REGIONAL STUDY DAY FEEDBACK

SUMMARIES FROM THE EAST ANGLIA REGIONAL STUDY DAY

IATROGENIC CUSHING'S

RETROSPECTIVE CASE REVIEW OF IATROGENIC CUSHINGS & ANDRENAL INSUFFICIENCY

BHIVA/BASHH FEEDBACK

EXPERIENCES FROM A FIRST NATIONAL CONFERENCE ATTENDANCE

HIVPA NEWS

LATEST UPDATES FROM THE COMMITTEE

HIVPA

HIV Pharmacy Association

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HIVPA News

Hello and welcome to the HIVPA bulletin! We've become accustomed to online virtual spaces as a meeting points for learning, sharing and networking over the past year. Spring 2021 has been packed with engaging events such as CROI, CPC and spring BHIVA/BASHH, including presentations from HIVPA members! While these highlight the ability of the HIV field to adapt to the changing situation, I for one, look forward to a time where we can all meet in person.

A huge thanks to all those who have found the time to contribute to this edition. As always I welcome any contributions, no matter the size. If you have been involved in a project, attended a conference, enjoyed recent success or have any suggestions please get in touch directly at yemi.daramola@nhs.net. It would be great to hear about different experiences over the last year and of any permanent changes as a result.

Yemi Daramola, HIVPA Bulletin Lead

HIVPA CONFERENCE

Due to uncertainty as a result of the COVID-19 pandemic, the HIVPA committee have decided to postpone the conference until the autumn of 2021. More information will be disseminated later in the year with full details of the event. Keep an eye out for updates on the HIVPA website or via email.
https://hivpa.org/hivpa-conference-2021/

BHIVA COVID-19 STATEMENTS

COVID vaccine effectiveness in people with HIV

Data on how protective the COVID vaccines are in people with HIV remains limited but there is some data from a pre-print of a study of the Astra Zeneca vaccine in 54 men living with well-controlled HIV ...
https://www.bhiva.org/covid-risk-and-vaccine-updates-may-2021

CHIVA AFFILIATE MEMBERSHIP

CHIVA have revamped their membership structure and now includes a new free-of-charge affiliate membership. The membership enables members to receive CHIVA newsletters, bulletins and updates.
https://www.chiva.org.uk/ourworkprof/chiva-membership/

VIRTUAL EDUCATIONAL CONTENT

HIVPA Virtual Education Events

A reminder that recordings of the virtual educational events which replaced the HIVPA study days are available to watch online. Links can be found on the HIVPA eHIVe site.
https://ehive.hivpa.org/training-modules/

Virology Education and AME

Virology Education have produced a catalogue of free to access HIV related online educational content in addition to organising virtual meetings and conferences.
https://academicmedicaleducation.com/

CROI 2021 webcasts

For those who were unable to attend BHIVA's CROI feedback sessions, or wish to catch up with some of the data presented at the conference. The BHIVA feedback session is available online via the BHIVA website and webcasts of the CROI presentations are available also.
http://www.croiwebcasts.org/y/2021
https://www.bhiva.org/BestofCROI2021

BHIVA/BASHH PEP GUIDELINES

BHIVA & BASHH have released updated guidance on post exposure prophylaxis recommending tenofovir-disoproxil and raltegravir 1200mg OD as the preferred PEP regimen. In conjunction, HIVPA have developed a new patient information leaflet to which services can add their contact information.

https://hivpa.org/wp-content/uploads/2021/04/HIVPA-PEP-PIL-April-2021-generic-TDF-FTC-RAL-OD-Final.pdf

Please be aware that any promotional content of this bulletin is not the responsibility of HIVPA

SPONSORS

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Dr Reddy's Laboratories

HIVPA Study Days

Dates and Topics for 2021

HIV and paediatrics **SEPTEMBER**

Mental health – practicalities, prison, managing vulnerability, chemsex **NOVEMBER**

Recordings of past study events can be accessed via the eHIVe site

Due to the COVID-19 pandemic and national restrictions, the HIVPA study days will be replaced by a series of online pre-recorded sessions from expert speakers. The talks will be released simultaneously on a date in the designated month and members will be notified by email once the presentations are available on the eHIVE site.

