Taiwan Food and Drug Administration

Assessment Report

Trade Name：鎵連坊鍺 68/鎵 68 孳生器(GalliaPharm 0.74－1.85 GBq radionuclide generator)

Active Ingredient：Germanium (^{68}Ge) chloride/ Gallium (^{68}Ga) chloride

License Number：MOHW-PI-R00105

Applicant：恩典科研股份有限公司

Approval Date：2023/06/16

Indication：
本品不可直接使用於病人。本品產生之氯化鎵洗脫液(gallium(^{68}Ga) chloride solution)適用於和已核准之造影劑載體進行體外放射性標記，標記完成之造影劑將用於正子斷層掃描(positron emission tomography)造影。

This medicinal product is not intended for direct use in patients.
The eluate from the radionuclide generator (gallium (^{68}Ga) chloride solution) is indicated for in vitro labelling of specific carrier molecules developed and approved for radiolabelling with such solution to be used for positron emission tomography (PET) imaging.

Background Information

Trade Name	鎵連坊鍺 68/鎵 68 孳生器(GalliaPharm 0.74–1.85 GBq radionuclide generator)
Active Ingredient(s)	Germanium (^{68}Ge) chloride/ Gallium (^{68}Ga) chloride
Applicant	恩典科研股份有限公司
Dosage Form & Strengths	Radionuclide generator
Indication	本品不可直接使用於病人。本品產生之氯化鎵洗脫液(gallium(^{68}Ga) chloride solution)適用於和已核准之造影劑載體進行體外放射性標記，標記完成之造影劑將用於正子斷層掃描(positron emission tomography)造影。 This medicinal product is not intended for direct use in patients. The eluate from the radionuclide generator (gallium (^{68}Ga) chloride solution) is indicated for in vitro labelling of specific carrier molecules developed and approved for radiolabelling with such solution to be used for positron emission tomography (PET) imaging.
Posology	Please refer to package inserts
Pharmacological Category ATC Code	V09X.

2. Summary Report

2.1 Chemistry, Manufacturing and Controls Evaluation

2.1.1 Drug substance

The active substance used in the ^{68}Ge/^{68}Ga-generator is germanium (^{68}Ge) chloride and gallium (^{68}Ga) chloride in equilibrium.

^{68}Ge decays with a half-life of 270.95 days by electron capture into the short-lived isotope ^{68}Ga. The daughter nuclide ^{68}Ga decays with a half-life of 67.71 mins by positron emission to stable ^{68}Zn. The principal photons useful for diagnostic imaging are the 511 keV gamma photons, resulting from the interaction of the emitted positron with an electron.

Adequate information of characterization of the drug substance has been provided.

Adequate specification has been presented for the drug substance and the test items include clarity of solution, identity ^{68}Ge, radionuclidic purity, concentration activity, specific radioactivity, content of non-active chemical impurities, hydrochloric acid concentration and residual solvents. Batch analysis data from commercial scale batches of the drug substance are provided and the test results are within the specifications.

2.1.2 Drug product

The GalliaPharm, 0.74-1.85 GBq, radionuclide generator is a radionuclide generator consisting of a titanium dioxide column with adsorbed ^{68}Ge. ^{68}Ge decays constantly under production of ^{68}Ga that can be eluted by sterile ultrapure 0.1 mol/l hydrochloric acid. The specifications for excipients used in the drug product are adequate.

Adequate specification has been presented for the drug product and the test items includes description, identity, particulate contamination, pH value, chloride, purity, assay and microbiological quality. Batch analysis data from commercial scale batches of the drug product are provided and the test results are within the specifications. Analytical methods are described well and validated.

Stability studies of drug product under long-term condition (25°C) and accelerated condition (40°C) have been carried out. Up to 12 months of long-term and 6 months of accelerated stability data are submitted. No significant chemical or physical changes are observed for the drug product, the shelf life and storage condition of drug product can be granted for 12 months under the storage condition of 25°C.

2.2 Preclinical Pharmacology/Toxicology Evaluation

2.2.1 Pharmacological Studies

GalliaPharm is not intended for direct use in patients. Therefore, it is acceptable that no pharmacological studies were carried out for GalliaPharm.

2.2.2 Toxicological Studies

GalliaPharm is not intended for direct use in patients. Therefore, it is acceptable that no

toxicological studies were carried out for GalliaPharm.

2.3 Clinical Pharmacology Evaluation

2.3.1 General Pharmacodynamics and Pharmacokinetics

No biopharmaceutical studies and clinical pharmacology studies have been performed with the $^{68}Ge/^{68}Ga$-generator, since only the final radiolabelled medicinal product is to be used. The final product characteristics depend mainly on the carrier to be labelled.

2.3.2 Interaction Studies

GalliaPharm is not intended for direct use in patients. Therefore, it is acceptable that no drug interactions studies were conducted for GalliaPharm.

2.3.3 Special Populations

GalliaPharm is not intended for direct use in patients. Therefore, it is acceptable that PK evaluations in special populations were not conducted for GalliaPharm.

2.4 Clinical Efficacy and Safety Evaluation

2.4.1 Efficacy Results

This product is a radionuclide generator, a device used to extract the positron-emitting gallium(^{68}Ga) from a source of decaying germanium-68(^{68}Ge). The eluate from GalliaPharm is not intended for direct use in patients. The eluate from the radionuclide generator is used for in vitro labelling of specific carrier molecules developed and approved for radiolabelling with such solution to be used for positron emission tomography (PET) imaging. The biodistribution and clinical usage will be changed by being attached with different carriers. Therefore, it is acceptable that no clinical data were provided for GalliaPharm.

2.4.2 Safety Results

Base on the same reason, it is acceptable that no clinical safety data were provided for GalliaPharm.

2.5 Bridging Study Evaluation

Because GalliaPharm is not intended for direct use in patients, thus ethnic sensitivity is not a concerned issue.

2.6 Conclusion

The multidisciplinary review recommend approval of GalliaPharm. The approval indication is:

This medicinal product is not intended for direct use in patients.

The eluate from the radionuclide generator (gallium (^{68}Ga) chloride solution) is indicated for

in vitro labelling of specific carrier molecules developed and approved for radiolabelling with such solution to be used for positron emission tomography (PET) imaging.

3. Post-Marketing Requirements

N/A