CURIUM™

Package leaflet: Information for the patient

Pulmocis 2 mg kit for radiopharmaceutical preparation
macroaggregated human albumin

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 Pulmocis is and what it is used for

Pulmocis contains the active substance macroaggregated human albumin which is a natural protein from human blood.

This medicine is a radiopharmaceutical product for diagnostic purposes use only.

Pulmocis should be radiolabelled with 'technetium-99m' and obtained product is used for scintigraphic imaging in adults and children.

When it is injected, the product is temporarily taken up by certain organs. Since the product contains a small amount of radioactivity, it can be visualised from outside the body using special cameras, and an image can be taken (known as a scan). This scan shows the distribution of the radioactivity in the organ and how that organ is functioning.

Pulmocis is used for lungs scans. These scans provide information about the structure of the lungs and the blood flow through the lung tissue.
Pulmocis is also used to show how the blood flows through the veins.

The use of Pulmocis 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 Pulmocis is used

Pulmocis must not be used:
- If you are **allergic** to human serum albumin or any of the other ingredients of this medicine (listed in section 6).
- if you have severe pulmonary hypertension (unusually high blood pressure in the arteries of the lungs). In case of doubt, it is important to consult your doctor.

Warnings and precautions
You should inform your nuclear medicine doctor:
- if you have unusually high blood pressure in the arteries of the lungs (severe pulmonary hypertension), respiratory insufficiency or if you are aware of having a cardiac anomaly known as a cardiac right-to-left shunt.
- if you are pregnant or believe you may be pregnant.
- if you are breastfeeding.
- if you suffer from kidney or liver disease.

Your nuclear medicine doctor will inform you if you need to take any special precautions in those cases.
Talk to your nuclear medicine doctor if you have any questions.

Before administration of PULMOCIS you should
- drink plenty of water before the start of the examination in order to urinate as often as possible during the first hours after the study.

Children and adolescents
Talk to your nuclear medicine doctor if you are or your child is under 18 years old.

Medicines made from human blood or plasma

When medicines are made from human blood or plasma, certain measures are put in place to prevent infections being passed on to patients. These include:
- careful selection of blood and plasma donors to make sure those at risk of carrying infections are excluded,
- the testing of each donation and pools of plasma for signs of virus/infections,
- the inclusion of steps in the processing of the blood or plasma that can inactivate or remove viruses.

Despite these measures, when medicines prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections.
There are no reports of virus infections with albumin manufactured according to European Pharmacopoeia requirements by established processes.

It is strongly recommended that every time you receive a dose of Pulmocis the name and batch number of the medicine are recorded in order to maintain a record of the batches used.

Other medicines and Pulmocis
Tell you nuclear medicine doctor if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription, since they may interfere with the interpretation of the images.

Specific examples include:
- **a medicine to prevent blood clotting** (heparin)
- **cancer medicines** (busulfan, cyclophosphamide, bleomycin, methotrexate)
- **medicines used to treat asthma and chronic obstructive pulmonary disease** (bronchodilators)
- **some antibiotics** (for example nitrofurantoin)
- **some medicines used in the prevention of headache** (for example methysergide)
- **a medicine used for substitution of electrolytes** (magnesium sulphate)
- **drugs of abuse** (heroin)

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

You must inform the nuclear medicine doctor before the administration of Pulmocis 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 Pulmocis during pregnancy if a benefit is expected which would outweigh the risks.

If you are breastfeeding:
Tell your nuclear medicine doctor, as he/she will advise you to stop doing so until the radioactivity has left your body. This takes **about 12 hours**. The expressed milk should be discarded.
Please ask you nuclear medicine doctor when you can resume breastfeeding.

Driving and using machines
It is considered unlikely that Pulmocis will affect your ability to drive or to use machines.

Pulmocis contains sodium
This medicine contains less than 1 mmol of sodium (23 mg) per administration, that is to say essentially 'sodium-free'.

3. How Pulmocis is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Pulmocis 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 Pulmocis to be used in your case. It will be the smallest quantity necessary to require getting the desired information. The quantity to be administered usually recommended for an adult ranges from 40 to 200 MBq
(MBq: megabecquerel, the unit used to express radioactivity).

Use in children and adolescents
In children and adolescents under 18 years, the quantity to be administered will be adapted to the child's weight.

Administration of Pulmocis and conduct of the procedure
Pulmocis is administered by injection into a vein.

One injection is sufficient to conduct the test that your doctor needs. The tests can be carried out any time after you have received the injection. Precisely when the test will be carried out depends on the type of examination.

After injection, you will be offered a drink and asked to urinate immediately preceding the test.

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

After administration of Pulmocis, you should:
- avoid any close contact with young children and pregnant women for the initial 12 hours following the administration.
- drink as much as possible the day after treatment. This will help the traces of radioactivity leave your body more quickly.
- urinate frequently in order to eliminate the product from your body.

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 PULMOCIS than you should:
An overdose is impossible because you will only receive a single dose of Pulmocis precisely controlled by the nuclear medicine doctor supervising the procedure. However, an administration of a very high number of particles can lead to a vascular blockage. Take care if pronounced changes in respiration, pulse or blood pressure occur; in this case your nuclear medicine doctor will take adequate measures.
However, in the case of an overdose, you will receive the appropriate treatment. In particular, the nuclear medicine doctor in charge of the procedure may recommend that you drink abundantly in order to facilitate the elimination of Pulmocis from your body.

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

4. Possible side effects

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

Frequency not known (cannot be estimated from the available data)
Allergic reactions (Frequency not known): Urticaria (hives), shivering fits, fever, nausea, reddening of the face and sweating as well as impairments of cardiac and circulatory functions in the form of changes in respiration, pulse, blood pressure and collapse. Local allergic reactions in the form of redness, swelling, and itching at the injection site have been observed. In such case you should contact your nuclear medicine doctor.

Very rare: (Less than 1 patient out of 10000)
Serious allergic reactions: Serious allergic reactions including shock with possible fatal outcome have been reported. The appearance of these reactions may also not be immediate.
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 doctor or nuclear medicine doctor. 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 PULMOCIS 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.

6. Contents of the pack and other information

What PULMOCIS contains:
- The active substance is 2 mg human albumin as macroaggregates.
- The other ingredients are human albumin, stannous chloride dihydrate, sodium chloride, sodium caprylate.

What PULMOCIS looks like and contents of the pack
The product is a kit for radiopharmaceutical preparation.

Pack size: kit of 5 multidose vials.

Marketing Authorisation Holder and Manufacturer
CIS bio international
RN 306-Saclay
B.P. 32
F-91192 Gif-sur-Yvette Cedex
France

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

The leaflet was last revised in 08/2019.

Other sources of information

Detailed information on this medicine is available on the web site of the HPRA.

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

The complete SmPC of Pulmocis 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.

Please refer to the SmPC included in the box.

CIS bio international, Member of Curium group
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