Any further changes to the educational format will be communicated nearer the time.

Previous feedback comments from study day attendees:

Very informative and highlights areas that may not be experienced in each clinic.

A very interesting and extremely informative meeting.

Very informative study day, lots of very useful information + some very impressive speakers. Starting later a good idea in terms of travel. Thanks!

Dates for your dairy

11th IAS 2021 (IAS 2021)

Berlin & Virtual, 18 - 21 July 2021

https://www.ias2021.org

15th Annual CHIVA Conference

London & Virtual, 15th September 2021

https://www.chiva.org.uk/ourworkprof/conferences/

IDWeek 2021

Virtual, 29th October - 3rd October 2021

https://idweek.org/

18th European AIDS Conference (EACS 2021)

London & Virtual, 27– 30 October 2021

https://eacs-conference2021.com/

BHIVA Autumn Conference — details TBC

East Anglia Regional Study Day – January 2021

A regional Study Day was held in East Anglia in January. Organised and chaired by Portia Jackson, HIVPA Regional Lead and Regional Representative for East Anglia, the event was kindly sponsored by Gilead Sciences Ltd and well-attended by specialist pharmacists and nurses, pharmacy technicians and clinical psychologists working in the field across the region.

Community experience of HIV during the COVID-19 pandemic

The day began with a presentation delivered by Chris Woolls, Director, River House Trust and Susan Cole-Haley, Patient and Community Group Engagement Lead, National AIDSMAP (NAM) reflecting on the community experience of HIV during the COVID-19 pandemic. Chris presented the results of a survey run in January 2021 exploring the impact of COVID-19 on older people living with HIV (PLWH), all of whom were River House members. This examined the impact of pandemic on daily life, accessing care and antiretroviral therapy (ART), finances and mental health, the challenges of social isolation and loneliness, and thoughts about the vaccine. Ninety per cent of the 97 respondents reported no problems in accessing care/medication and the majority were happy or very happy with communications from their clinic. However, seventy per cent reported that their finances had been negatively affected to some degree by the pandemic and a significant majority reported feeling more isolated and lonely and that their mental health was now worse or much worse as a result. The majority of respondents were keen or very keen to be vaccinated against COVID-19 but just under

10% reported being unwilling or not keen to be vaccinated and approximately 13% were undecided.

Susan's presentation supplemented this by providing an overview of experiences of the pandemic of those in the community in terms of the personal impact on their care and emotional well-being and on the concerns of people from BAME communities. She also outlined some of the innovations that NAM have introduced to engage with PLWH in response to the pandemic, including new virtual broadcasts and aidsmapCHAT with international expert guests and views from around the world. She also referred to aidsmapWOMEN, a resource launched specifically to support women. The session highlighted the considerable impact of the pandemic on PLWH and the challenges it has presented, whilst also demonstrating the diverse range of opinions and experiences across this patient cohort.

Gilead—Autumn conference feedback

A session presented by Ross Hamilton-Shaw, Medical Scientist, Gilead Sciences Ltd followed, providing feedback from the Autumn Conference season 2020. A summary of a number of key studies was presented covering a wide range of topical issues, including risk of mortality in PLWH hospitalised with COVID-19, meeting the fourth 90, menopause and frailty. In addition, updated data from the BRAAVE 2020 study (W48), pooled GEMINI 1 and 2 Studies (W144), the TRIO health study, Owen Clinic Study and real world data from the BICSTaR Cohort was presented. This provided a valuable and interesting synopsis of some of the key messages and hot topics emanating from the autumn conference season.

