PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Optiray 350 - 50 ml Injection

Optiray 350 - 75 ml Injection

Optiray 350 - 100 ml Injection

Optiray 350 - 125 ml Injection

Optiray 350 Injection

Optiray 320 - 50 ml Injection

Optiray 320 - 100 ml Injection

Optiray 300 - 30 ml Injection

Optiray 300 - 50 ml Injection

Optiray 300 - 100 ml Injection

Optiray 300 - 125 ml Injection

Read all of this leaflet carefully before you are given Optiray.

- Keep this leaflet. You may need to read it again.
- If you have further questions please ask your doctor or X-ray specialist.
- **Optiray** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT OPTIRAY CONTAINS

The active substance of **Optiray 350** is ioversol [741,0 mg per ml ioversol] equivalent to 35 % (350 mg/ml) organically bound iodine.

The active substance of **Optiray 320** is ioversol [678,0 mg per ml ioversol] equivalent to 32 % (320 mg/ml) organically bound iodine.

The active substance of **Optiray 300** is ioversol [636,0 mg per ml ioversol] equivalent to 30 % (300 mg/ml) organically bound iodine.

The other ingredients are trometamol, trometamol hydrochloride, sodium hydroxide and/or hydrochloric acid (for pH: 6,0 to 7,4), sodium calcium edetate, water for injections.

2. WHAT OPTIRAY IS USED FOR

Optiray is an iodine-containing X-ray contrast medium. It is injected into a blood vessel and is distributed in the body by the blood stream. The iodine in **Optiray** blocks X-rays and can therefore mark the blood vessels and the inner organs supplied with blood. **Optiray** is for diagnostic use only.

3. BEFORE YOU ARE GIVEN OPTIRAY

There are circumstances where **Optiray** may not be suitable for you or where special care is required. **If you have any of the conditions listed below, tell your doctor or X-ray specialist before you are given the product.**

You should not be given Optiray:

- if you have had an allergic reaction to contrast media or to any of the other ingredients of **Optiray**.
- if you have an overactive thyroid (hyperthyroidism).

Special care is required with Optiray:

Tell your doctor or healthcare professional before being given the injection:

- if you have a history of allergy or hypersensitivity reactions.

- if you have heart failure, high blood pressure (hypertension), disorders of the circulation or have had a stroke.
- if you have diabetes.
- if you have kidney disease.
- if you have brain disorders.
- if you have problems with your bone marrow (e.g. multiple myeloma).
- if you have sickle cell anaemia.
- if you have a tumour of the adrenal gland that affects your blood pressure (phaeochromocytoma).
- if you have a metabolic disorder affecting amino acids (homocystinuria).
- if you are very elderly.

Optiray should not be administered to persons who are allergic to iodine.

Using Optiray with food and drink:

It may be necessary to restrict your food and drink prior to the examination, so please ask for advice. However, if you have kidney disease, water should not be restricted because dehydration (lack of water in the body tissue) may further decrease the kidney function.

Pregnancy and Breastfeeding:

Optiray should not be used during pregnancy or lactation.

Pregnancy: If you are pregnant or there is any possibility that you may be pregnant or if you are breastfeeding your baby, please consult your doctor or X-ray specialist or other healthcare professional for advice before being given Opitray. The risk to the unborn baby with use of **Optiray** in pregnancy, cannot be excluded. However, any X-ray investigations during pregnancy may have a risk for the unborn baby.

Breastfeeding: It is not known whether **Optiray** is excreted in human breast milk. However, approximately 1 % of iodine-containing X-ray contrast media similar to **Optiray** is excreted into breast milk. Although it has not been established that this would affect your baby, you should rather discontinue breastfeeding your baby for one day after the injection. Discuss this with your doctor or X-ray specialist.

Using other medicines with Optiray:

Always tell your doctor, X-ray specialist or healthcare professional if you are taking or have recently taken any other medicines. (This includes complementary or traditional medicines.) It is particularly important for the following:

- **metformin** – used for treatment of diabetes. Your kidney function should be measured before and after having X-ray contrast media. As metformin may accumulate in the body and lead to a serious metabolic disorder, it should be stopped at the time of the investigation, not started for at least 48 hours, and only re-started when your kidney function has returned to normal;
- **interleukin**, used in certain types of tumours - the rate of side effects to **Optiray** may be increased;
- **medicines increasing the blood pressure** (vasopressors) - the use of **Optiray** should be postponed because the risk of neurologic (nervous) effects is increased.

If you are having a general anaesthetic, the occurrence of adverse events is more likely.

If you are scheduled for a radioactive iodine uptake study of your thyroid gland it should be postponed because **Optiray** may lead to incorrect results for up to 16 days.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **Optiray** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

4. HOW TO RECEIVE OPTIRAY

You will not be expected to give yourself **Optiray**. It will be given to you by a person who is qualified to do so.

Optiray is a non-ionic X-ray contrast medium that is used for several types of X-ray procedures including computed tomography (CT) body scans and imaging vessels, both arteries and veins, kidneys. It will be injected into a blood vessel once or several times during the X-ray procedure, and should be warmed to body temperature before use. The precise dose will be determined by a person who is qualified to do so, by the specific procedure you are having and other factors such as your general state of health and age. The lowest dose consistent with producing adequate X-ray images will be used.

If you received more Optiray than you should:

Since a healthcare professional will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

Overdose of **Optiray** is potentially fatal and may affect the breathing (respiratory) and cardiovascular system.

5. POSSIBLE SIDE EFFECTS

Optiray can have side effects.

Not all side effects reported for **Optiray** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while being given this medicine, please consult your doctor or X-ray specialist for advice.

Mild discomfort may occur in up to 50 % of patients, and the symptoms include a sensation of heat or cold, pain during the injection and/or transient bad taste. However, serious and life-threatening reactions may occur.

