo@gilead.com. Odefsey is a trademark. **Date of approval:** June 2016; ODE/UK/16-05/MM/1015.

▼ This medicinal product is currently subject to additional monitoring. Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse reactions to Odefsey should be reported to Gilead via email to Safety_FC@gilead.com or by telephone +44 (0) 1223 897500.

PRESCRIBING INFORMATION Consult the Summary of Product Characteristics before prescribing.
TRUVADA® emtricitabine 200mg/tenofovir disoproxil (as fumarate) film coated tablets.
Indications: In antiretroviral combination therapy for treatment of HIV-1 infected adults. In combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in adults at high risk. **Dosage:** Adults: One tablet once daily. Paediatric population (<18 years): Safety & efficacy has not yet been established. Elderly: No dose adjustment required. Renal impairment: exposure to emtricitabine and tenofovir increases in individuals with renal dysfunction, refer to SPC for dosing recommendations. **Contraindications:** Hypersensitivity to emtricitabine, tenofovir disoproxil fumarate (TDF), or any of the excipients. Use of Truvada for PrEP in individuals with unknown or positive HIV-1 status. **Warnings and Precautions:** *Transmission of HIV:* While effective viral suppression with antiretroviral therapy has been proven to substantially reduce the risk of sexual transmission, a residual risk cannot be excluded. Precautions to prevent transmission should be taken in accordance with national guidelines. Truvada is not always effective in preventing the acquisition of HIV-1. The time to onset of protection after commencing Truvada is unknown. Truvada should only be used for PrEP as part of an overall HIV-1 infection prevention strategy including the use of other HIV-1 prevention measures (e.g. consistent and correct condom use, knowledge of HIV-1 status, regular testing for other sexually transmitted infections). *Risk of resistance with undetected HIV-1 infection:* Truvada should only be used to reduce the risk of acquiring HIV-1 in individuals confirmed to be HIV negative. Individuals should be re-confirmed to be HIV-negative at frequent intervals (e.g. at least every 3 months) using a combined antigen/antibody test while taking Truvada for pre-exposure prophylaxis. *Adherence:* HIV-1 uninfected individuals should be counselled to strictly adhere to the recommended dosing schedule. The effectiveness of Truvada in reducing the risk of acquiring HIV-1 is strongly correlated with adherence as demonstrated by measurable drug levels in blood. *Renal:* Renal failure and impairment, elevated creatinine, hypophosphataemia and proximal tubulopathy (including Fanconi syndrome) have been reported with use of TDF in clinical practice. It is recommended that CrCl is calculated in all patients prior to therapy initiation and renal function monitored after 2 to 4 weeks of treatment, after 3 months of treatment and every 3 to 6 months thereafter. In patients at risk of renal impairment, a more frequent monitoring of renal function is required. Truvada for PrEP has not been studied in HIV-1 uninfected individuals with creatinine clearance < 60 mL/min and is therefore not recommended for use in this population. Risk-benefit assessment and monitoring of renal function is needed when Truvada is used for treatment of HIV-1 in patients with CrCl <60ml/min. Monitor for signs of toxicity and changes in viral load following introduction of Truvada at prolonged dosing intervals. If CrCl is decreased to <50ml/min (for HIV-1 infected patients) or < 60ml/min (use as PrEP) or serum phosphate is decreased to <1.5mg/dl, renal function should be re-evaluated within one week. Consideration should also be given to interrupting treatment with in individuals with CrCl decreased to < 50 ml/min (for HIV-1 infected patients) or <60ml/min (use as PrEP) or decreases in serum phosphate to < 1.0 mg/dl (0.32 mmol/l). Interrupting treatment should also be considered in case of progressive decline of renal function when no other cause has been identified. Avoid with concurrent or recent use of nephrotoxic medicinal product. If concomitant use with nephrotoxic agents is unavoidable, monitor renal function weekly. If co-administered with a NSAID, renal function should be monitored adequately. A higher risk of renal impairment has been reported in patients receiving TDF in combination