East Anglia Regional Study Day – January 2021

Mental Health & HIV Case Study

In the afternoon, Dr Mas Chaponda, Consultant in Infectious Diseases, and Eimear Railton, Clinical Nurse Specialist, both from the Royal Liverpool University Hospital joined forces to present a case-study based session looking at mental health and sleep disturbance in HIV. They examined the prevalence of psychological problems among PLWH and the additional risk factors for this, the evidence for sleep disorders in PLWH and the negative impact that poor mental health can have upon physical health, treatment adherence, productivity and healthcare resources. It also looked at the used of various tools employed for screening for mental health conditions, including The Wellness Thermometer, General Anxiety Disorder-7 (GAD-7) screen, PHQ-9 screen for depression and the Sleep-o-meter, and reviewed the stepped care model for managing anxiety, depression and sleep disturbances. The session concluded that by looking at the role of ART and central nervous system impairment, highlighting how the selection of ART can further compound this challenge for PLWH and outlining various clinical trials investigating the association between various antiretrovirals and neuropsychiatric adverse effects and discontinuation rates resulting from these. The session highlighted that mental health issues in PLWH may be associated with risk of HIV infection itself or with adaption to, and living with, HIV, and how they may be a predictor of health outcomes.

Reflection on practice during the pandemic

The day drew to a close with an interactive session reflecting on our own experiences of practicing during the pandemic. We explored the challenges that have presented, how we have navigated our way through these and the changes and innovations in practice we have adopted which we feel have improved the quality of patient care. We considered the impact of these on both clinicians delivering care and patients.

Overall feedback from the study day was very positive with attendees reporting finding it enjoyable and informative and very much valuing having the forum it provided to learn. Attendees valued the opportunity to reflect on the last year, the impact it has had, and to share these experiences with multi-disciplinary colleagues working across the region.

Portia Jackson, Lead Pharmacist iCaSH
HIVPA Regional Lead and Regional Representative for East Anglia

Conference Feedback— First BHIVA/BASHH

It was only my first year working in the HIV field last year. Understandably, I was very excited to receive the notification of my abstract acceptance at the BHIVA 2020 Conference. Little did I know, the COVID-19 pandemic was to become the spotlight of the world. The BHIVA Spring Conference 2020 was subsequently cancelled.

One year later, I was fortunate enough to attend the 5th Joint BHIVA/BASHH Conference virtually. Due to high viewing demands, there were some minor technical issues throughout the programme. However, overall it was a very enjoyable experience. I was able to immerse myself in the ocean of knowledge, learning from experts of various backgrounds.

Conference Feedback— First BHIVA/BASHH

One of my favourite talks, amongst the pharmacokinetic considerations of injectables and many others, was the clinic-pathological case and patient perspective. It was very interesting to look at the case from both the patient and the clinical team perspective. It highlighted the importance of having a shared agenda and involving patients into the decision-making process. The patient originally presented with neck pain, however, this has led to a series of invasive diagnostic tests for over 5 months. Both parties were frustrated towards the end. The patient became noticeably depressed as she was getting endless procedures every day; on the other hand, the team was unable to obtain a confirmed diagnosis from the existing test results which hindered on treatment planning. Ultimately, the decision to stop investigation and move to discharge planning was led by the patient. This has demonstrated fundamentally the essence of person-centred care, although this means we have to embrace the discomfort in existing in uncertainty.

Virtual conferences can be tiring. While I was learning a lot, I was reading abstracts of other people's work even during break time. With an early start at 8am until 5-6 pm finish, I realised that it was imperative to have some breaks in between. It would be helpful if more time was allocated to poster browsing. While the abstract book was useful, I find the visual impact of posters more powerful in conveying messages to the audience. It might be beneficial to have a poster book as well along with the abstract book.

The virtual conference was made as interactive as possible. Nonetheless, I would still prefer attending a face-to-face one once we are allowed, hopefully in the near future.

Suki Leung, Specialist Pharmacist HIV/GUM
Chelsea & Westminster NHS Trust

Co-prescribing of steroids and boosted regimens: preventing the inevitable

Hasan Mohammed (CA), Nadia Naous, David Asboe, Marta Boffito

Introduction

Co-administration of systemic corticosteroids with ritonavir or cobicistat in people living with HIV (PLWH) can lead to significant increases in steroid exposure, resulting in iatrogenic Cushing's syndrome and secondary adrenal insufficiency (AI). Despite measures to raise awareness of the interaction with both patients and colleagues, co-prescribing continues to occur within our large London cohort.

