Package leaflet: Information for the patient

Read all of this leaflet carefully before you start taking 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.

Iodopol 37-7400 MBq, capsules, hard

Sodium iodide (^{131}I)

What is in this leaflet

1. What Iodopol is and what it is used for

Iodopol is a medicine used in adults, children and adolescents to treat:
- thyroid gland tumours,
- overactive thyroid gland,
- large, compressive thyroid gland.

This medicine contains sodium iodide (^{131}I), a radioactive substance which accumulates in certain organs such as the thyroid gland.
This medicine is radioactive, but your doctors consider that the medicine's beneficial effect on your condition outweigh the possible harm from the radiation.

2. What you need to know before you take Iodopol

Do not take Iodopol

if you are
- allergic to sodium iodide or any of the other ingredients of this medicine (listed in section 6)
- pregnant or think you might be pregnant
- breast-feeding

if you have
- swallowing problems
- obstructed gullet
- stomach problems
- reduced abdominal or bowel movement

If any of these apply to you, **tell your nuclear medicine doctor.**

Warnings and precautions

Tell the nuclear medicine doctor
- if you have reduced kidney function.
- if you have problems passing urine,
- if you have digestive or stomach problems,
- if protruding eyes are part of the symptoms of the disease you are suffering from (Graves' disease-induced ophthalmopathy).

Low sodium blood levels have been observed in elderly patients who have had their thyroid removed. This event is most likely to occur in women and in patients taking medicines that increase the amount of water and sodium that is excreted in the urine (diuretics, such as hydrochlorothiazide). If you are included in some of these groups, your doctor may perform regular blood tests to check the amount of electrolytes (e.g. sodium) in your blood.
If any of these apply to you, talk to your nuclear medicine doctor. Iodopol may not be suitable for you.
Your doctor will inform you if you need to take any special precautions after using this medicine.
Speak with your nuclear medicine doctor if you have any questions.

Before you take Iodopol you should:
- follow a low iodine diet,
- drink plenty of water before the start of the procedure so that you pass urine as often as possible in the first hours after taking Iodopol,
- be fasting on the day of application.

Children and adolescents

Talk to your nuclear medicine doctor if you are under 18 years old, or if you cannot swallow a capsule.

Other medicines and Iodopol

Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription.
Please tell your nuclear medicine doctor if you are taking or have been given any of the following medicines or substances, since they may affect how well this treatment works.
Your doctor may recommend that you stop the following medicines before treatment:
- **medicines to reduce thyroid gland function**, such as carbimazole, methimazole, propylthiouracil perchlorate for 1 week;
- **salicylates:** medicines to reduce pain, fever or inflammation such as aspirin for 1 week;
- **cortisone:** medicines to reduce inflammation or prevent organ transplant rejection for 1 week;
- **sodium nitroprusside:** a medicine to reduce high blood pressure, and also used during an operation for 1 week;
- **sodium sulfobromophtalein**: a medicine to test liver function for 1 week;

other medicines for 1 week;
- to **reduce blood coagulation**
- to **treat parasitic** infestation
- **antihistamines:** used to treat allergies
- **penicillins** and **sulphonamides**: antibiotics
- **tolbutamide:** a medicine to reduce blood sugar
- **thiopentone**: an anaesthetic used in operations to reduce brain pressure, and to treat serious epileptic fits;
- **phenylbutazone:** a medicine to reduce pain and inflammation, for 1-2 weeks;
- iodine containing **medicines to help free the airways of sputum**, for 1-2 weeks;
- **iodide**-containing medicines that are used only on a restricted area of the body for 1-9 months;
- iodine containing **contrast agents** up to 1 year;
- **vitamins** containing iodine salts for 2 weeks;
- medicines containing **thyroid hormones** such as, levothyroxine (for 6 weeks) or triiodothyronine (for 2 weeks);
- **benzodiazepines:** medicines which calm mood and help patients sleep and relax muscles, for 4 weeks;
- **lithium:** a medicine to treat of bipolar disorder for 4 weeks;
- **amiodarone:** a medicine to treat heart rhythm disorders for 3-6 months;

Iodopol with food

Your doctor may recommend a low iodine diet before treatment and may ask you to avoid foods such as shellfish and crustaceans.

