

PAMISCAN[®] 370

INN : Iopamidol 370 mg of iodine per ml
Injectable solution

Please read all of this leaflet carefully before taking this medicine.

- Keep this leaflet, you may need to read it again.
- If you have other questions, if you have any doubt, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Never give it to someone else, even if the symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- 1- What PAMISCAN[®]370 (370 mg of iodine per ml) and in which cases it is used for?
- 2- What you need to know before taking PAMISCAN[®] 370 (370 mg of iodine per ml)?
- 3- How to use PAMISCAN[®] 370 (370 mg of iodine per ml)?
- 4- What are the possible side effects?
- 5- How to store PAMISCAN[®] 370 (370 mg of iodine per ml)?
- 6- Further Information.

1. WHAT PAMISCAN[®]370 (370 mg of iodine per ml) AND IN WHICH CASES IT IS USED FOR ?

PAMISCAN[®] is used for diagnostic use only.

A contrast product for use in:

- Explorations with conventional equipment or CT in adults and in children: aortography, angiocardiology child, ventriculographie and coronary, renal abdominal selective angiography, opacification of the entire body.
- Intravenous urography
- Hysterosalpingography.

2. WHAT YOU SHOULD KNOW BEFORE USING PAMISCAN[®]370 ?

Never use PAMISCAN[®] in the following cases :

- If you are allergic to PAMISCAN[®]370 solution for injection or any other ingredients in PAMISCAN[®] 370.
- If you have already had a major or immediate skin reaction delayed after injection PAMISCAN[®] (see Adverse Reactions).
- If you suffer from an excess of thyroid hormones (thyrotoxicosis).

In case of doubt, ask the advice of your doctor or pharmacist.

Take special care with PAMISCAN[®] 370 (370 mg of iodine per ml) :

As with all iodinated contrast media and regardless of the route of administration and dose, there is a possibility of side effects, which may be minimal but can go up to vital prognosis. These reactions can occur within an hour or, more rarely, up to 7 days after administration. They are often unpredictable, but have an increased risk if you have had a reaction to previous administration of iodinated contrast (see Adverse effects).

Accordingly, it should prevent the radiologist who will conduct the injection if you have experienced an adverse effect during a previous radiological examination with iodinated contrast.

Report also any other illness you may have so that the doctor who will conduct the injection can take the necessary precautions.

Also tell your doctor:

- If you have already submitted a reaction to a previous injection of iodinated contrast;
- If you have kidney failure (kidney); if you have diabetes, if you have myeloma.
- If you have heart failure (the heart); coronary heart disease, or other heart disease;
- If you have both liver failure (liver) and renal;
- If you have asthma and if you have asthma attack within 8 days before the examination;
- If you suffer from neurological disorders such as epilepsy or stroke, or pheochromocytoma (producing excessive hormone causing severe hypertension), or myasthenia gravis (autoimmune muscle disease);
- If you have a thyroid disease or if you have a history of thyroid disease;
- If you are anxious, nervous or suffer from pain in these situations the side effects may be increased beings;
- If you have a disease of the pancreas (pancreatitis);
- If you have a disease of the bone marrow (monoclonal gammopathy : multiple myeloma or Waldenström's disease);
- If you have a recent history of intracranial hemorrhage;
- If you have a cerebral edema.

In case of alcoholism or drug addiction, it is important that your doctor or radiologist warned.

If you must have soon a thyroid examination or treatment with radioactive iodine, report to the radiologist.

If in doubt, do not hesitate to seek the advice of your doctor.

Taking other medicines :

Please tell your doctor or pharmacist any illness you have or if you are taking or have recently taken any other medicines, even if they are medicines obtained without a prescription.

Be particularly careful if you are taking medication prescribed for diabetes (metformin), hypertension (diuretics and beta-blockers), pain (analgesics), vomiting (antiemetics) or if you have received interleukin-2, the neuroleptics, tranquilizers (sedatives).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even if they are medicines obtained without a prescription.

Interactions with food and drinks :

Not applicable.

Interactions with herbal products or alternative therapies :

Not applicable.

Pregnancy and lactation :

Pregnancy:

It is imperative to inform the doctor your pregnancy, or delay menstruation before making your practice radiological examination.

Ask your doctor or pharmacist before taking any medicine.

Nursing:

It is recommended to stop breastfeeding for at least 24 hours after administration of the contrast agent.

Ask your doctor or pharmacist before taking any medicine.

Sports:

Not applicable.

Driving and using machines:

No specific risk known to date.

3. HOW TO USE PAMISCAN[®] 370 ?

Posology :
The injected dose, which can vary depending on the type of examination, the technique used but also according to your weight and general condition, is strictly determined by the doctor.