Methods

Cases of steroid co-prescribing between August 2020 and January 2021 were identified using the Trust incident reporting system.

Results

10 cases were reported during the 6 month period. Short synacthen test (SST) was performed in 7/10 PLWH: two had confirmed AI; one had reduced response. Oral steroids were commenced in 3/7 PLWH.

Age, Gender, Ethnicity	Steroid / route / duration of exposure	Prescribed by	AM cortisol (>450nmol/l)	Clinical features	Outcome
49, M, Asian - Other	Fluticasone, inhaled, 9 months	GP	222	Asymptomatic	Reduced response to SST Rescue pack of steroids
42, F, Black African	Budesonide, inhaled, 5 years intermittently	GP	369	Asymptomatic	Nil
52, M, White British	Fluticasone, inhaled, 1 month	GP	<28	Fatigue	Confirmed AI Oral steroids
52, F, White British	Triamcinolone, intralesional, x1 dose	Plastics	70	Asymptomatic	Nil
53, M, White British	Budesonide, inhaled, 1 year	GP	142	Asymptomatic	Nil

Co-prescribing of steroids and boosted regimens: preventing the inevitable

72, M, White British	Fluticasone, inhaled, 2 years intermittently	GP	250	Asymptomatic	Nil
53, M, Black African	Triamcinolone, intralesional, x4 doses over 1 year	Dermatology	374	Asymptomatic	Nil
46, M, White British	Fluticasone, inhaled, 6 months	GP	30	Weight gain, fatigue, facial swelling, shortness of breath	Confirmed AI Oral steroids
47, M, Other – not stated	Fluticasone, inhaled, 2 years	GP	<28	Dizziness, abdominal pain, diarrhoea and vomiting	Normal SST Oral steroids commenced based on symptoms
48, M, White - Other	Mometasone, intranasal, 2 years	GP	273	Asymptomatic	Nil

Conclusion

Co-prescribing incidents continue to occur with harmful outcomes in PLWH. The observed increase in cases highlights the potential impact of reduced HIV services during the COVID-19 pandemic.

A revised approach is needed in providing education to patients, other specialities and primary care colleagues. Strategies we are implementing include: local and national teaching, publication in Trust safety bulletins, patient information displayed on waiting room screens and Yellow Card reporting via MHRA to trigger national safety alerts.

Hasan Mohammed, Highly Specialist Pharmacist HIV&GUM
Chelsea & Westminster NHS Trust

Celebrating International Nurses Day 2021 and International Year of the Nurse 2020

This article is contributed by Samm Kabagambe, Medical Scientist, **Gilead Sciences Ltd.**

This year, 12th May 2021 is International Nurses Day. The World Health Organisation designated 2020 - Florence Nightingale's bicentennial year- as the first ever Global Year of the Nurse and Midwife. It was an opportunity to celebrate and acknowledge the work of 28 million nurses and 2 million midwives who make up half of the health workforce globally.

Nurses and midwives make up the largest numbers of the NHS workforce. They are highly skilled, multi-faceted professionals from a host of backgrounds that represent our diverse communities. It is an opportunity to say thank you and showcase their diverse talents and expertise

As part of The Summit Webinar Series, Gilead Sciences Ltd organised a webinar dedicated to nurses, by nurses for them to share their story and recognise the value of their professions, how the roles have adapted and identify learnings from across different therapy areas.

The webinar was chaired by **Moses Shongwe** (HIV Network Lead Nurse, Barts Health)**,** with an expert panel of **Alison Kent** (Rheumatology Nurse Specialist, Salisbury), **Liz Foote** (Clinical Services Manager HIV, Royal Liverpool) **Rose Ellard** (Cellular Therapy Clinical Nurse Specialist, Royal Marsden), **Ruth Adora** (ICU Staff Nurse, St James's Dublin) and **Hannah Alexander** (National BBV Lead Nurse). The themes from this meeting – many of which will resonate with pharmacists and other healthcare professionals, are captured in the artwork below.

