

KryptoScan [81mKr]

radionuclide generator

Active substance: ^{81}Rb Rubidium / $^{81\text{m}}\text{Kr}$ Krypton

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.

What is in this leaflet:

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

1. What KryptoScan is and what it is used for

This medicine is a radiopharmaceutical product for diagnostic use only.

KryptoScan is used through a scan to examine the

- **lung function** and
- **blood circulation in the lungs**

This medicine contains a radioactive substance, from which another radioactive substance called $^{81\text{m}}\text{Kr}$ Krypton can be received. $^{81\text{m}}\text{Kr}$ Krypton collects in the lungs when inhaled.

The radioactive substance can be photographed from outside the body, using special cameras which take a scan. This scan shows the distribution of radioactivity within the lung. This also gives the doctor valuable information about the structure and function of the lung.

The use of KryptoScan does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

2. What you need to know before KryptoScan is used

Warnings and precautions

KryptoScan is given by specialists, who will take responsibility for any necessary precautions.

Your doctor will inform you if you need to take any special precautions before or after using this medicine. Contact your doctor if you have any questions.

Children

Talk to your nuclear medicine doctor if you are under 18 years old.

Other medicines and KryptoScan

Tell your nuclear medicine doctor if you are using, have recently used or might use any other **medicines**, since they may **interfere** with the interpretation of the images:

- diazepam: a medicine to calm and induce sleep
- general anaesthetics

Pregnancy and breast-feeding

You must inform the nuclear medicine doctor before the administration of KryptoScan if there is a possibility:

- you might be pregnant
- if you have missed your period or
- if you are breast-feeding

When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

- If you are **pregnant**

The nuclear medicine doctor will **only** administer this product during pregnancy **if a benefit is expected which would outweigh the risks**.

- If you are **breast-feeding**

Your doctor may **delay treatment** until breast-feeding is finished. However, if your doctor considers administration of KryptoScan is absolutely necessary, breast-feeding need not be interrupted.

Driving and using machines

It is considered unlikely that KryptoScan will affect your ability to drive or to use machines.

3. How KryptoScan is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. KryptoScan will only be used in special controlled areas. This product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this product and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the quantity of KryptoScan to be used in your case. It will be the smallest quantity necessary to get the desired information.

The usual dose is

The quantity to be administered usually recommended for an adult corresponds to approximately 18 MBq per kg body weight per scan. 4 to 6 scans are usually sufficient.

MBq is the unit used to express radioactivity.

Use in children under 18 years

In children the quantity to be administered will be adapted to the child's weight.

Administration of KryptoScan and conduct of the procedure

KryptoScan is administered by inhalation using a face mask or airway. The scans will be made as soon as you begin inhaling continuously. You will be asked to stop inhaling between the different scans, so that the camera may be repositioned. This is necessary to acquire different images.

Duration of the procedure

Your nuclear medicine doctor will inform you about the usual duration of the procedure.

After administration of KryptoScan

The nuclear medicine doctor will inform you if you need to take any special precautions after receiving this medicine. Contact your nuclear medicine doctor if you have any questions.

If you have been given more KryptoScan than you should

An overdose is unlikely because you will only receive KryptoScan precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you only need to move away from the source of the inhalation gas to an area free from radioactivity.

Should you have any further question on the use of KryptoScan, please ask the nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, this medicine can cause side effects, however there is no knowledge of any side effects of this product.

This radiopharmaceutical will deliver low amounts of ionising radiation associated with the least risk of cancer and hereditary abnormalities.

Reporting of side effects

If you get any side effects, talk to your Nuclear medicine doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How KryptoScan is stored

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only:

- Store below 25°C.
- KryptoScan must not be used after the expiry date which is stated on the label.

6. Contents of the pack and other information

What KryptoScan contains

- The active substance is ^{81}Rb Rubidium / $^{81\text{m}}\text{Kr}$ Krypton
The generator produces Krypton gas obtained from Rubidium and available with activities ranging between 74-740 MBq.
- The other ingredient is a cation exchange resin which binds Rubidium.

What KryptoScan looks like and contents of the pack

KryptoScan is a shielded generator producing a colourless, odourless, inert gas for inhalation.

Marketing Authorisation Holder and Manufacturer

Mallinckrodt Medical B.V.

Westerduinweg 3

1755 LE Petten

The Netherlands

This leaflet was last revised in 09/2015

The following information is intended for medical or healthcare professionals only:

The complete SmPC of KryptoScan is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.