

PACKAGE LEAFLET: INFORMATION FOR THE USER

PULMOTEC, graphite crucible for the preparation of Technegas inhalation

High purity graphite

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What PULMOTEC is and what it is used for
2. What you need to know before PULMOTEC is used
3. How PULMOTEC is used
4. Possible side effects
5. How PULMOTEC is stored
6. Contents of the pack and other information

1. What PULMOTEC is and what it is used for

This medicine is for diagnostic use only.

PULMOTEC, when in the presence of sodium pertechnetate (Tc-99m) and heated to 2550°C in an atmosphere of high purity argon, produces an aerosol of carbon micro-particles labelled with technetium (Tc-99m), called Technegas.

After inhalation of Technegas, imaging of the lungs can be recorded.

These images help your doctor or the specialist in nuclear medicine to see whether your lungs are abnormally ventilated. The use of Technegas is generally combined with the injection in your veins of another radiopharmaceutical agent to detect any abnormality in the blood flow to the lungs.

2. What you need to know before PULMOTEC is used

Warnings and precautions

-Technegas is administered by specially-trained, qualified staff. Laws governing the use, possession and handling of radioactive substances stipulate that this medicine may only be used in hospitals or similar institutions.

Your doctor or the specialist in nuclear medicine who will perform the investigation will tell you if you need to take any special precautions after using this medicine.

If in any doubt, please ask your doctor or the specialist in nuclear medicine who will perform the investigation for advice

- The use of Technegas involves the administration of a tiny amount of radioactivity. The risk arising from this use is very small. Your doctor or the specialist in nuclear medicine will prescribe this procedure only if he or she considers that this risk is greatly outweighed by the potential benefits.

Other medicines and PULMOTEC

No interaction with other medicines known to date.

Tell your nuclear medicine doctor if you are taking, have recently taken or might take other medicines, including medicines without prescription.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before you are given this medicine.

It is important to tell your doctor or the specialist in nuclear medicine if there is any possibility you might be pregnant, or if you are breast-feeding.

If you are pregnant:

The use of a radiopharmaceutical during pregnancy requires very special care.

Your doctor or the specialist in nuclear medicine will prescribe this procedure only if he or she considers that its benefits outweigh the risk incurred.

If you are breast-feeding:

If the use of Technegas proves essential while you are breast-feeding, your doctor or the specialist in nuclear medicine will ask you not to breast-feed for 12 hours after use, and to discard the milk produced during that time.

Driving and using machines

No studies have been done on the effect of this medicine on driving or using machines.

3. How PULMOTEC is used

Your doctor or the specialist in nuclear medicine will know how much Technegas you will need to use to get an image that gives the required medical information. For adults, the usual inhaled dose is about 40 MBq.

The becquerel (Bq) is a unit of radioactivity. MBq means megabecquerel.

For children lower doses are used.

- Technegas is inhaled. As the first inhalation contains no oxygen, oxygen may be given to you for a few moments before you inhale the Technegas. There are several possible ways to use this product: to determine which way is best in your case you will be asked first to try breathing through the mouthpiece with no Technegas, and then to repeat this with the mouthpiece connected to the Technegas generator.
- If you experience discomfort when using the medicine, you may take the mouthpiece out of your mouth between two inhalations of Technegas.
- To get an even distribution of the medicine in your lungs, you may have to use Technegas in a lying-down position.
- A series of 4 to 6 images is usually enough for your doctor or the specialist in nuclear medicine to get the required information.

If you used more PULMOTEC than you should:

- An overdose is practically impossible. The doses are carefully prepared and checked.
- If an overdose is suspected, your doctor or the specialist in nuclear medicine will ask you to drink a lot and urinate frequently.

If you have any further questions on the use of this product, ask your doctor or specialist in nuclear medicine who will perform the investigation.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The frequencies for undesirable effects are defined as follows:

Very common	Affects more than one user in 10
Common	Affects less than one user in 10
Uncommon	Affects less than one user in 100
Rare	Affects less than one user in 1,000
Very rare	Affects less than one user in 10,000
Not known	Frequency cannot be estimated from the available data

- Rare cases of giddiness, light headedness and nausea have been reported. These are thought to be caused by a temporary drop in oxygen in the blood, which can happen during the first inhalation of Technegas, which contains no oxygen. This risk is minimised by giving oxygen before inhaling Technegas.
- If you feel these effects, the doctor or the specialist in nuclear medicine will let you breathe normal air or give you oxygen.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How PULMOTEC is stored

You will not have to get or store this medicine for diagnostic purposes. The qualified staff of the nuclear medicine centre where this investigation is performed, will do this.

The label on the medicine states the proper storage conditions and the expiry date. The hospital staff will make sure the medicine is stored in the conditions stated and is not used after its expiry date.

6. Content of the pack and other information

What PULMOTEC contains

- The active substance is high purity graphite: 1.340 g per one crucible
- There is no other ingredient.

What PULMOTEC looks like and contents of the pack

Kit for radiopharmaceutical preparation.
Solid for inhalation powder.

The Technegas is obtained by heating the radioactive agent sodium pertechnetate (99mTc) to 2550 °C in a high purity graphite crucible (a piece of carbon with a specific shape). Technegas. is an aerosol (microscopic particles suspended in argon gas).

For PULMOTEC 135 microlitre crucibles:

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

For PULMOTEC 300 microlitre crucibles:

Five thermoformed blister packs (PVC – cardboard) of 10 PULMOTEC, 300 microlitres crucibles in a

cardboard box.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Cyclomedica Ireland Ltd.
Unit A5 Calmount Business Park
Ballymount
Dublin 12
Ireland

Manufacturer:

Pharmapac Ltd
Unit D1
Willow Drive
Naas Enterprise Park
Newhall, Naas
Co. Kildare
W91 E797
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This leaflet was last revised in 06/2022.

The following information is intended for medical or healthcare professionals only:
See the summary of product characteristics.