The past year has highlighted, more so than ever, the courageous work nurses and midwives do every day alongside other healthcare professionals. Health services worldwide are in the spotlight, and the eyes of the world are watching the irreplaceable work they do in the face of this global pandemic. If you would like to find out more about The Summit Webinar Series including details of future events please contact Samm.Kabagambe@gilead.com or Christopher.Robinson@gilead.com

UK-UNB-0185 May 2021

Dovato
dolutegravir 50 mg/
lamivudine 300 mg tablets

POWER REIMAGINED

DOVATO IS NOW REIMBURSED THROUGHOUT THE UK IN LINE WITH NHS' COMMISSIONING CRITERIA[1-3]

Dovato prescription is recommended in line with SmPC requirements and inclusion, which should be evaulated by a Healthcare Professional

DHHS

NOW A RECOMMENDED INITIAL REGIMEN[4]

Recommended as an initial regimen for most PLHIV (A1)* and as a good option for virologically suppressed patients who have no evidence of resistance to either drug

Exclusions for treatment-naive patients:†
- HIV viral load >500,000 copies/mL
- HBV co-infection
- Where ART is to be started before the results of HIV genotype resistance testing for reverse transcriptase or HBV testing are available

EACS

NOW A RECOMMENDED INITIAL REGIMEN[5]

Recommended as an initial regimen for treatment-naïve patients and as a switch strategy for virologically suppressed patients

Requirements for treatment-naive patients:†
- HBsAg negative
- HIV viral load <500,000 copies/mL

IAS

NOW A RECOMMENDED INITIAL REGIMEN[6]

Recommended as an initial regimen for most people living with HIV and recommended as an appropriate switch strategy

Exclusions for treatment-naïve patients:†
- Rapid start because baseline laboratory evaluation results must be reviewed before initiation
- Chronic hepatitis B
- HIV-1 RNA >500,000 copies/mL (perhaps a CD4 T-cell count <200 cells/mm^3 although unclear)
- Patients being treated for an active opportunistic infection

***Rating of recommendation:** A=strong; **Rating of evidence:** I=data from randomised controlled trials;
†The requirements and exclusions listed here are not the full list as shown in the Dovato SmPC

DOVATO is indicated for the treatment of HIV-1 in adults and adolescents above 12 years weighing at least 40 kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine.

Prescribing Information

Adverse events should be reported. For the UK, reporting forms and information can be found at *https://yellowcard.mhra.gov.uk* or search for **MHRA Yellowcard** in the **Google Play** or **Apple App store**. Adverse events should also be reported to GlaxoSmithKline on 0800 221441.

References: 1. NHS England Clinical Commissioning Policy http://www.england.nhs.uk/publication/dolutegravir-lamivudine-for-the-treatment-of-human-immunodeficiency-virus-hiv-1-infected-adults-and-adolescents-over-12-years-of-age/ Accessed November 2020; **2.** Scottish Medicines Consortium Advice on Dovato http://www.scottishmedicines.org.uk/media/4708/dolutegravir-plus-lamivudine-dovato-abbreviated-final-august-2019-for-website.pdf Accessed November 2020; **3.** All Wales Medicines Strategy Group Advice on Dovato http://www.awmsg.org/awmsgonline/app/appraisalinfo/3659 Accessed November 2020; **4.** Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. Department of Health and Human Services. Dec 18, 2019. http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Accessed November 2020; **5.** European AIDS Clinical Society Guidelines. Version 10.1, October 2020. https://www.eacsociety.org/files/guidelines-10.1.finalsept2020. pdf Accessed November 2020; **6.** Saag MS, *et al.* JAMA 2020;324(16):1651-69.

