Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

PULMOTEC Kit for radiopharmaceutical preparation

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One crucible (high pure graphite 99.9%) 1.340 g
which, heated to 2550° C, under ultra pure argon in the presence of sodium pertechnetate [Tc-99m], produces an aerosol of carbon micro-particles labelled with technetium [Tc-99m], called Technegas.

The radioisotope, Tc-99m Sodium Pertechnetate, is not a part of this supplied kit for radiopharmaceutical preparation.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Kit for radiopharmaceutical preparation.

Aerosol for inhalation containing hexagon shaped Tc-99m nanoparticulates dispersed in high purity argon gas.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.
Scintigraphy of alveolar spaces, in particular in the context of the diagnosis of pulmonary embolism.

4.2 Posology and method of administration

Posology

The recommended activity of sodium pertechnetate [Tc-99m] to be deposited in the crucible is between 250 and 700 MBq for adults.

The activity present in the lungs after each inhalation varies from one patient to another. It is recommended to follow the pulmonary count rate during inhalation of Technegas, using a gamma camera equipped with a standard collimator (low energy, low/medium resolution), until a lung count rate of between 1.5 and 2 Kcps is obtained. Inhalation has then to be stopped. This corresponds for adults approximatively to 40 MBq of Technegas inhaled.

The activity to be administered to children is a fraction of the recommended activity for adults, according to the EANM Dosage Card (Paediatric and Dosimetry Committees EANM, 2016), and is given by the following calculation:

A[MBq]Administered Baseline Activity* x Multiple

*baseline activity = 49.0 MBq

Therefore recommended activity of sodium pertechnetate [Tc-99m] to be deposited in the crucible will vary between 100 MBq and 686 MBq for children following the table below:

Weight (kg)	**Activity administered (crucible loading activity) (MBq)**
3	100
4	100
6	100

8	104,9
10	132,8
12	153,9
14	174,9
16	196
18	217,1
20	238,1
22	259,2
24	279,8
26	300,9
28	315,1
30	336,1
32	357,2
34	378,3
36	392
38	413,1
40	434,1
42	447,9
44	468,9
46	490
48	504,2
50	524,8
52-54	553,2
56-58	588
60-62	622,8
64-66	658,1
≥ 68	686

Adequate quality images are obtained in children with a pulmonary count rate of 500-1000 cps in the lungs monitored as described for adults. It is recommended to follow the pulmonary count rate during inhalation of Technegas, using a gamma camera equipped with a standard collimator (low energy, low/medium resolution), until a lung count rate of between 0.5 and 1Kcps is obtained. Inhalation has then to be stopped.

Method of administration

Technegas is administered by inhalation, at most ten minutes after preparation, through the "Patient Administration Set". This contains a plastic tube, to be connected to the Technegas generator, fitted with a mouthpiece and a filter.

Staff should wear disposable gloves and are recommended to wear aprons and masks, especially when the patient has a productive cough.

Adult patients should be instructed to breathe through the mouthpiece selected from one of the models of administration described below, chosen to match the patient's ability:

1. Normal breathing with deep inhalation without breath-holding (recommended method).
2. Slow deep breathing from the residual functional capacity (end of calm expiration), followed by a 5-second breath-hold.
3. Rapid and deep inspiration from the residual functional capacity followed by a breath-hold of about 5 seconds at the end of the respiration.
4. Paediatric patients should be instructed to breathe through the mouthpiece or paediatric mask, in line with normal breathing, without breath-holding.

Dyspnoeic patients may remove the mouthpiece between the inhalations of Technegas.

As the first inhalation of Technegas contains no oxygen, pre-oxygenation of the patient is recommended prior to inhalation of Technegas, especially for patients with severely compromised respiration.

To yield uniform apex-to-base deposition, it is recommended to perform the administration with the patient in the supine position.

4.3 Contraindications

None known.

4.4 Special warnings and precautions for use

Radiopharmaceuticals should be received, used and administered only by authorized persons in designated clinical settings and receipt, storage, use, transfer and disposal are subject to the regulations and appropriate licences of the competent authorities.
Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements.
Technegas should be administered ten minutes at most after preparation.
A careful assessment of the risk/benefit ratio should be made before use of the product in children, particularly since use of Technegas results in an increased effective dose and absorbed organ doses in children (see 11. Dosimetry).

The 300 µL PULMOTEC crucible shall only be used in a TechnegasPlus generator (or later model). The 300 µL PULMOTEC crucible may be used in older model Technegas generators where those Technegas Generators have been modified and calibrated for use with the 300 µL PULMOTEC crucible by an authorised service agent.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

No interaction studies in vitro or in vivo with inhaled or any medicinal drugs have been performed.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential
When it is necessary to administer radioactive medicinal products to women of childbearing potential, information should always be sought about pregnancy. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. Where uncertainty exists, it is important that radiation exposure should be the minimum consistent with achieving the desired clinical information. Alternative techniques which do not involve ionising radiation should be considered.

