Summary of Product Characteristics

ERtracER Solution for Injection

1 NAME OF THE MEDICINAL PRODUCT
ERtracER Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
1 ml contains 110 – 10,000 MBq fludeoxyglucose (^{18}F) at the date and time of calibration. The activity per vial ranges from 110 MBq to 50,000 MBq at the date and time of calibration.

Fluorine (^{18}F) decays to stable oxygen (^{18}O) with a half-life of 110 minutes by emitting positronic radiation of maximum energy of 634 keV, followed by photonic annihilation radiations of 511 keV.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Solution for Injection.

Clear, colourless or slightly yellow solution.

4 CLINICAL PARTICULARS
4.1 Therapeutic Indications
This medical product is for diagnostic use only.

Fludeoxyglucose (^{18}F) is indicated for use with positron emission tomography (PET) in adults and the paediatric population.

Oncology
In patients undergoing oncologic diagnostic procedures describing function or diseases where enhanced glucose influx of specific organs or tissues is the diagnostic target. The following indications are sufficiently documented (see also section 4.4):

Diagnosis:
- Characterisation of solitary pulmonary nodule
- Detection of cancer of unknown origin, revealed for example by cervical adenopathy, liver or bones metastases
- Characterisation of a pancreatic mass

Staging:
- Head and neck cancers including assistance in guiding biopsy
- Primary lung cancer
- Locally advanced breast cancer
- Oesophageal cancer
- Carcinoma of the pancreas
- Colorectal cancer particularly in restaging recurrences
- Malignant lymphoma
- Malignant melanoma, Breslow > 1.5 mm or lymph node metastasis at first diagnosis.

Monitoring of therapeutic response:
- Malignant lymphoma
- Head and neck cancers

Detection in case of reasonable suspicion of recurrence:
- Glioma with high grade of malignancy (III or IV)
- Head and neck cancers
- Thyroid cancer (non-medullary): patients with increased thyroglobulin serum levels and negative radioactive iodine whole body scintigraphy
- Primary lung cancer
- Breast cancer
- Carcinoma of the pancreas
- Colorectal cancer
- Ovarian cancer
- Malignant lymphoma
- Malignant melanoma

Cardiology
In cardiology the diagnostic target is viable myocardial tissue that takes-up glucose but is hypo-perfused, as it must be assessed beforehand using appropriate blood-flow imaging techniques.

Evaluation of myocardial viability in patients with severe impaired left ventricular function who are candidates for revascularisation when conventional imaging modalities are not contributive.

Neurology
In neurology interictal glucose hypometabolism is the diagnostic target. Imaging in patients with the following neurological conditions:
- Epilepsy, including:
  - Temporal lobe epilepsy
  - Localisation of epileptogenic foci in the presurgical evaluation of partial temporal epilepsy
- Dementia, including
  - Alzheimer's dementia
  - Picks disease
  - Multi-infarct (vascular) dementia
  - Parkinsons disease
- Recurrent brain tumours, and a range of other neurological conditions in which focal abnormalities of carbohydrate metabolism of brain tissue is known to occur.

Infectious or inflammatory diseases
In infectious or inflammatory diseases, the diagnostic target is tissue or structures with an abnormal content of activated white blood cells.

In infectious or inflammatory diseases, the following indications are sufficiently documented:

Localisation of abnormal foci guiding the aetiologic diagnosis in case of fever of unknown origin.

Diagnosis of infection in case of:
- Suspected chronic infection of bone and/or adjacent structures: osteomyelitis, spondilitis, diskitis or osteitis including when metallic implants are present
- Diabetic patient with a foot suspicious of Charcot's neuroarthropathy, osteomyelitis and/or soft tissue infection
- Painful hip prosthesis
- Vascular prosthesis
- Fever in an AIDS patient
- Detection of septic metastatic foci in case of bacteraemia or endocarditis (see also section 4.4.).