ViiV Healthcare

Date of preparation: November 2020 | PM-GB-DLL-ADVT-200008 V3

MSD

Delstrigo® ▼ doravirine/lamivudine/tenofovir disoproxil fumarate

Pifeltro® ▼ doravirine

An option in HIV-1

Make Doravirine▼ a Part of Every Day

Flexible and Convenient Dosing[1,2]

DELSTRIGO

Tablets are not to scale

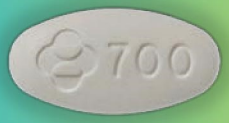
Complete regimen

Can be taken once daily, any time of day

Free of food restrictions

Doravirine does not contain a booster

PIFELTRO



Tablets are not to scale

Single agent to be used as part of a regimen with other ARVs

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DELSTRIGO®▼ Doravirine/Lamivudine/Tenofovir disoproxil fumarate

PRESCRIBING INFORMATION

Refer to Summary of Product Characteristics before prescribing)

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MSD, UK (Tel: 0208 154 8000). By clicking the above link you will leave the MSD website and be taken to the MHRA website.

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie. Adverse events should also be reported to MSD (Tel: 01-299 8700).

PRESENTATION

Pifeltro: film-coated tablet containing 100 mg doravirine.

Delstrigo: film-coated tablet containing 100 mg doravirine, 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate, equivalent to 245 mg of tenofovir disoproxil.

USES

Pifeltro: For use in combination with other antiretrovirals, for the treatment of HIV-1 without past or present evidence of resistance to non-nucleoside reverse transcriptase inhibitors (NNRTI).

Delstrigo: For the treatment of HIV-1 without past or present evidence of resistance to NNRTIs, lamivudine or tenofovir.

DOSAGE AND ADMINISTRATION

Therapy should be initiated by a physician experienced in HIV infection management. **Pifeltro:** One 100 mg tablet once daily. **Delstrigo:** One 100/300/245 mg tablet once daily. **Pifeltro and Delstrigo:** If co-administered with rifabutin or other moderate CYP3A inducers, increase doravirine dose to 100 mg twice daily (12 hours apart). **Pifeltro:** *Elderly:* No dose adjustment necessary. *Renal impairment:* No dose adjustment necessary. *Hepatic impairment:* mild to moderate: no dosage adjustment required; severe: use with caution. **Delstrigo:** *Elderly:* Special care advised. *Renal impairment:* estimated creatinine clearance (CrCl) ≥ 50 mL/min: no dose adjustment necessary; estimated CrCl <50 mL/min: not recommended. *Hepatic impairment:* mild to moderate: no adjustment required; severe hepatic: use with caution.

CONTRA-INDICATIONS

Hypersensitivity to the active substance or excipients Co-administration with strong CYP3A inducers.

PRECAUTIONS

A residual risk of sexual transmission of HIV-1 cannot be excluded and precautions should be taken in accordance with national guidelines. Use with CYP3A inducers may reduce the exposure of doravirine. Autoimmune disorders and immune reactivation syndrome have been reported in patients treated with combination antiretroviral therapy which may require investigation and treatment. Contains lactose monohydrate.

Delstrigo: Post-treatment exacerbation of HBV (including hepatic decompensation and liver failure) have been reported in patients co-infected with HIV-1 and HBV following discontinuation of lamivudine or tenofovir disproxil. Monitor patients co-infected with HIV-1 and HBV after discontinuation of Delstrigo and if appropriate initiate anti-HBV therapy. Renal impairment, including acute renal failure and Fanconi syndrome have been reported with tenofovir disoproxil. Assess estimated CrCl prior to initiation and during therapy. In patients at risk of renal dysfunction, serum phosphorus, urine glucose, and urine protein should also be assessed. Discontinue therapy if estimated CrCl declines below 50 mL/min. Avoid with concurrent or recent use of nephrotoxic medicinal products (e.g. high-dose or multiple NSAIDs). Evaluation of renal function is recommended for persistent or worsening bone pain, pain in extremities, fractures, and/or muscular pain or weakness. Assessment of bone mineral density should be considered for patients who have a history of pathologic bone fracture or other risk factors for osteoporosis or bone loss. Hypophosphatemia and osteomalacia secondary to proximal renal tubulopathy should be considered in patients at risk of renal dysfunction who present with persistent or worsening bone or muscle symptoms. Doravirine/lamivudine/tenofovir disoproxil must not be co-administered with other medicinal products containing lamivudine, tenofovir disoproxil, or tenofovir alafenamide or with adefovir dipivoxil.