with a ritonavir or cobicistat boosted protease inhibitor. A close monitoring of renal function is required in these patients. HBV or HCV co-infection: patients should be closely monitored for at least several months following discontinuation of Truvada for symptoms of exacerbation of hepatitis. The safety and efficacy of Truvada for PrEP in patients with HBV/HCV co-infection has not been established. Use with HCV antivirals: Co-administration of TDF with ledipasvir/sofosbuvir has been shown to increase plasma concentrations of tenofovir, especially when used together with an HIV regimen containing TDF and a pharmacokinetic enhancer (ritonavir or cobicistat). The safety of TDF in this setting has not been established. Assess potential risks and benefits of use particularly in patients at increased risk of renal dysfunction. Patients should be monitored for adverse reactions related to TDF. Hepatic: Patients with pre-existing liver dysfunction should be monitored; interruption or discontinuation of treatment must be considered if evidence of worsening liver disease. Other: Weight and levels of blood lipids and glucose may increase during antiretroviral therapy. Monitor blood lipids & glucose as per HIV treatment guidelines. Manage lipid disorders as clinically appropriate. Rare hereditary galactose intolerance, the Lapp lactase deficiency, glucose-galactose malabsorption. Mitochondrial dysfunction (*in utero* exposure). Immune Reactivation Syndrome. Osteonecrosis. Decreased bone mineral density and bone abnormalities. Avoid in antiretroviral experienced patients with strains harbouring K65R mutation. Consult the SPC before prescribing. **Interactions:** As a fixed combination, Truvada should not be administered concomitantly with medicinal products containing emtricitabine, TDF tenofovir alafenamide, cytidine analogues such as lamivudine or adefovir dipivoxil. Low potential for CYP450 mediated interactions with other medicinal products. Co-administration with medicinal products that are eliminated by active tubular secretion or via the anion transporter may lead to an increase in serum concentrations of Emtricitabine or the co-administered product. For a complete list of interactions refer to SPC. **Pregnancy & lactation:** May be considered during pregnancy. Breast-feeding: not recommended. **Side effects:** *HIV-1 infection:* Very common (≥1/10): hypophosphataemia, dizziness, headache, diarrhoea, nausea, vomiting, rash, elevated creatine kinase, asthenia. Common (≥1/100, <1/10): neutropenia, allergic reaction, hypertriglyceridaemia, hyperglycaemia, insomnia, abnormal dreams, flatulence, dyspepsia, abdominal pain, elevated serum lipase, elevated amylase including elevated pancreatic amylase, abdominal distention, hyperbilirubinaemia, increased transaminases, elevated serum aspartate aminotransferase &/or elevated serum alanine aminotransferase, pruritus, maculopapular rash, urticaria, vesiculobullous rash, pustular rash and skin discolouration (increased pigmentation), pain. In addition, anaemia was common and skin discoloration very common when emtricitabine was administered to paediatric patients. *PrEP:* No new adverse reactions to Truvada were identified from two randomised placebo-controlled studies. Refer to SPC for full information regarding side effects. **Legal Category:** POM. **Pack:** Bottle of 30 film-coated tablets. **Price:** UK NHS £355.73; Eire €691.74. **Marketing Authorisation Number:** EU/1/04/305/001-2. Further information is available from the local representative of the marketing authorisation holder: Gilead Sciences Ltd, 280 High Holborn, London, WC1V 7EE, UK; Telephone: +44 (0) 8000 113700. For Ireland: +353 214 825 999. E-mail: ukmedinfo@gilead.com. Truvada is a trademark. **Date of approval:** September 2016. 164/UK/16-08/MM/1079.

Any suspected adverse reactions to Truvada should be reported to Gilead via email to Safety_FC@gilead.com or by telephone +44 (0) 1223 897500.

Adverse events should be reported. For the UK, reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

For Ireland, suspected adverse reactions should be reported to the HPRA Pharmacovigilance using a Yellow Card obtained either from the HPRA, or electronically via the website at www.hpra.ie. Adverse reactions can also be reported to the HPRA by calling +353 1 6764971.

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