PATIENT INFORMATION LEAFLET

CHOLEDIAM
Kit for the preparation of technetium [^{99m}Tc] mebrofenin injection
Mebrofenin

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.

In this leaflet:

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

1. WHAT CHOLEDIAM IS AND WHAT IT IS USED FOR

This medicine is a radiopharmaceutical product for diagnostic use only.

- Choledíam is used to perform scans of the liver, the gall bladder and the bile duct which are usual paths of bile excretion.
  - This product is used in the preparation of a diagnostic radiopharmaceutical. When injected, the radiopharmaceutical temporarily collects in the liver and is excreted into bile.
  - Because the substance contains a small amount of radioactivity, it can be detected from outside the body using special cameras, and pictures, known as scans, can be taken. These scans will show exactly the distribution of the radiopharmaceutical within the organs and the target tissues. This gives the physician valuable information for the diagnosis of your disease.

The use of Choledíam 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 CHOLEDIAM IS USED

Choledíam must not be used
- if you are allergic (hypersensitive) to mebrofenin or any of the other ingredients of Choledíam (listed in section 6).

Warnings and precautions
Take special care with Choledíam
- if you are or think you may be pregnant or there is any possibility of pregnancy
- if you are breast-feeding
- Choledíam should only be used and administered by authorised persons
- your physician will inform you if you need to take any special precaution before or after the administration of the product.

Before administration of Choledíam you should
- be fasting for at least 6 hours.

Speak to your doctor before receiving Choledíam if you:
- have been receiving nutritional formulas intravenously
- have been dieting for a long time
- have just eaten before treatment
- have liver problems

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

Other medicines and Choledíam
Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines, since they may interfere with the interpretation of the images.

It is particularly important to tell your doctor if you are taking any of the following:
- opioid painkillers such as morphine
- barbiturates used for sedation such as phenobarbital
- vitamin B3 supplements
- cholecystokinin or somatostatin (peptide hormones)
- sincalide used to diagnosis gall bladder or pancreas problems
- atropine used for heart problems or eye tests.

Pregnancy
- You must inform the nuclear medicine doctor before you are given Choledíam 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.

Breast-feeding
- If you are breast-feeding, the nuclear medicine doctor will only give you this product if a benefit is expected which would outweigh the risks.

Please ask your nuclear medicine doctor when you can resume breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Effects on the ability to drive and use machines are not expected.

3. HOW CHOLEDIAM IS USED

There are strict laws on the use, handling and disposal of

radiopharmaceutical products. Choledíam 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 Choledíam to be used in your case. It will be the smallest quantity necessary to get the desired information.

The quantity to be administered usually recommended from 20 MBq for small children, up to a maximum of 300 MBq (Megabecquerel - the unit in which radioactivity is measured) for adults.

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

Administration of Choledíam and conduct of the procedure
The solution is administered by injection into a vein.
One injection is sufficient to provide your doctor with the information needed.

Duration of treatment
Scans may be taken at any time following injection. Your nuclear medicine doctor will inform you about the usual duration of the procedure.

After administration of Choledíam
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 Choledíam than you should
An overdose is unlikely since Choledíam is administered by a nuclear medicine doctor under strictly controlled conditions. However, in the case of an overdose, you will receive the appropriate treatment.

Should you have any further question on the use of Choledíam, please ask the nuclear medicine doctor who will supervise the procedure.

4. POSSIBLE SIDE EFFECTS

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

On very rare occasions, allergic type reactions may occur. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the 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 CHOLEDIAM 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 Choledíam contains
- The active ingredient is mebrofenin.
- The other ingredient is stannous chloride dehydrate

What Choledíam looks like and contents of the pack
15 ml, colourless, European Pharmacopoeia type I, drawn glass vials, closed with chlorobutyl rubber stoppers and aluminium capsules which may be labelled with 740 to 3700 megabecquerel (MBq) of technetium (a radioactive tracer).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

MEDIAM Pharma

MEDIAM
21, avenue de Verdun
F-59700 Marcq-en-Baroeul
Tel: +33 3 20 49 72 58
Fax: +33 3 20 88 16 71

Manufacturer
GIPHARMA S.r.l.
Str. per Crescentino
I - Saluggia (VC), 13040
Tel :+ 39 0161 487 141
Fax :+ 39 0161 487 140

MA number: PA 1229/001/001
This leaflet was last approved in 09/2017.

The following information is intended for medical or healthcare professionals only:
Please refer to the SmPC.