Doravirine/lamivudine/tenofovir disoproxil should not be administered with doravirine unless needed for dose adjustment (e.g. co-administered with rifabutin).

Drug interactions: Refer to SmPC for full information on drug interactions. **Pifeltro and Delstrigo:** Doravirine is metabolized primarily by CYP3A. Do not co-administer with strong CYP3A enzyme inducers. If co-administerationwith rifabutin or other moderate CYP3A inducers cannot be avoided, increase doravirine dose to 100 mg twice daily (taken 12 hours apart). Use with caution when co-administering doravirine with medicinal products that are sensitive CYP3A substrates that have a narrow therapeutic window (e.g., midazolam, tacrolimus and sirolimus). **Delstrigo:** Do not administer with other antiretroviral medicinal products. Co-administration of doravirine/lamivudine/tenofovir disoproxil with medicinal products that reduce renal function or compete for active tubular secretion may increase serum concentrations of lamivudine. Co-administration of doravirine/lamivudine/tenofovir disoproxil with medicinal products that reduce renal function or compete for active tubular secretion via OAT1, OAT3 or MRP4 may increase serum concentrations of tenofovir. Avoid with concurrent or recent use of nephrotoxic medicinal products.

Pregnancy and Lactation: **Pifeltro and Delstrigo:** Avoid use during pregnancy. An Antiretroviral Pregnancy Registry has been established. Breastfeeding is not recommended.

SIDE EFFECTS

Refer to SmPC for complete information on side-effects.

Pifeltro and Delstrigo: ***Common:*** abnormal dreams, insomnia, headache, dizziness, somnolence, nausea, diarrhoea, abdominal pain, vomiting, rash, fatigue, flatulence, increased alanine aminotransferase. ***Uncommon:*** depression, hypophosphataemia, suicidal ideation, paraesthesia, asthenia. ***Rare:*** rash pustular, hypomagnesaemia, aggression, hallucination, dyspnoea, acute kidney injury, renal disorder, calculus urinary, nephrolithiasis, chest pain. *Delstrigo:* ***Common:*** cough, nasal symptoms, alopecia, muscle disorders, fever. ***Uncommon:*** neutropenia, anaemia, thrombocytopenia, pancreatitis, rhabdomyolysis, proximal renal tubulopathy (including Fanconi syndrome). ***Rare:*** lactic acidosis, hepatitis, angioedema, myopathy, acute renal failure, renal failure, acute tubular necrosis, nephritis (including acute interstitial) and nephrogenic diabetes insipidus. ***Very Rare:*** pure red cell aplasia, peripheral neuropathy (or paraesthesia).

Delstrigo: Lactic acidosis has been reported with tenofovir disoproxil alone or in combination with other antiretrovirals. Predisposing factors such as decompensated liver disease, or patients receiving concomitant medications known to induce lactic acidosis are at increased risk of experiencing severe lactic acidosis during tenofovir disoproxil treatment, including fatal outcomes.

PACKAGE QUANTITIES AND BASIC NHS COST

Pifeltro: Bottle of 30 tablets £471.41

Delstrigo: Bottle of 30 tablets £578.55

Marketing Authorisation number Great Britain:
Pifeltro: PLGB 53095 0045
Delstrigo: PLGB 53095 0015

Marketing Authorisation holder Great Britain:
Merck Sharp & Dohme (UK) Limited 120 Moorgate London EC2M 6UR UK

UK (Northern Ireland):
Pifeltro: EU/1/18/1332/001
Delstrigo: EU/1/18/1333/001

UK (Northern Ireland):
Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

Legal Category: POM

Date of review of prescribing information: February 2021

PI.PIF-DEL.20.GB-NI.7390.CoO.RCN019429.RCN019439

Merck Sharp & Dohme (UK) Limited,
120 Moorgate, London, United Kingdom EC2M 6UR
Telephone: +44(0) 208 154 8000
Email: medicalinformationuk@msd.com
www.msd-uk.com

References:
1. DELSTRIGO Summary of Product Characteristics.
2. PIFELTRO Summary of Product Characteristics.

GB-DOR-00165. Date of preparation: April 2021.

MSD