Package leaflet: Information for patients

Ioflupane (^{123} I) ROTOP, 74 MBq/ml, solution for injection

Ioflupane (^{123} I)

Please read this leaflet carefully before administration as it contains important information for the patient.

- Keep this leaflet so that you can read it again if necessary.
- If you are in any doubt, ask the nuclear medicine physician who will supervise the procedure.
- If you experience any side effects, including any side effects not listed in this leaflet, tell your nuclear medicine doctor. See section 4.

Table of contents of the leaflet:

1. What Ioflupane (^{123} I)ROTOP is and what it is used for

This medicine is a radiopharmaceutical for diagnostic use only.

The drug Ioflupane (^{123} I)ROTOP contains the active substance ioflupane (^{123} I), used to help diagnose (diagnose) certain brain diseases. The drug belongs to a group of substances with low radioactivity, referred to as radiopharmaceuticals.

- When injected, this radiopharmaceutical accumulates in specific organs or areas of the body for a short period of time.
- Because it contains a small amount of radioactive substance, it can be detected from outside the body using special cameras.
- An image, referred to as a 'scan', can be taken. The scan shows the exact location of the radioactivity within the organ and the body. This allows the doctor to gain valuable information about how the organ works.

When injected into an adult patient, the drug Ioflupane (^{123} I)ROTOP is distributed through the body with the blood. It accumulates in a small area of the brain. Changes in this area of the brain occur in the following disorders:

- Parkinsonism (including Parkinson's disease) and
- dementia with Lewy bodies.

The scan will provide the doctor with information about any changes in this area of the patient's brain. The attending physician may find that the information obtained from the scan will be helpful in gaining a more thorough understanding of the patient's disease and in making decisions about possible treatment.

After the administration of Ioflupane (^{123} I)ROTOP, the patient is exposed to a small dose of radiation. This dose is less than during some X-ray examinations. The patient's treating physician and the nuclear medicine physician considered that the benefits of this study with a

radiopharmaceutical outweighs the risk of exposure to these small amounts of radiation.

2. Important information before using Ioflupane (^{123}I)ROTOP

When not to use Ioflupane (^{123}I)ROTOP

- if you are allergic to Ioflupane (^{123}I)or any of the other ingredients of this medicine (listed in section 6);
- if the patient is pregnant.

Warnings and precautions
Before starting Ioflupane (^{123}I)ROTOP, discuss this with your nuclear medicine physician if you have moderate or severe kidney or liver disease.

Before administering Ioflupane (^{123}I)ROTOP and starting the study, the patient should
drink plenty of water to urinate as often as possible during the first hours after the test.

Children and adolescents
The administration of Ioflupane (^{123}I)ROTOP to children aged 0 to 18 years is not recommended.

Ioflupane (^{123}I)ROTOP and other medicines
Tell your nuclear medicine doctor about all medicines you are currently or recently taking. Some medicines or substances may affect the effect of this medicine. These include:

- bupropion [used to treat depression (despondency)],
- benzatropine (used to treat Parkinson's disease),
- mazyndol (reduces appetite, used to treat obesity),
- sertraline [used to treat depression (despondency)],
- methylphenidate [used to treat hyperactivity in children and narcolepsy (excessive sleepiness)],
- fentermine (reduces appetite, used to treat obesity),
- amphetamine [used to treat hyperactivity in children and narcolepsy (excessive sleepiness); also an illicit psychoactive substance],
- cocaine (sometimes used for anaesthesia before nasal surgery; also an illicit psychoactive substance).

Some medications may impair the quality of images obtained. The physician may advise the patient to discontinue such medications shortly before the administration of Ioflupane (^{123}I)ROTOP.

Pregnancy and breast-feeding
If the patient is pregnant or breastfeeding, suspects that she may be pregnant or if she is planning to have a baby, she should consult her nuclear medicine physician before taking this medicine.

If there is a possibility that the patient is pregnant, if her menstrual bleeding is delayed or if the patient is breastfeeding, she should inform her nuclear medicine physician before administering Ioflupane (^{123}I)ROTOP.

If in doubt, advise the nuclear medicine physician who will supervise the study.

If the patient is pregnant, Ioflupane (^{123}I)ROTOP should not be used in her. Otherwise, the baby may receive a dose of radioactivity. The use of other techniques not using ionising radiation should be considered.

If the patient is breastfeeding, the nuclear medicine physician may delay the use of Ioflupane

(^{123}I) ROTOP or recommend discontinuation of breastfeeding. It is not known whether Ioflupane (^{123}I)passes into the milk of breastfeeding women.

- The patient should not breastfeed for 3 days after administration of Ioflupane (^{123}I)ROTOP.
- During this time, the baby should be fed with milk replacer. Express and remove milk at regular intervals.
- This should be continued for 3 days until there is no more radioactivity in the patient's body.

Driving and operating machinery
Any effect of Ioflupane (^{123}I)ROTOP on the ability to drive and operate machines is not known.

Ioflupane (^{123}I)ROTOP contains 4 vol% alcohol (ethanol).
This medicine contains up to 158 mg of alcohol per dose. The amount of alcohol in a dose of this medicine is equivalent to less than 4 ml of beer or 1.6 ml of wine.
A small amount of alcohol in this medicine will not cause noticeable effects.

The drug contains less than 1 mmol (23 mg) of sodium per vial, i.e. the drug is considered 'sodium free'.

