PACKAGE LEAFLET: INFORMATION FOR THE USER
Niopam 340 solution for injection
(Iopamidol)

The name of your medicine is Niopam 340 solution for injection, which will be called Niopam throughout this leaflet.

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 doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet, see section 4.

What is in this leaflet:

1. What is Niopam and what it is used for
Niopam is a special dye (or contrast agent) which blocks X-rays because it contains iodine. Niopam works by helping your doctor to see the internal body structures on an X-ray picture. Your doctor has prescribed Niopam to help view the blood vessels, kidney, bladder or joints using X-rays.

This medicine is for diagnostic use only.

2. What you need to know before you are given Niopam

You should not be given Niopam if you:
• Are allergic to Iopamidol, or any other ingredients of this medicine (listed in Section 6)

Take special care with Niopam and tell your doctor if you have any of the following conditions:
• A history of allergy or asthma
• Diabetes
• Heart problems
• High blood pressure in the lungs
• Kidney or liver problems
• Over-active thyroid gland (this is particularly important in newborn babies)
• A history of epilepsy
• Myelomatosis (Cancer of the plasma cells in the blood)
• Severe systemic disease (a disease affecting more than one part or organ of the body)

• Sickle cell disease (your body produces abnormally shaped red blood cells, which leads to aneamia)
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• Myasthenia gravis (a disease causing weak muscles)
• Brain tumour or other brain diseases
• Alcoholism
• Phaeochromocytoma (a tumor of the adrenal gland)
• Homocystinuria (an inherited disease where the amino acid methionine cannot be broken down completely by the bodyand heart)
• Multiple sclerosis (MS) (a disease of the brain and spinal cord in which inflammation destroys the protective covering around nerves and damages the nerve)
• Poor general health
• If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Niopam or other iodinated contrast media

Take special care with Niopam:

Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (Lyell's syndrome or TEN) and acute generalised exanthematous pustulosis (AGEP), have been reported in association with the use of Niopam.

Seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4**.**

During or shortly after the imaging procedure you may experience a short-term brain disorder called encephalopathy. Seek medical attention immediately if you notice any of the symptoms related to this condition described in Section 4.

Particular care should be taken in children under one year of age and in the elderly. These groups might be susceptible to adverse reactions.

Tell your doctor if you have had thyroid function tests performed in the past.

Thyroid disorders may be observed after administration of iopamidol. Special care should be taken in newborns, including those whose mother received iopamidol during pregnancy and premature infants. Doctors may check the child's thyroid gland function.

Other medicines and Niopam
Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription. Especially tell your doctor if you are taking the following medicines, as they may react with Niopam:
• metformin (a treatment for diabetes)
• anti-epileptics (treatment for epileptic fits)
• painkillers
• neuroleptics (treatments for mental illness)
• antiemetics (treatments that prevent vomiting)
• antihistamines (treatments for allergies)
• sedatives
• vasopressors such as papaverine (used to treat impotence)

• beta blockers (drugs to be used to treat heart or blood pressure)
• interleukin-2 (treatment for cancer)

Niopam may affect the results of laboratory tests such as thyroid function test, bilirubin, proteins or other substances. Always tell your doctor or laboratory staff that you have been given Niopam.

It may still be all right for you to be given Niopam and your doctor will be able to decide what is suitable for you.

Using with food and drink
If you have a disorder of your body water or body salts balance this will be corrected before the examination. Do not reduce the amount you normally drink before the investigation, especially if you have any of the following:
• Severe kidney problems
• Severe liver problems
• Severe cardiac problems
• Multiple myeloma (disease of the bone marrow)
• Diabetes
• Blood disease
• Sickle cell disease
• Abnormal production of urine (large or small amounts)
• Poor general health

Also do not reduce the fluid intake of babies or young children.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, you should only be given Niopam if your doctor believes it is clearly necessary. Tell your doctor if you are or believe you might be pregnant. Stopping breastfeeding is not necessary.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
There is no known effect of Niopam on the ability to drive or operate machines.

Niopam contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per bottle, that is to say essentially "sodium-free".

3. How you are given Niopam

Niopam will be given to you by a doctor or a nurse in hospital or clinic.
It will be injected into an artery or a vein or into the heart or in a joint.

Dosage
The recommended dose depends on which part of the body is being X-rayed and is usually in the range 2-100 ml. Your doctor may decide to vary this dose or to repeat the dose if required.
The dose for children depends also on the age and the body size.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you are given more Niopam than you should:

You should know that the hospital area or clinic where Niopam is given to you is well equipped to treat any effects of overdose.

4. Possible side effects

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

Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body). These are signs of an allergic reaction which can be serious and might require medical treatment.
Seek medical attention immediately if you notice any of the following symptoms:

- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).

