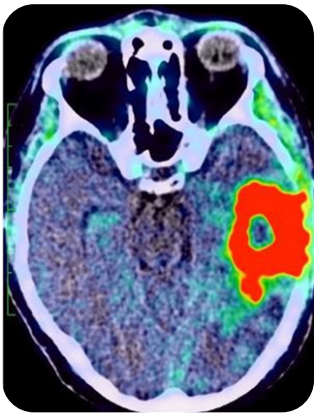
Pixclara®
(floretyrosine F 18)

READER SUPPORT SERVICES FOR PIXCLARA® (^{18}F FET) PET IMAGING

Specialized support is available with the reader assistance program.



As with any diagnostic modality, there can be challenges associated with imaging interpretation. Telix is pleased to offer a training program for readers to assist in the interpretation of Pixclara (floretyrosine F 18) injection imaging of glioma. Telix will connect requesting physicians with a Board Certified Nuclear Medicine/ Molecular Imaging Specialist for peer-to-peer Virtual assistance. (Microsoft Teams Platform).

HOW TO REQUEST PEER-TO-PEER COLLABORATION:

Click here to submit your request via email

Please include the following information in your email:

- Provide Physician Name
- Provide Institution or Practice Name and location
- Preferred date and time for 1 hr virtual meeting

Services are provided by independent physician contractors. Services are consultative only and not a substitute for the reader's professional judgment. Please review your institutional policies before engaging these services. Telix does not recommend, endorse or make any representation about the efficacy,appropriateness or suitability of any specific tests, products, procedures, treatments, services, opinion, or results by independent physician contractors. Telix is not responsible nor liable for any advice, course of treatment, diagnosis, or any other information, services, or products that are obtained through independent physician contractors, whose views and opinions are solely their own.

INDICATIONS AND USAGE
PIXCLARA is indicated for use with positron emission tomography (PET) to differentiate recurrent or progressive glioma from treatment-related change, in conjunction with other diagnostic evaluations, in adults and pediatric patients 1 month of age and older.

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS

RISK FOR MISINTERPRETATION
Image misinterpretation may occur with PIXCLARA PET. A negative image does not rule out the presence of recurrent or progressive glioma and a positive image does not confirm the presence of recurrent or progressive glioma. Equivocal findings may occur with PIXCLARA PET, including low-level or atypical uptake patterns, which may result in false positive or false negative interpretations.

Interpret PIXCLARA PET findings with caution and correlate results with available clinical evaluations, such as histopathology, cross-sectional imaging, and/or clinical history to support appropriate clinical decision-making.

RADIATION RISKS
PIXCLARA contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. Ensure safe drug handling to protect patients and health care providers from unintentional radiation exposure. Advise patients to hydrate before and after administration and to void frequently after administration.

ADVERSE REACTIONS
Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of PIXCLARA was evaluated in 382 patients with gliomas. Among these 382 patients, 371 adult patients received at least one intravenous dose of PIXCLARA at a mean activity of 204 ± 18 MBq (5.5 ± 0.47 mCi). The remaining 11 pediatric patients received at least one intravenous dose of PIXCLARA at a mean activity of 155 ± 53.5 MBq (4.2 ± 1.4 mCi).

The mean age of the patients was 57 years (range: 5 years to 86 years). Sex was 59% male, 37% female, and 3% unreported. Distribution by race was 26% White, 6% Asian, <1% Black or African American, and 67% other or unreported. Distribution by ethnicity was 3% Hispanic/Latino, 96% non-Hispanic/Latino, and <1% unknown or unreported.

Adverse reactions that occurred in ≥0.5% of patients receiving PIXCLARA were headache (0.5%).

Adverse reactions that occurred in <0.5% of patients were nausea, injection site reaction, fatigue, and malaise.

Adverse Reactions in Pediatric Patients
Overall, the safety profile observed in pediatric patients from the clinical study was consistent with the safety profile in adult patients.

Please note that this information is not comprehensive.
Please see the Full Prescribing Information at pixclara.com/prescribinginformation
You are encouraged to report suspected adverse reactions of prescription drugs to the FDA. Visit MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088.
You may also report adverse reactions to Telix Pharmaceuticals (US) by calling 1-844-455-8638 or emailing pharmacovigilance@telixpharma.com.

Telix

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