Detection of the extension of inflammation in case of:
- Sarcoidosis
- Inflammatory bowel disease
- Vasculitis involving the great vessels

Therapy follow-up:
Unresectable alveolar echinococcosis, in search for active localisations of the parasite during medical treatment and after treatment discontinuation

4.2 Posology and method of administration

Posology
Adults and elderly population
The recommended activity for an adult weighing 70 kg is 100 to 400 MBq (this activity has to be adapted according to the body weight of the patient, the type of camera used and acquisition mode), administered by direct intravenous injection.

Renal and hepatic impairment
Careful consideration of the activity to be administered is required since increased radiation exposure is possible in these patients.

Extensive dose-range and adjustment studies with this product in normal and special populations have not been performed. The pharmacokinetics of fludeoxyglucose (^{18}F) in renally impaired patients have not been characterised.

Paediatric population
Use in children and adolescents has to be considered carefully, based upon clinical needs and assessing the risk/benefit ratio in this patient group. The activities to be administered to children and adolescents may be calculated according to the recommendations of the European Association of Nuclear Medicine (EANM) paediatric dosage card; the activity administered to children and to adolescents may be calculated by multiplying a baseline activity (for calculation purposes) by the weight-dependent multiples given in the table below.

$A[MBq]_{Administered}$ = Baseline Activity x Multiple
The Baseline Activity for 2D imaging is 25.9 MBq and for 3D imaging 14.0 MBq (recommended in children).

Weight[kg]	Multiple	**Weight[kg]**	Multiple	**Weight[kg]**	Multiple
3	1	**22**	5.29	**42**	9.14
4	1.14	**24**	5.71	**44**	9.57
6	1.71	**26**	6.14	**46**	10.00
8	2.14	**28**	6.43	**48**	10.29
10	2.71	**30**	6.86	**50**	10.71
12	3.14	**32**	7.29	**52-54**	11.29
14	3.57	**34**	7.72	**56-58**	12.00
16	4.00	**36**	8.00	**60-62**	12.71
18	4.43	**38**	8.43	**64-66**	13.43
20	4.86	**40**	8.86	**68**	14.00

Method of administration
For intravenous, multidose use.

Use within four hours of withdrawing the first dose.

The activity of fludeoxyglucose (^{18}F) has to be measured with a radioactive calibrator immediately prior to injection.

The injection of fludeoxyglucose (^{18}F) must be intravenous in order to avoid irradiation as a result of local extravasation, as well as imaging artefacts.

For instructions on dilution of the medicinal product before administration, see section 12.

For patient preparation, see section 4.4.

Image acquisition
The emission scans are usually started 45 to 60 minutes after injection of fludeoxyglucose (^{18}F). Provided that a sufficient activity remains for adequate counting statistics, fludeoxyglucose (^{18}F) PET can also be performed up to two to three hours after administration, thus reducing background activity.

If required, repeated fludeoxyglucose (^{18}F) PET examinations can be reiterated within a short period of time.

4.3 Contraindications
Hypersensitivity to the active substance and to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use
Individual benefit/risk justification

For each patient, radiation exposure must be justified by the likely benefit. The activity administered should in every case be as low as reasonably achievable to obtain the required diagnostic information.

Pregnancy
See section 4.6.

Potential for hypersensitivity or anaphylactic reactions
If hypersensitivity or anaphylactic reactions occur, the administration of the medicinal product must be discontinued immediately and intravenous treatment initiated, if necessary. To enable immediate action in emergencies, the necessary medicinal products and equipment such as endotracheal tube and ventilator must be immediately available.

Renal and hepatic impairment
Due to the major renal excretion of fludeoxyglucose (^{18}F) in patients with reduced kidney function careful consideration of the benefit risk ratio in these patients is required since increased radiation exposure is possible. Activity should be adjusted if necessary.

Paediatric population
For information on the use in paediatric population, see sections 4.2 or 5.1.

Careful consideration of the indication is required since the effective dose per MBq is higher in children than in adults (see section 11 "Dosimetry").

Patient preparation
ERtracER solution for injection should be given to sufficiently hydrated patients fasting for a minimum of 4 hours, in order to obtain a maximum target activity, since glucose uptake in cells is limited ("saturation kinetics"). The amount of liquid should not be limited (beverages containing glucose must be avoided).