Pregnancy and breast-feeding

This medicine must not be used during pregnancy. Therefore, **you must tell the nuclear medicine doctor before taking Iodopol** if there is a possibility you might be pregnant or if you have missed your period, or think you may be pregnant or are planning to have a baby.

If you are pregnant

Do not take Iodopol if you are pregnant. Any possibility of pregnancy must be ruled out before using this medicine.

Contraception in males and females

Women should not become pregnant for at least 6 months after using Iodopol. Women are advised to use contraception for a time period of 6 months. As a precaution, men should not father a child for a time period of 6 months after treatment with Iodopol to allow the replacement of irradiated by non-irradiated spermatozoa.

Fertility

Treatment with Iodopol may temporarily reduce fertility in men and women.
In men, high doses of sodium iodide (^{131}I) may affect **sperm production** temporarily. If you would ever like to father a child, speak to your doctor about saving your sperm in a sperm bank.

If you are breast-feeding

Tell your doctor if you are breast-feeding because you should **stop breast-feeding before treatment. Breast-feeding should not be resumed after treatment with Iodopol.**

Driving and using machines

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

Iodopol contains sodium and quinoline yellow (E 104)

Iodopol contains maximum 97 mg sodium (main component of cooking/table salt) in each capsule. This is equivalent to 4.85% of the recommended maximum daily dietary intake of sodium for an adult. This is to be taken into consideration if you are on a controlled sodium diet.
Iodopol contains colouring agent quinoline yellow (E 104). It may cause allergic reactions. It may have an adverse effect on activity and attention in children.

3. How to take Iodopol

There are strict laws on the use, handling and disposal of radioactive products for medical treatment. Iodopol will only be used in specialized, controlled areas. This medicine will only be given by people who are trained and qualified to use it safely. These people will take special care use this medicine safely and they will talk to you about what they are doing.
The nuclear medicine doctor supervising the procedure will decide on the right dose of Iodopol for you. It will be the smallest quantity necessary to get the desired effect.
Iodopol is given as one single capsule by specialists, who will take responsibility for any necessary precautions.
The activity usually recommended for an adult are:
- 200-800 MBq to treat overactive or large, compressive thyroid gland;
- 1,850-3,700 MBq for partial or complete removal of the thyroid gland and for treating the spread of cancer cells, known as metastases;
- 3,700-11,100 MBq for follow up treatment of metastases.

MBq (megabecquerel) is the unit used to measure the amount radioactivity the medicine.
Use in children and adolescents under 18 years
Lower doses are used for children and adolescents.

How Iodopol is given and what the procedure involves

Iodopol is given to you as one single capsule.
Your stomach should be empty when you take the capsule.
Take the capsule with plenty of water so that it enters your stomach as quickly as possible.
Young children should take the capsule together with mashed food.
Drink as much water as possible the day after treatment. This will wash away the active substance from your bladder.

Duration of the procedure

Your nuclear medicine doctor will tell you how long the procedure will take.

After you take Iodopol

The nuclear medicine doctor will tell you if you need to take any special precautions after receiving this medicine. Particularly, you
- must avoid any close contact with infants and pregnant women for a few days. Your nuclear medicine doctor will tell you how long this should be.
- should drink plenty of fluids and pass urine frequently in order to remove the medicine from your body
- should flush the toilet carefully and wash your hands thoroughly as your bodily fluids will be radioactive for a few days
- should have drinks or sweets that contain citric acid, e.g. orange, lemon or lime juice to help produce saliva and stop the saliva building up in your saliva glands

- should have laxatives to stimulate the bowel, if you have less than one bowel movement per day.