PAMISCAN[®] 370 :

Angiography:

The average doses to be used vary depending on the type of examination. The dose should not exceed 4 to 5 ml / kg injection iterative not more than 100 ml per injection. The injection rate depends on the type of examination.

- Thoracic Aortography: 50-80 ml.
- Peripheral Arteriography: 30-50 ml.
- Cardiac Angiography:
 - ventricular: 40-70 ml
 - intracoronary: 8-15 ml.

In urography:

Doses should be adjusted to the weight and renal function of the patient, who should be fasting without fluid restriction.

- Newborn (<1 month): 1.2 g iodine / kg, as 3.2 ml / kg.
- Children (1 month to 2 years): 1 g iodine / kg, as 2.7 ml / kg.
- Child (2-11 years): 0.5 g iodine / kg, as 1.4 ml / kg.
- Adolescent and Adult: 30 to 50 ml.

In hysterosalpingography:

In intrarterial injection, vaginally.

Mode of administration :

Injectable solution by intravascular route.

To avoid physicochemical incompatibility, do not inject other medication with the same syringe.

If you have used more PAMISCAN[®] 370 (370 mg of iodine per ml) than you should :

Not applicable.

If you forget to use PAMISCAN[®] 370 (370 mg of iodine per ml) :

Not applicable.

If you stop using PAMISCAN[®] 370 (370 mg of iodine per ml) :

Not applicable.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS OF PAMISCAN[®]370?

Like all medicines, PAMISCAN[®]370 (370 mg iodine per ml) solution for injection may cause side effects, although not everybody will not matter.

Hypersensitivity reactions (allergic reactions) may be severe and may be in the form of :

- Immediate reactions with itching (pruritus), skin redness (erythema), localized or widespread urticaria, angioedema (swelling of the face or mucous membranes);
- Delayed reactions in the skin such as maculopapular rash, and so exceptional toxic epidermal necrolysis or Stevens-Johnson (significant impairment of the skin lesions such as blisters);
- respiratory symptoms: cough, rhinitis throat tightness, difficulty breathing, bronchial spasm, laryngeal edema, respiratory arrest;
- cardiovascular events hypotension, dizziness, malaise, tachycardia, bradycardia, cardiac arrest;
- Other events: nausea, vomiting.

Other side effects may include :

Cardiovascular, neurosensory, gastrointestinal, renal, respiratory, local (pain and swelling, minor and transient at the injection site, adverse events, local thrombophlebitis in case of release of the product outside the vessel local inflammation or necrosis the skin can be observed), skin hypersensitivity reactions.

If you notice any side effects not listed in this leaflet, or if the side effects gets serious, please tell your doctor or pharmacist.

5. HOW TO STORE PAMISCAN[®] 370 ?

Keep out of the reach and sight of children.

Keep the primary packaging in the outer carton to protect from light.

Check the clarity of the solution if cloudy or white precipitate. Do not use the bottle.

Although exceptional, crystallization phenomena may be observed with the Iopamidol solutions, as with other hydrosoluble opacifiers, it is possible to dissolve these crystals by heating. However, precisely because of the extreme rarity of this event, Medis recommends only to not use the incriminated bottle. Do not store above 30°C

6. FURTHER INFORMATION :

What contain PAMISCAN[®] 370 (370 mg d'iodine per ml) :

	PAMISCAN [®] 370 (bottle of 50 ml)	PAMISCAN [®] 370 (bottle of 100 ml)
Actif ingredient :		
Iopamidol	37,75 g	75,5 g
Excipients :		
Trometamol, disodium calcium edetate, hydrochloride acid, sodium hydroxydes.q.		
Water For Injection W.F.I.	50 ml	100 ml

What PAMISCAN[®] contents of the pack and M.A. number :

PAMISCAN[®]370 mg bottle of 50 ml : injectable solution in 50 ml bottle – box of 01bottle – M.A. N° 923 374 6

PAMISCAN[®]370 mg bottle of 100 ml : injectable solution in 100 ml bottle – box of 01 bottle – M.A. N° 923 374 7

Delivery conditions: List I- drug subject to medical prescription.

Authorization Holder of the marketing and manufacturer

Authorization Holder of the Marketing : Laboratories MEDIS - Tunis road Km 7 - BP206 - 8000 Nabeul.

Manufacturer :Les Laboratoires MEDIS -Tunis road Km 7 - BP206 - 8000 Nabeul.

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THIS IS A DRUG

- A drug is a product but not like the others.
- A drug is a product that is on your health and its non-conformity with the requirements consumption exposes you to danger.
- Follow strictly the doctor's prescription and the instructions that tells you to follow the advice of your pharmacist.
- Your doctor and pharmacist know about the drug, its indications and cons-indications.
- Do not stop your own treatment during the prescribed period.
- Do not pick up, do not increase the dose without consulting your doctor.

Keep drugs out of the reach of children

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