Inform your doctor immediately if you develop any of the following **signs of serious side effects:**

- heart attack or an inability to breathe
- severe chest pain, which could indicate heart vessel spasms or blood clots
- stroke, blue lips, fainting
- loss of memory
- speech disorders
- sudden movements
- temporary blindness
- acute kidney failure
- severe skin rash with fever and blisters
- signs of allergic reactions, such as
    - allergic shock
    - tightened airways
    - swelling of the voice box, throat, tongue
    - breathing difficulties
    - cough, sneezing
    - reddening and/or swelling of the face and eyes
    - itching, rash and hives

Side effects can occur with the following frequencies:

Frequent:

- feeling hot, pain

Less frequent:

- severe allergic reaction, swelling and narrowing of airways, including throat tightness, wheezing, difficult breathing, swelling of the face, including eyes, tongue & lips, skin redness, itching, rash, hives
- confusion, anxiety, restlessness
- fainting, uncontrollable shaking, dizziness, light-headedness, abnormal sensation, such as pricking, tingling, headache, taste disturbance, loss of consciousness, numbness, muscle cramps, paralysis, drowsiness, speech disorders, reduced sense of touch or sensation
- blurred vision, allergic eye inflammation causing red, watery and itchy eyes
- ringing or buzzing in the ears
- racing pulse, irregular heartbeats, slow pulse, chest pain, heart activity changes measured using ECG, disease which disturbs blood flow through the brain
- low blood pressure, flushing, high blood pressure, vein inflammation
- larynx cramps, inflammation inside the nose which causes sneezing and blocked nose, cough, throat irritation, fluid accumulation in the lung, low oxygen in the blood
- nausea, vomiting, dry mouth, abdominal pain, salivary gland inflammation, swelling of the tongue, difficulty in swallowing, increased salivation
- an urge to urinate, acute kidney failure or abnormal kidney function, urinary incontinence, blood in urine, low urination
- chills, feeling cold, mostly painful severe swelling of deep skin layers, mainly in the face, increased sweating, tissue swelling caused by excess fluid, injection site reactions including pain, reddening, bleeding or degeneration of cells, feeling unwell or abnormal, tiredness, sluggishness

Frequency not known:

- severe allergic shock reaction
- temporarily underactive thyroid in newborns

- fits
- movement disorder
- loss of memory
- temporary blindness
- heart arrest, life-threatening irregular heartbeat
- extra heartbeat
- heart artery cramps, pounding of the heart
- blue skin colouration due to low oxygen in the blood
- shock
- blood clot or spasm in a blood vessel
- inability to breathe, tightened airways
- reduced ability to produce voice sounds using the vocal organs
- diarrhoea
- severe skin rash with fever and blisters
- paleness
- absent or painful/difficult urination
- fever

If you notice any side effects not mentioned in this leaflet, please inform your doctor or X-ray specialist.

6. STORING AND DISPOSING OF OPTIRAY

Store all medicines out of reach and sight of children.

Keep the container in the outer carton in order to protect from light. Protect from X-rays. Store at or below 25 °C. **Optiray** may be stored for one month at 37 °C in a contrast media warmer with circulating air.

Do not use the solution in case of discolouration or particulate matter.

Do not use the product after the expiry date stated on the label.

7. PRESENTATION OF OPTIRAY

Optiray is packaged in type 1, colourless glass vials, fitted with 20 mm or 32 mm bromobutyl rubber closures and aluminium cap seals.

Vials: 30 ml (box of 10); 50 ml (box of 10 and 25); 100 ml (box of 10 and 12); 200 ml (box of 10 and 12); 500 ml (box of 5, 6 and 10)

Optiray is also supplied in prefilled hand-held syringes and power-injector syringes made of polypropylene. Blue syringe tip cap and piston are made of natural rubber.

Prefilled hand-held syringes: 50 ml (box of 10)

Prefilled power-injector syringes: 75, 100, 125 ml (box of 10)

Not all pack sizes and box sizes may be marketed.

Optiray formulations are sterile, non-pyrogenic, aqueous solutions intended for intravascular administration as diagnostic radio-opaque media.

8. IDENTIFICATION OF OPTIRAY

Clear, colourless to pale yellow solution containing no solids.

9. REGISTRATION NUMBERS:

Optiray 350 – 50 ml: Z/28/420

Optiray 350 – 75 ml: A40/28/0246

Optiray 350 – 100 ml: Z/28/422

Optiray 350 – 125 ml: 30/28/0282

Optiray 350: 34/28/0101

Optiray 320 – 50 ml: Z/28/412

Optiray 320 – 100 ml: Z/28/421

Optiray 300 – 30 ml: Z/28/414

Optiray 300 – 50 ml: Z/28/418

Optiray 300 - 100 ml: Z/28/417

Optiray 300 – 125 ml: 30/28/0281

10. THE NAME AND ADDRESS OF REGISTRATION HOLDER

Guerbet South Africa (Pty) Ltd

Stoneridge Office Park Building A, Ground Floor 8 Greenstone Drive, Modderfontein

Johannesburg

South Africa, 1609

11. DATE OF PUBLICATION

Registration date: 26 May 2006

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Botswana: Schedule 2

Optiray 300: BOT 0700947; Optiray 350: BOT 0700948

Namibia: Schedule 2

Optiray 300-30 ml 19/28/0001; Optiray 300-50 ml 19/28/0002; Optiray 300-100 ml 19/28/0004; Optiray 300-125 ml 19/28/0005; Optiray 350-50 ml 19/25/0007; Optiray 350-75 ml 19/28/0008; Optiray 350-100 ml 19/28/0009; Optiray 350-125 ml 19/28/0010; Optiray 350 19/28/0011