Pregnancy
Radionuclide procedures carried out on pregnant women also involve radiation
doses to the foetus. Only imperative investigations should be carried out during pregnancy when likely benefit exceeds the risks incurred by mother and foetus.

Breastfeeding
Before administering a radioactive medicinal product to a mother who is breastfeeding, consideration should be given to whether the investigation could be reasonably delayed until the mother has ceased breastfeeding and whether the most appropriate radiopharmaceutical product has been chosen, bearing in mind secretion in breast milk.
If the administration of this radioactive product is essential, breastfeeding must be interrupted for at least 12 hours and the excreted milk must be discarded.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

4.8 Undesirable effects

The frequencies for undesirable effects are defined as follows:		
Very common	≥ 1/10	
Common	≥ 1/100 to <	1/10
Uncommon	≥ 1/1,000 to <	1/100

Rare	≥ 1/10,000 to <	1/1,000
Very rare	< 1/10,000	
Not known	Cannot be estimated from the available data	

Rare cases of dizziness, light headedness and nausea have been reported. These have been ascribed to hypoxia which may occur during inhalation of Technegas which initially contains no oxygen.
If a patient shows signs of hypoxia, he/she should immediately be allowed to breathe air and, if necessary, oxygen.
For each patient, exposure to ionising radiation must be justifiable on the basis of likely benefit. The activity administered must be such that the resulting radiation dose is as low as reasonably achievable bearing in mind the need to achieve the diagnosis.
Exposure to ionising radiation can lead to cancer or development of hereditary defects. The effective dose resulting from a inhaled activity of 40 MBq of this radiopharmaceutical being only 0.6 mSv (70 kg adult), these adverse events can be expected with a very 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 via the national reporting system listed in Appendix V.

4.9 Overdose

An overdose of carbon cannot happen. In case of radioactivity overdose, there is no way of increasing the elimination of radiopharmaceutical product and reducing the radiation exposure.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Diagnostic radiopharmaceuticals; Technetium (^{99m}Tc), inhalants. ATC code: V09EA02

In the concentrations used for diagnostic examinations, Technegas is an inert suspension and has no pharmacological effect.

5.2 Pharmacokinetic properties

After inhalation, Technegas is absorbed on the walls of pulmonary alveoli and remains in the lungs. There is no intra vascular clearance and elimination of radioactivity is by the physical decay of the technetium-99m.

Part of the carbon micro-particles may be retained in the upper and central airways and is greater in patients with airway obstruction. These particles are cleared by ciliary action and, after swallowing, are eliminated through the gastro-intestinal tract without absorption.

5.3 Preclinical safety data

Toxicological data on PULMOTEC are not available.
A single administration of inhaled radioactivity of 5.5 MBq in a rat was well tolerated with most of the radioactivity inhaled found in the lung.
Studies of oral administration of solution of Technegas in rats showed that the radioactivity remained almost exclusively in the gastro-intestinal tract.
No study of effects on reproductive functions, of a mutagenic and carcinogenic potential has been carried out.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 years.

Technegas should be used within 10 minutes after preparation.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

For PULMOTEC 135 µL crucibles:
Five thermoformed blister packs (PVC – cardboard) of 10 PULMOTEC, 135 µL crucibles in a cardboard box.

For PULMOTEC 300 µL crucibles:
Five thermoformed blister packs (PVC – cardboard) of 10 PULMOTEC, 300 µL crucibles in a cardboard box.

6.6 Special precautions for disposal and other handling

The administration of radiopharmaceuticals creates risks for other persons from external radiation in particular for the chest or by contamination from vomiting and sputum. Radiation protection precautions in accordance with national regulations must therefore be taken.

Radioactive waste must be disposed of in accordance with national and international regulations.

7 MARKETING AUTHORISATION HOLDER

Cyclomedica Ireland Ltd
Ulysses House (Third floor)
Foley Street
Dublin 1
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1034/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th September 2000
Date of last renewal: 23rd February 2010

10 DATE OF REVISION OF THE TEXT

April 2026

11 DOSIMETRY

Technetium (Tc-99m) decays with the emission of gamma radiation with a mean energy of 140,5 KeV and a half-life of 6 hours, to technetium (Tc-99) which can be regarded as stable.

The biokinetic model for Technegas assumes that 95% of the inhaled material is deposited in the lungs with 5% in the main bronchi airways, with a biological half-time of 4 days.

