

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

208624Orig1s000

Trade Name: VIEKIRA XR

Generic or Proper Name: dasabuvir, ombitasvir, paritaprevir, and ritonavir

Sponsor: AbbVie, Inc.

Approval Date: July 22, 2016

Indication: VIEKIRA XR is indicated for the treatment of adult patients with chronic hepatitis C virus (HCV)

- genotype 1b infection without cirrhosis or with compensated cirrhosis
- genotype 1a infection without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.

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APPROVAL LETTER



NDA 208624

NDA APPROVAL

AbbVie, Inc.
Attention: Sherie Masse, M.S., RAC.
Director, Regulatory Affairs
1 N. Waukegan Road
Dept. PA 77/Bldg. AP30
North Chicago, Illinois, 60064

Dear Ms. Masse:

Please refer to your New Drug Application (NDA) dated and received on September 29, 2015, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VIEKIRA XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir) extended release tablets, 200 mg dasabuvir, 8.33 mg ombitasvir, 50 mg paritaprevir, and 33.33 mg ritonavir.

This new drug application provides for the use of VIEKIRA XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir) extended release tablets for the treatment of adult patients with chronic hepatitis C virus (HCV) with:

- genotype 1b infection without cirrhosis or with compensated cirrhosis
- genotype 1a infection without cirrhosis or with compensated cirrhosis for use in combination with ribavirin

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

WAIVER OF HIGHLIGHTS SECTION

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>.

Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the Medication Guide). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 208624.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

MARKET PACKAGE

Please submit one market package of the drug product when it is available to the following address:

Suzanne Strayhorn, M.S.
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 6349
10903 New Hampshire Avenue
Silver Spring, Maryland
*Use zip code **20903** if shipping via United States Postal Service (USPS).*
*Use zip code **20993** if sending via any carrier other than USPS (e.g., UPS, DHL, FedEx).*

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for children less than three years of age and for pediatric patients weighing less than forty-two (42) kilograms because necessary studies would be impossible or highly impractical. This is because it is highly impractical to formulate all of the components of VIEKIRA XR into a suitable once-daily dosage form for young pediatric patients and it is unlikely that pediatric patients weighing under forty-two kilograms would be able to swallow the adult version of VIEKIRA XR.

We are deferring submission of your pediatric study for this application in pediatric patients weighing greater than or equal to forty-two (42) kilograms and who can swallow Viekira XR tablets, because this product is ready for approval for use in adults and the pediatric study has not been completed.

Your deferred pediatric study required by section 505B(a) of the FDCA are required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(C) of the FDCA. This required study is listed below.

3107-1 Evaluate the pharmacokinetics, safety and treatment response (using sustained virologic response as the primary endpoint) of ombitasvir, paritaprevir, ritonavir, dasabuvir (VIEKIRA XR™) in pediatric patients greater than 3 years of age with chronic hepatitis C virus infection, who weigh at least 42 kg and are able to swallow tablets.

Final Protocol Submission: July 31, 2015 (submitted)
Study Completion: April 30, 2022
Final Report Submission: August 31, 2022

Submit the protocol(s) to your IND 122839, with a cross-reference letter to this NDA.

Reports of this required pediatric postmarketing study must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert, Medication Guide to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf>).

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>. Information and Instructions for completing the form can be found at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Suzanne Strayhorn, Regulatory Project Manager, at (240) 402-4247 or (301) 796-1500.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosures:
Content of Labeling
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JEFFREY S MURRAY
07/22/2016