Your blood, stools, urine or possible vomit may be radioactive for a few days and should not come into contact with other people.
Contact your nuclear medicine doctor if you have any questions.

If you have been given more Iodopol than you should

An overdose is unlikely, because you will only receive a single dose of Iodopol precisely controlled by the nuclear medicine doctor supervising the procedure
However, in the case of an overdose, you will receive the appropriate treatment.
If you have any further question on the use of Iodopol, ask your 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.
Frequent adverse reactions are: hypothyroidism (an underactive thyroid gland), temporary hyperthyroidism (an overactive thyroid gland), salivary and tear gland disorders, and local radiation effects. In cancer treatment, additionally stomach and gut side effects and reduction in the production of blood cells in the bone marrow suppression may frequently occur.
If you have serious allergic reaction occurs, which causes difficulty in breathing or dizziness, or if you have severe overactive thyroid crisis, contact your doctor immediately.
All the side effects with Iodopol are listed below, grouped according to the condition Iodopol is being used for as they depend on the activity used for the different treatments.

Treatment of overactive or large, compressive thyroid gland

Very common, may affect more than 1 in 10 people
- underactive thyroid

Common (may affect up to 1 in 10 people)
- a type eye inflammation, called endocrine ophthalmopathy (after treatment of Graves` disease)
- temporarily overactive thyroid
- salivary gland inflammation

Very rare (may affect up to 1 in 10,000 people)
- vocal cord paralysis

Frequency not known (frequency cannot be estimated from the available data)
- serious allergic reaction which causes difficulty in breathing or dizziness
- severe overactive thyroid crisis
- thyroid inflammation
- reduced tear gland function characterized with dry eyes
- reduction or loss of parathyroid hormone production with tingling in the hands, fingers, and around the mouth to more severe forms of muscle cramps
- thyroid hormone deficiency in the offspring
- abnormal function of the liver

Treatment of cancers

Very common (may affect more than 1 in 10 people)
- severe reduction in blood cells which can cause weakness, bruising or make infections more likely
- lack of red blood cells
- bone marrow failure with reduction of red blood cells, white blood cells, or both
- disturbance or loss of the sense of smell or taste
- nausea (feeling sick)
- decreased appetite
- failure of function of the ovaries
- flu-like illness
- headache, neck pain
- extreme tiredness or drowsiness
- inflammation causing red, watery and itchy eyes
- salivary gland inflammation with symptoms such as dry mouth, nose and eyes; tooth decay, tooth loss

Common (may affect up to 1 in 10 people)
- abnormal, cancerous increase of white blood cells
- lack of white blood cells or platelets
- runny nose
- breathing difficulty
- vomiting
- areas of tissue swelling

Rare (may affect up to 1 in 1,000 people)
- severe or temporarily overactive thyroid

Frequency not known (frequency cannot be estimated from the available data)
- serious allergic reaction which causes difficulty in breathing or dizziness
- cancer, including that of the bladder, large bowel, stomach
- permanent or severe reduction of blood cell production in the bone marrow
- thyroid inflammation
- reduction or loss of parathyroid hormone production
- increased parathyroid hormone production
- underactive thyroid
- inflammation of the trachea and/or throat narrowing
- proliferation of connective tissue in the lungs
- difficulty or wheezy breathing
- lung inflammation
- vocal cord paralysis, hoarseness, reduced ability to produce voice sounds using the vocal organs
- mouth and throat pain
- fluid build-up in the brain
- inflammation of the stomach lining
- difficulty in swallowing
- inflammation of the bladder
- disturbed menstrual cycle
- decreased male fertility, low sperm count or loss of sperm
- thyroid hormone deficiency in the offspring
- abnormal function of the liver
- low sodium concentration in the blood

If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:
Departament Monitorowania Niepożądanych Działań Produktów Leczniczych Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych:
Al. Jerozolimskie 181C
02-222 Warszawa
Phone: +48 22 49 21 301
Fax: +48 22 49 21 309
e-mail: ndl@urpl.gov.pl
Web site: https://smz.ezdrowie.gov.pl
Side effects may also be reported to the marketing authorisation holder.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Iodopol

Patient will not have to store this medicine.
This medicine is stored under the responsibility of the specialist in appropriate premises. It will be stored in accordance with national regulation on radioactive materials.
The following information is intended for the specialist only.
Iodopol must not be used after the expiry date which is stated on the label after "EXP".