3. How to use the drug Ioflupane (^{123}I)ROTOP

There are strict regulations regarding the use, transfer and disposal of radiopharmaceutical preparations. The drug Ioflupane (^{123}I)ROTOP will always be used in a hospital or similar facility. This drug will only be prepared and administered to patients by people who are appropriately trained and qualified to use it safely. These persons will tell the patient everything that needs to be done for this medicine to be used safely.

The nuclear medicine physician overseeing the study will determine the dose of Ioflupane (^{123}I)ROTOP suitable for the patient. This will be the lowest dose necessary to obtain the information needed.

Before administering Ioflupane (^{123}I)ROTOP, the doctor will advise the patient to take iodine tablets or liquid. This will prevent the accumulation of radioactivity in the thyroid gland. It is important to take the tablets or liquid exactly as prescribed by your doctor.

Administration of Ioflupane (123 I)ROTOP and conduct of the study
Ioflupane (^{123}I)ROTOP is given by injection, usually into a vein in the arm. The dose usually recommended for adults is between 111 and 185 MBq (MBq= megabecquerel is the unit of measurement of radioactivity). One injection is sufficient.

Duration of the examination
The scan using a special camera is usually performed 3 to 6 hours after the injection of Ioflupane (^{123}I)ROTOP.
The nuclear medicine physician will inform the patient of how long the test usually takes.

After the administration of Ioflupane (^{123}I)ROTOP, **the patient should** urinate frequently to rapidly remove the drug from the body.

Your nuclear medicine doctor will tell you if any special precautions will be needed after receiving this medicine. Ask your nuclear medicine doctor if you have any questions.

Taking more than the recommended dose of Ioflupane (^{123}I)ROTOP
Because Ioflupane (^{123}I)ROTOP is administered by your doctor under controlled conditions, it is unlikely that you will receive too high a dose. The nuclear medicine physician will advise the patient to drink large amounts of fluids to facilitate the removal of the drug from the body. You will need to take appropriate precautions when urinating - your doctor will tell you what to

do. This is standard practice for the use of medicines such as Ioflupane (^{123} I)ROTOP. Any possible residue of Ioflupane (^{123} I)ROTOP in the patient's body will spontaneously lose radioactivity.

If you have any further concerns about the use of this medicine, contact the supervising nuclear medicine physician.

4. Possible side effects

Like all medicines, this medicine may cause undesirable effects, although these will not occur in everyone. The incidence of side effects is as follows:

Common: may occur in up to 1 in 10 people
- headache

Uncommon: may affect up to 1 in 100 people
- increased appetite
- dizziness
- taste disturbance
- nausea
- dry mouth
- a swirling sensation
- brief annoying tingling sensation
- severe pain (or a burning sensation) at the injection site. This effect was observed in patients who received Ioflupane (^{123} I)ROTOP into a small vein.

Frequency unknown (frequency cannot be determined from the available data)
- hypersensitivity (allergy)
- dyspnoea
- reddening of the skin
- itching
- rash
- urticaria
- excessive sweating
- vomiting
- lowered blood pressure
- a feeling of heat.

This radiopharmaceutical product will deliver a small amount of ionising radiation, which is associated with a very low risk of cancer and birth defects.

Reporting of side effects
If you experience any side effects, including any side effects not listed in this leaflet, tell your nuclear medicine doctor. Adverse reactions can be reported directly to the Adverse Drug Reactions Monitoring Department of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products:
Al. Jerozolimskie 181C
PL-02 222 Warsaw
Tel:+ 48 22 49 21 301
Fax:+ 48 22 49 21 309
Website: https://smz.ezdrowie.gov.pl
Side effects can also be reported to the responsible entity.
By reporting side effects, more information on the safety of the medicine can be gathered.

5. How to store Ioflupane (^{123}I)ROTOP

The patient will not store this medicine. This medicine will be stored by professional medical staff in appropriate facilities. Radiopharmaceuticals shall be stored in accordance with local regulations for radioactive substances.

The following information is intended for professional medical personnel only. Do not use this medicine after the expiry date on the label.

Hospital staff will ensure that the product is properly stored and disposed of and not used after the expiry date on the label.

6. Package contents and other information

What does the drug Ioflupane (^{123}I)ROTOP

contain?

- The active substance of the drug is ioflupane (^{123}I). Each millilitre of solution contains 74 MBq of ioflupane (^{123}I)per day and reference hour (0.07 to 0.13 µg/ml ioflupane).
- The other ingredients are glacial acetic acid, sodium acetate trihydrate, ethanol anhydrous and water for injection.

What Ioflupane (^{123}I)ROTOP looks like and what the pack contains

Ioflupane (^{123}I)ROTOP is a colourless solution for injection. 2.5 ml or 5 ml of this solution is supplied in a 10 ml vial of type I colourless glass, with a type I chlorobutyl rubber stopper, with an aluminium *flipp-off* cap, in a lead container.

Marketing authorisation holder and manufacturer

ROTOP Radiopharmacy GmbH
Bautzner Landstrasse 400
01328 Dresden
Germany
Telephone: +49 (0)351 26 31 01 00
Fax: +49 (0)351 26 31 03 03
E-mail: service@rotop-pharmaka.de

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Information intended for professional medical personnel only:
The full Summary of Product Characteristics (SmPC) of Ioflupane (^{123}I)ROTOP is provided as a tear-off section at the end of the printed package leaflet to provide professional medical personnel with additional scientific and practical information on the administration and use of this radiopharmaceutical product. See the SmPC.