In order to obtain images of best quality and to reduce the radiation exposure of the bladder, patients should be encouraged to drink sufficient amounts and to empty their bladder prior to and after the PET examination.

Oncology and neurology and infectious diseases
In order to avoid hyperfixation of the tracer in muscle, it is advisable to avoid all strenuous physical activity prior to the examination and to remain at rest between the injection and examination and during acquisition of images (patients should be comfortably lying down without reading or speaking).

Cerebral glucose metabolism depends on brain activity. Thus neurological examinations should be performed after a relaxation period in a darkened room and with low background noise.

A blood glucose test should be performed prior to administration since hyperglycaemia may result in a reduced sensitivity of ERtracER, especially when glycaemia is greater than 8 mmol/l. Similarly, PET with fludeoxyglucose (^{18}F) should be avoided in subjects presenting uncontrolled diabetes.

Cardiology
Since glucose uptake in the myocardium is insulin-dependent, for a myocardial examination a glucose loading of 50 g approximately 1 hour prior to the administration of ERtracER is recommended. Alternatively, especially for patients with diabetes mellitus, the blood sugar level can be adjusted by a combined infusion of insulin and glucose (Insulin- glucose-clamp) if needed.

Interpretation of the PET images with fludeoxyglucose (^{18}F)
In the exploration of inflammatory bowel diseases, the diagnostic performance of fludeoxyglucose (^{18}F) has not been directly compared with that of scintigraphy using labelled white blood cells which may be indicated prior to fludeoxyglucose (^{18}F) PET or after fludeoxyglucose (^{18}F) PET when inconclusive.

Infectious and / or inflammatory diseases as well as regenerative processes after surgery can result in a significant uptake of fludeoxyglucose (^{18}F) and therefore lead to false positive results, when a search for infectious or inflammatory lesions is not the aim of the fludeoxyglucose (^{18}F) PET. In cases where fludeoxyglucose (^{18}F) accumulation can be caused by either cancer, infection or inflammation, additional diagnostic techniques for the determination of the causative pathologic alteration may be required to supplement the information obtained by PET with fludeoxyglucose (^{18}F). In some settings e.g. staging of myeloma, both malignant and infectious foci are searched for and may be distinguished with a good accuracy on topographic criteria: e.g. uptake at extramedullary sites and/or bone and joint lesions would be atypical for multiple myeloma lesions and identified cases associated with infection. There are currently no other criteria to distinguish infection and inflammation by means of fludeoxyglucose (^{18}F) imaging.

Because of the high physiologic uptake of fludeoxyglucose (^{18}F) within brain, heart and kidneys, PET/CT with fludeoxyglucose (^{18}F) has not been evaluated for the detection of septic metastatic foci in these organs when the patient has been referred due to bacteraemia or endocarditis.

False positive or false negative results with PET fludeoxyglucose (^{18}F) cannot be excluded after radiotherapy within the first 2-4 months. If the clinical indication requires an earlier diagnosis by PET with fludeoxyglucose (^{18}F), the reason for the earlier PET with fludeoxyglucose (^{18}F) examination must be reasonably documented.

A delay of at least 4-6 weeks after the last administration of chemotherapy is optimal, in particular to avoid false negative results. If the clinical indication requires an earlier diagnosis by PET with fludeoxyglucose (^{18}F), the reason for the earlier PET with fludeoxyglucose (^{18}F) examination must be reasonably documented. In case of chemotherapy regimen with cycles shorter than four weeks, the PET with fludeoxyglucose (^{18}F) examination should be done just before re-starting a new cycle.

In low-grade lymphoma, lower oesophagus cancer and suspicion of recurrent ovarian cancer, only positive predictive values have to be considered because of a limited sensitivity of PET with fludeoxyglucose (^{18}F).

Fludeoxyglucose (^{18}F) is not effective in detecting brain metastases.

The accuracy of fludeoxyglucose (^{18}F) PET imaging is better using PET/CT than PET cameras alone.