The material absorbed from the GI-tract is assumed to behave as orally administered ^{99m}Tc-pertechnetate (ICRP, 1987). (ICRP Publication 80)

Absorbed dose per unit activity administered (mGy / MBq)					
Organ	**Adult**	**15 years**	**10 years**	**5 years**	**1 year**
Adrenals	0.0068	0.0091	0.013	0.020	0.034
Bladder	0.00032	0.00045	0.00074	0.0012	0.0028
Bone surfaces	0.0049	0.0063	0.0088	0.014	0.026
Brain	0.00025	0.00033	0.00058	0.00094	0.0015
Breast	0.0067	0.0073	0.013	0.019	0.027
Gall bladder	0.0023	0.0032	0.0055	0.0084	0.011
GI-tract Stomach	0.0044	0.0062	0.0088	0.0013	0.022
SI	0.00087	0.0013	0.0022	0.0039	0.0078
Colon	0.0014	0.0019	0.0034	0.0059	0.012
ULI	0.0019	0.0025	0.0046	0.0077	0.015
LLI	0.00074	0.0010	0.0018	0.0034	0.0070
Heart	0.013	0.017	0.023	0.032	0.048
Kidneys	0.0020	0.0030	0.0046	0.0072	0.0013
Liver	0.0057	0.0078	0.010	0.015	0.025
Lungs	0.11	0.16	0.22	0.33	0.63
Muscles	0.0028	0.0036	0.0049	0.0073	0.013
Oesophagus	0.0082	0.010	0.015	0.019	0.027
Ovaries	0.00041	0.00055	0.0011	0.0020	0.0042
Pancreas	0.0052	0.0073	0.010	0.016	0.028
Red bone marrow	0.0033	0.0038	0.0050	0.0066	0.011
Salivary glands	0.0028	0.0036	0.0063	0.0098	0.018
Skin	0.0012	0.0013	0.0022	0.0033	0.0059
Spleen	0.0048	0.0063	0.0093	0.015	0.025
Testes	0.000061	0.000091	0.00020	0.00033	0.0011
Thymus	0.0082	0.010	0.015	0.019	0.027
Thyroid	0.0029	0.0039	0.0069	0.011	0.020
Uterus	0.00030	0.00046	0.00083	0.0016	0.0036
Remaining organs	0.0027	0.0035	0.0047	0.0068	0.012
Effective dose (mSv / MBq)	0.015	0.022	0.031	0.047	0.087

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Technegas is generated exclusively using the medical device called Technegas generator. It is essential to follow the instructions described below to ensure proper quality of the product inhaled.

Handling of the Technegas generator is detailed in the instruction manual for the medical device.

Technegas is produced by heating to 2550°C the PULMOTEC crucible to which a solution of sodium pertechnetate [Tc-99m] (Eur.Ph.), from a standard Technetium (Tc-99m) Generator, is added and dry-evaporated.
The preparation of the Technegas is performed under an atmosphere of inert argon of purity equal to at least 99.99 %.

1. Using forceps supplied with the Technegas Generator, remove the PULMOTEC crucible from its protective packaging and place it on a glass watch or other suitable support.

2. Rinse only the hole of the PULMOTEC crucible as follows: using a needleless syringe, fill the hole of the crucible with ≥ 95 % ethanol and empty it by upturning the crucible. Do NOT use methylated alcohol as it may leave residues after evaporation that could lead to pyrolysis products in the Technegas generation stage.

3. Wear disposable gloves to prevent any eventual contamination during the following operations.

4. Open the Technegas Generator drawer and, using forceps, insert the wetted crucible between the support electrodes (Brass Contacts with carbon inlay) of the generator.

5. Rotate the crucible to ensure good electrical contact is made with the support electrodes. Ensure the hole is upright.

6. Using a syringe and needle, load the crucible (note that the walls of the crucible hole must be wet with ethanol) with 250 to 700 MBq of sodium pertechnetate [Tc-99m]:

a. For PULMOTEC 135 microlitre crucible, the maximum volume for each fill cycle is 0.1 ml.
b. For PULMOTEC 300 microlitre crucible, the maximum volume for each fill cycle is 0.3 ml.

NB:When loading the crucible ensure that the meniscus is concave or flat and not convex. If the meniscus is convex, draw back the excess of sodium pertechnetate [Tc-99m] using the syringe.

7. Close the drawer of the Technegas Generator and proceed to evaporate of sodium pertechnetate [Tc-99m] solution.

NOTE: At this stage of preparation, an additional load of sodium pertechnetate [Tc-99m] may be introduced to obtain the desired activity. To perform this, simply repeat the steps 6 and 7.

8. Proceed to the heating cycle to generate the Technegas.

9. Administer Technegas within 10 minutes of preparation, following the instructions given above (cf. section 4.2).

10. PULMOTEC is intended for single use. The Technegas Generator machine breaks the crucible at the end of the synthesis to prevent accidental re-use. Crucible fragments should be considered as radioactive waste.

The Technegas generator includes several automatic security devices to ensure safe and effective generation and delivery of the diagnostic agent.
The purge phase allows automatic elimination of air introduced during preparation and check the chamber seal.

The Technegas generator inhibits delivery of the diagnostic agent if the maximum temperature is not reached or if the Technegas has been prepared for more than 10 minutes.