6. Contents of the pack and other information

What Iodopol contains:
The active substance is sodium iodide (^{131}I).
Each hard capsule contains 37-7400 MBq of sodium iodide (^{131}I).
The other ingredients are:
- Sodium carbonate
- Sodium hydrogen carbonate
- Sodium hydroxide
- Disodium phosphate dihydrate
- Sodium thiosulfate

Gelatin capsule composition:
Quinoline yellow (E 104)
Erythrosine (E 127)
Titanium dioxide (E 171)
Gelatin

What Iodopol looks like and contents of the pack

The polypropylene vial placed in a shielding lead container, closed with a lead stopper which contains polypropylene insert with iodine absorber. The package contains a single capsule. Each package is accompanied by a separate polypropylene applicator for capsule administration.

Marketing Authorisation Holder and Manufacturer

Narodowe Centrum Badań Jądrowych
ul. Andrzeja Sołtana 7
05-400 Otwock
Poland
Phone: +48 22 7180700
Fax: +48 22 7180350
e-mail: polatom@polatom.pl

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria:	Iodopol 37-7400 MBq Hartkapseln
Bulgaria:	Iodopol
Czech Republic:	Iodopol
Estonia:	Iodopol
Germany:	Iodopol
Lithuania:	Sodium iodide (^{131}I) POLATOM 37-7400 MBq kietosios kapsulės
Poland:	Iodopol
Slovak Republic:	Iodopol
Slovenia:	Natrii iodidum (^{131}I) POLATOM, 37-7400 MBq trde kapsule

For more detailed information, please contact the doctor or the representative of marketing authorisation holder.

This leaflet was last revised in: 22.01.2024

The following information is intended for medical or healthcare professionals only:
Instructions for opening the container with the radioactive product using the applicator:

1. Check the radioactivity and calibration date placed on the outer package.
2. Tear off the upper cover of the metal tin.
3. Remove the upper styrofoam inlay.
4. Take the capsule shielding container out.
5. Tear the paper-foil mouthpiece wrapping and take out the mouthpiece.
6. Open the capsule shielding container. To do this, hold the bottom part of the container and pull the upper part upwards. The vial containing the capsule should remain in the shielding container.
7. Connect the mouthpiece to the vial. To do this, screw in the mouthpiece into the vial containing the capsule.
8. During the administration of the capsule it is recommended to keep the vial containing the capsule in the shielding container. The patient holding the shielding container in his hand takes the mouthpiece in his mouth and then tilts it to get the capsule from the vial through the mouthpiece. When required, it is possible to administer a capsule without using the shielding container. The patient grasps the mouthpiece, takes the capsule vial out from the shielding container, takes the mouthpiece in his mouth and then tilts it to get the capsule from the vial through the mouthpiece.
9. After the administration of the capsule, the mouthpiece and the vial should be disposed of. The shielding container should be returned to the manufacturer.
10. To disconnect the mouthpiece from the vial, put the vial with the mouthpiece in the shielding container, and then holding the container with your hand screw off the mouthpiece in order to disconnect it.
11. In order to measure the capsule activity, take the mouthpiece fixed to the capsule vial with the gripping device of the dose calibrator and load in the dose calibrator. When the measurement is finished remove the mouthpiece fixed to the capsule vial and place it back in the shielding container. When transferring the capsule to another room is necessary, the mouthpiece should be disconnected from the vial according to above instruction. After disconnecting the mouthpiece, cover the shielding container with a lid.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.