When a hybrid PET-CT scanner is used with or without administration of CT contrast media, some artefacts may occur on the attenuation-corrected PET images.

After the procedure
Close contact with infants, young children and pregnant women should be restricted during the initial 12 hours following the injection.

Specific warnings
Depending on the time when you administer the injection, the content of sodium may in some cases be greater than 1 mmol (23 mg). This should be taken into account in patients on a low sodium diet.

Radiopharmaceutical products should be received, used and administered only by authorised persons in designated clinical settings. The receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licences of the competent official organisations.

Radiopharmaceuticals should be prepared by the user in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

Fludeoxyglucose (^{18}F) should be stored and handled in adequate shielding, so as to protect patients and hospital staff as much as possible. In particular, it is recommended to protect oneself from the effects of beta+ radiation and annihilation photons by using an appropriate shielding when performing withdrawals from the vial and injections.

Precautions with respect to environmental hazard see section 6.6.

4.5 Interaction with other medicinal products and other forms of interaction
All medicinal products that modify blood glucose levels can affect the sensitivity of the examination (e.g. corticosteroids, valproate, carbamazepine, phenytoin, phenobarbital and catecholamines).

Under administration of colony-stimulating factors (CSFs) there is an increased uptake of fludeoxyglucose (^{18}F) in the bone marrow and the spleen for several days. This must be taken into account for the interpretation of PET imaging. Separating CSF therapy from PET imaging by an interval of at least 5 days may diminish this interference.

The administration of glucose and insulin influences the influx of fludeoxyglucose (^{18}F) into the cells. In the case of high blood glucose levels as well as low plasma insulin levels, the influx of fludeoxyglucose (^{18}F) into organs and tumours is reduced.

No formal studies on the interaction between fludeoxyglucose (^{18}F) and any contrast for computed tomography have been performed.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential

When an administration of radiopharmaceuticals to a woman of childbearing potential is intended, it is important to determine whether or not she is pregnant. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. If in doubt about her potential pregnancy (if the woman has missed a period, if the period is very irregular, etc), alternative techniques not using ionising radiation (if there are any) should be offered to the patient.

Pregnancy:

Radionuclide procedures carried out on pregnant women involve radiation doses to the foetus.

Only essential investigations should therefore be carried out during pregnancy, when the likely benefit far exceeds the risk incurred by the mother and foetus.

Breastfeeding:

Before administering radiopharmaceuticals to a mother who is breast-feeding, consideration should be given to the possibility of delaying the administration of radionuclide until the mother has ceased breast feeding, and to what is the most appropriate choice of radiopharmaceuticals, bearing in mind the secretion of activity into breast milk. If the administration is considered necessary, breast feeding should be interrupted for 12 hours and the expressed feeds discarded.

Close contact with infants and young children should be restricted during the initial 12 hours following injection.

Fertility

No studies on fertility have been performed.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 7.6 mSv when the maximum recommended activity of 400 MBq is administered, these adverse events are expected to occur with a low probability.

Reporting of suspected adverse reactions

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. Healthcare professionals are asked to report any suspected adverse reactions.

Within the Republic of Ireland please report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

For suspected adverse reactions within the United Kingdom please report via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

4.9 Overdose

In the event of administration of a radiation overdose with fludeoxyglucose (^{18}F) the absorbed dose to the patient should be reduced where possible by increasing the elimination of the radionuclide, from the body by forced diuresis and frequent bladder voiding. It might be helpful to estimate the effective dose that was applied.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Diagnostic radiopharmaceuticals ATC code: V091 X04

Pharmacodynamic effects

At the chemical concentrations used for diagnostic examinations, fludeoxyglucose (^{18}F) does not appear to have any pharmacodynamic activity.

5.2 Pharmacokinetic properties

Distribution

Fludeoxyglucose (^{18}F) is a glucose analogue which is accumulated in all cells using glucose as primary energy source. Fludeoxyglucose (^{18}F) is accumulated in tumours with a high glucose turnover.