The frequency of these side-effects is not known.

The following side effects have been reported following injection of Niopam in a blood vessel

Common: (more than 1 out of 100 persons and less than 1 out of 10 persons)
• headache,
• feeling sick (nausea),
• feeling hot.

Uncommon: (more than 1 out 1,000 persons and less than 1 out of 100 persons)
• dizziness,
• taste disturbance,
• abnormal or irregular heartbeat, uncoordinated twitching of heart muscle,
• low or high blood pressure,
• redness of the skin,
• vomiting, diarrhoea,
• skin rash, itchy rash, itching, reddening of the skin, sweating increased,
• back pain,
• inability of the kidneys to work properly (acute renal failure),
• chest pain, injection site pain, fever, feeling cold,
• abnormal laboratory test results for creatinine (this can be detected by a test carried out by a doctor).

Rare: (more than 1 out 10,000 persons and less than1 out of 1,000 persons)
• confusion,
• sensations like numbness, tingling, pins and needles,
• slow heart rates,
• water in the lungs, asthma, excessive contraction of the airway muscles causing breathing difficulty,
• muscle cramps,

• swelling at the site of injection.

Not known: (cannot be estimated)
• reduced blood platelet count (this can be detected by a test carried out by a doctor),
• sudden, severe allergic reaction,
• coma,
• mini- stroke,
• fainting low level of consciousness, loss of consciousness, fits,
• inability to move one side of the body,
• brain disorder (encephalopathy) with symptoms including headache, difficulties with vision, loss of vision, confusion, seizures, loss of coordination, loss of movement in one side of the body, problems with speech and loss of consciousness,
• temporary loss of vision, vision difficulties, redness and discomfort in the eye (conjunctivitis), abnormal sensitivity of the eyes to light,
• heart attack, heart not pumping blood as well as it should (heart failure), cessation of breathing and of heart beating, increased heart rate, heart attack caused by an allergic reaction,
• failure of the blood circulation (circulatory collapse),
• stopped breathing, inability of the lungs to work properly, acute respiratory distress syndrome (a severe lung disease), abnormal breathing, suspension of breathing, swelling of the throat, difficulty breathing,
• increased salivation, swollen salivary glands,
• severe disease of the skin (see on top of the section),
• skin necrosis after product leakage out of the vessel, swelling of the face,
• muscle pain with abnormal sensations (compartment syndrome),
• pain in the bones, muscles, ligaments, tendons and /or nerves,
• weakness of the muscles,
• shaking chills, pain, feeling generally unwell,
• redness, heat and pain at injection site,
• abnormal electrocardiogram (this can be detected by a test carried out by a doctor).

Children
Thyroid disorders have been reported in newborns born prematurely.

The following side effects have been reported after administration of Niopam into a body cavity:

• Increased blood amylase (examination of the pancreas)
• Allergic reactions, mainly manifesting in the form of skin reactions
• Inflammation of the pancreas, with symptoms of severe abdominal pain in the upper abdomen, radiating towards the back, as well as nausea and vomiting (pancreatitis)
• Reactions reported in cases of X-ray examination of the joints (arthrography) and fistulas (fistulography) are mostly irritations that occur in addition to tissue inflammation.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
If you think you notice any side effects after receiving an injection of Niopam, immediately tell the medical staff.
If you have any other questions not answered in this leaflet please ask the medical staff.

Reporting 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 HPRA Pharmacovigilancewebsite: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Niopam

You will not be required to store the medicine yourself. Your doctor or hospital pharmacist will know how to store Niopam.
Keep out of the sight and reach of children.
Keep this medicine stored in the original package in order to protect from light.
Do not use this medicine after the expiry date which is stated on the label after "Exp". The expiry date refers to the last day of that month.
Niopam should be given to you immediately once drawn up into the syringe.
Do not throw away any medicine via wastewater or household waste. These measures will help to protect the environment.

6. Contents of the pack and other information

What Niopam contains
The active substance is iopamidol. Each ml contains 694 mg of iopamidol, equivalent to 340 mg iodine/ml.
The other ingredients are trometamol, hydrochloric acid, sodium calcium edetate and water.

What Niopam looks like and contents of the pack
50 ml, 70 ml, 100 ml and 200 ml clear, colourless glass bottles with rubber/aluminium caps.
Not all packs sizes may be marketed.

Marketing Authorisation Holder
Bracco Imaging spa, Via Egidio Folli 50, 20134 Milano, Italy

Manufacturers
Patheon Italia S.p.A., 2° Trav. SX Via Morolense 5, 03013 Ferentino (FR), Italy
Bracco Imaging S.p.A., Bioindustry Park, Via Ribes 5, 10010 Colleretto Giacosa (TO), Italy

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