Following intravenous injection, the pharmacokinetic profile of fludeoxyglucose (^{18}F) in the vascular component is biexponential. It has a distribution time of 1 minute and an elimination time of approximately 12 minutes.

In healthy subjects, fludeoxyglucose (^{18}F) is widely distributed throughout the body, particularly in the brain and heart, and to a lesser degree in the lungs and liver.

Organ uptake

The cellular uptake of fludeoxyglucose (^{18}F) is performed by tissue-specific carrier systems, which are partly insulin- dependent and thus can be influenced by eating, nutritional condition and the existence of diabetes mellitus. In patients with diabetes mellitus a reduced uptake of fludeoxyglucose (^{18}F) into the cells occurs due to a changed tissue distribution and glucose metabolism.

Fludeoxyglucose (^{18}F) is transported via the cell membrane in a similar fashion to glucose, but only undergoes the first step of glycolysis, resulting in the formation of fludeoxyglucose (^{18}F) -6-phosphate, which remains trapped within the tumour cells and is not further metabolised. Since subsequent dephosphorylation by intracellular phosphatases is slow, fludeoxyglucose (^{18}F)-6-phosphate is retained in the tissues over several hours (trapping mechanism).

Fludeoxyglucose (^{18}F) passes the blood-brain barrier. Approximately 7% of the injected dose is accumulated in the brain within 80-100 minutes after injection. Epileptogenic foci exhibit a reduced glucose metabolism in the seizure- free phases.

Approximately 3% of the activity is taken up by the myocardium within 40 minutes. The distribution of fludeoxyglucose (^{18}F) in normal heart is mainly homogenous, however, regional differences of up to 15% are described for the interventricular septum. During and after a reversible myocardial ischaemia, an increased glucose uptake occurs into the myocardial cell.

0.3 and 0.9-2.4% of the injected activity is accumulated in the pancreas and lungs respectively.

Fludeoxyglucose (^{18}F) is also bound to a lesser extent to ocular muscle, pharynx and intestine. Binding to muscle may be seen following recent exertion and in the event of muscular effort during the examination.

Elimination

The elimination of fludeoxyglucose (^{18}F) is chiefly renal with 20% of activity being excreted in urine in the two hours following injection.

Binding to renal parenchyma is weak, but because of renal elimination of fludeoxyglucose (^{18}F) the entire urinary systems, particularly the bladder, exhibits marked activity.

5.3 Preclinical safety data

Toxicological studies with mice and rats have demonstrated that with a single intravenous injection of 0.0002 mg/kg no deaths were observed. Toxicity with repeated administration was not performed because fludeoxyglucose (^{18}F) is administered in a single dose. This medicinal product is not intended for regular or continuous administration.

Mutagenicity studies and long-term carcinogenicity studies have not been carried out.

Environmental Risk Assessment (ERA)

The relevant guideline states that carbohydrates are exempted from the requirements for ERA because they are unlikely to result in significant risk to the environment. The potential entry of fludeoxyglucose (^{18} F) to the environment from the administration to patients will be very small and is not of immediate risk to the environment. The half life of 110 minutes means that there will be no cumulative effect on the environment.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Water for Injections
Sodium dihydrogen phosphate dihydrate

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 12.

6.3 Shelf life

12 hours.

The shelf-life after the first dose has been withdrawn is 4 hours. The expiry time and date are stated on the label of each vial.

6.4 Special precautions for storage

Do not store above 30°C.

The vial does not contain a preservative agent. If the product is for multiple use, then each dose must be prepared under aseptic conditions.

Storage of radiopharmaceuticals should be in accordance with national regulations concerning radioactive materials.

6.5 Nature and contents of container

Type 1 (Ph. Eur.) glass vial (maximum size 11 ml) closed with either a bromobutyl or ETFE-coated chlorobutyl rubber stopper and sealed with an aluminium crimp cap. The vial is shielded by a lead container within a sealed outer container.

One vial contains 1-10 ml of solution, corresponding to 110 to 50,000 MBq at calibration time.

6.6 Special precautions for disposal and other handling

General warning

Radiopharmaceuticals should be received, used and administered only by authorised persons in designated clinical settings. Their receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licences of the competent official organisation.

Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

The administration of radiopharmaceuticals creates risks for other persons from external radiation or contamination from spills of urine, vomiting, etc. Radiation protection precautions in accordance with national regulations must be taken.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Curium Pharma Ireland Ltd
Blackrock Clinic, Blackrock, Dublin, Ireland
Tel: 00353 1-206-4266. E-mail: info.ie@curiumpharma.com

8 MARKETING AUTHORISATION NUMBER

PA 1125/002/001 PL 32203/0003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 27th February 2015

10 DATE OF REVISION OF THE TEXT

25th March 2021

11 DOSIMETRY

The data listed below are from ICRP 106 publication.

Organ	Dose absorbed per unit of activity administered (mGy / MBq)				
	Adults	**15 year old**	**10 year old**	**5 year old**	**1 year old**
Adrenals	0.012	0.016	0.024	0.039	0.071
Bladder	0.130	0.160	0.250	0.340	0.470
Bone surfaces	0.011	0.016	0.022	0.034	0.064
Brain	0.038	0.039	0.041	0.046	0.063
Breasts	0.0088	0.011	0.018	0.029	0.056
Gall bladder	0.013	0.016	0.024	0.037	0.070
Gastrointestinal tract:					
Stomach	0.011	0.014	0.022	0.035	0.067
Small intestine	0.012	0.016	0.025	0.040	0.073
Colon	0.013	0.016	0.025	0.039	0.070
Upper large intestine	0.012	0.015	0.024	0.038	0.070
Lower large intestine	0.014	0.017	0.027	0.041	0.070
Heart	0.067	0.087	0.130	0.210	0.380
Kidneys	0.017	0.021	0.029	0.045	0.078
Liver	0.021	0.028	0.042	0.063	0.120
Lungs	0.020	0.029	0.041	0.062	0.120
Muscles	0.010	0.013	0.020	0.033	0.062
Oesophagus	0.012	0.015	0.022	0.035	0.066
Ovaries	0.014	0.018	0.027	0.043	0.076
Pancreas	0.013	0.016	0.026	0.040	0.076
Red marrow	0.011	0.014	0.021	0.032	0.059
Skin	0.0078	0.0096	0.015	0.026	0.050
Spleen	0.011	0.014	0.021	0.035	0.066
Testes	0.011	0.014	0.024	0.037	0.066
Thymus	0.012	0.015	0.022	0.035	0.066
Thyroid	0.010	0.013	0.021	0.034	0.065
Uterus	0.018	0.022	0.036	0.054	0.090
Remaining organs	0.012	0.015	0.024	0.038	0.064
Effective dose (mSv/MBq)	**0.019**	**0.024**	**0.037**	**0.056**	**0.095**

The effective dose resulting from the administration of a maximal recommended activity of 400 MBq of fludeoxyglucose (^{18}F) for an adult weighing 70 kg is about 7.6 mSv.

For an administered activity of 400 MBq, the radiation doses delivered to the critical organs, bladder, heart and brain are respectively 52 mGy, 27 mGy and 15 mGy.

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Method of preparation

The package must be checked before use and the activity measured using a radioactive calibrator.
The medicinal product may be diluted with sodium chloride 9 mg/ml solution for injection.

Withdrawals should be performed under aseptic conditions. The vials must not be opened before disinfecting the stopper, the solution should be withdrawn via the stopper using a single dose syringe fitted with suitable protective shielding and a disposable sterile needle or using an authorised automated application system.

If the integrity of the vial is compromised, the product should not be used.

Quality control

The solution should be inspected visually prior to use, using appropriate protective shielding. Only clear solutions, free of visible particles should be used.

Essentra Packaging Ireland Ltd.

Customer	M2i	Job No.	154382	Date issued	26-4-2021
Item No.	PKFDG02-6	Size	296 x 250mm	Proof No:	2
Colours	Black			Pharmacode	N/A

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