SELECT THE REQUIRED INFORMATION

PROFESSIONAL INFORMATION

PATIENT INFORMATION LEAFLET

Bayer (Pty) Ltd	**Date of revision of text: 02 September 2018**

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

GASTROGRAFIN

Aqueous solution

Read all of this leaflet carefully before you are given GASTROGRAFIN.
- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor or pharmacist.**
- **GASTROGRAFIN has been prescribed for you personally.**

1. WHAT GASTROGRAFIN CONTAINS:

1 ml GASTROGRAFIN contains sodium amidotrizoate 100,00 mg and meglumine amidotrizoate 660,00 mg (sodium diatrizoate and meglumine diatrizoate) in aqueous solution.
The other ingredients are: disodium edetate, polysorbate 80, purified water, saccharin sodium, sodium hydroxide and star anise oil.

2. WHAT GASTROGRAFIN IS AND WHAT IT IS USED FOR:

GASTROGRAFIN is provided as a solution for drinking or for use as an enema.
GASTROGRAFIN is a contrast medium for the X-ray examination, including computerised tomography, of the digestive system.
It helps to visualise lesions.
GASTROGRAFIN is often used when a barium enema or meal cannot be used. It can, however, be combined with barium to improve the X-ray picture. GASTROGRAFIN is also used to treat a specific type of bowel blockage in the newborn (meconium ileus).
Just as X-rays do not pass through bones in your body and thus can be used to produce a 'picture', X-rays are unable to pass through the iodine in contrast dyes. In this way, GASTROGRAFIN enables the radiologist to see the intestine more clearly.

3. BEFORE GASTROGRAFIN IS ADMINISTERED:

Fatal reactions (allergy-like hypersensitivity reactions ranging to severe reactions including shock) have been associated with the administration of water-soluble contrast media, such as GASTROGRAFIN. It is therefore of the utmost importance that a course of action be carefully planned in advance for the treatment of serious reactions, and that adequate and appropriate facilities and personnel be readily available in case of a severe reaction. Patients should be observed for a possible severe reaction during and for at least 30 to 60 minutes after administration.

You should not receive GASTROGRAFIN:

- If you are hypersensitive to iodine or to any of the ingredients of GASTROGRAFIN.
- If you are pregnant or breastfeeding your baby, as safety has not been established in pregnancy or during breastfeeding.
- You should not receive GASTROGRAFIN undiluted:

- If you have a low blood volume (for example lost body fluid or water through severe diarrhoea, vomiting, or as in newborns, infants and children) since complications due to low blood volume can become particularly serious.
- If it might be possible that GASTROGRAFIN accidentally comes into your respiratory system, since this may cause serious respiratory complications, even with fatal outcome.

Take special care with GASTROGRAFIN:

Before you receive GASTROGRAFIN **tell your doctor if any of the conditions listed below applies to you**. Your doctor will decide whether the intended examination is possible or not.

- If you are known to be allergic (hypersensitive), as this increases the risk for you to have anaphylactoid/hypersensitivity reactions.
- If you had a previous reaction to iodinated contrast media.
- If you suffer or have suffered from an allergy (e.g. hay fever, hives) or asthma.
- If you have or are suspected to have an overactive thyroid gland or goiter.
- If you have a disease of your heart or blood vessels.
- If you are in a very poor general state of health.

Allergy-like reactions, involving the heart, breathing or the skin, may occur with the use of GASTROGRAFIN. Severe reactions including shock are possible. Delayed reactions may occur (after hours or days) (see “Possible side effects”).

The doctor will test the thyroid function of newborns who have been exposed to GASTROGRAFIN either during pregnancy or after birth, because too much iodine can cause underactive thyroid (hypothyroidism), possibly requiring treatment.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, inform your doctor, pharmacist or other healthcare professional for advice.

GASTROGRAFIN should not be used by pregnant women or by women breastfeeding a child as safety in pregnancy and lactation has not been established.
Adequate and well-controlled studies in pregnant and breastfeeding women have not been conducted.
Tell your doctor if you are pregnant or could be pregnant before using GASTROGRAFIN.

Using other medicines with GASTROGRAFIN:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of GASTROGRAFIN with these medicines may cause undesirable interactions.

Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

These include especially:
- Interleukin-2.
- Radioactive substances for the thyroid gland.

Your doctor will give you advice.

4. HOW GASTROGRAFIN IS ADMINISTERED:

Do not share GASTROGRAFIN with others.

You will receive GASTROGRAFIN for drinking or as an enema. The actual dosage of GASTROGRAFIN that is right for you will be worked out by your doctor and will depend on your age and the type of X-ray examination that is being done.
GASTROGRAFIN must not be given as an injection.

If you receive more GASTROGRAFIN than you should:

Overdosing is unlikely. If it does happen, the doctor will treat any symptoms that follow. This may involve water and salt replacement through an intravenous drip.

5. POSSIBLE SIDE EFFECTS:

Not all side effects reported for GASTROGRAFIN are included in this leaflet. Should your general health worsen while taking GASTROGRAFIN, please consult your doctor, pharmacist or other healthcare professional for advice.

GASTROGRAFIN can cause side effects.

Severe and life-threatening reactions as well as deaths have been reported. Vomiting, nausea and diarrhoea are frequently reported side effects.

Below is a list of other possible side effects by how frequent they occur:

Frequent:
- Vomiting, feeling sick (nausea), diarrhoea.

Less frequent:
- Allergy-like reaction, including severe reaction (shock).
- Overactive thyroid gland (hyperthyroidism).
- Fluid and salt imbalance.
- Disturbances in consciousness, headache, dizziness.
- Cardiac arrest, fast heart beat (tachycardia).
- Shock, low blood pressure (hypotension).
- Breathing difficulties (dyspnoea, bronchospasm), entry of medication in the respiratory tract (aspiration), build-up of fluid in the lungs following aspiration (pulmonary oedema), inflammation of the lungs following aspiration (aspiration pneumonia).
- Bowel rupture (intestinal perforation), stomach (abdominal) pain, blistering in the lining of the mouth.
- Severe skin reaction with intense reddening, peeling of the top layer of skin, large blisters (toxic epidermal necrolysis), hives (urticaria), rash, severe itching (pruritus), redness of the skin (erythema), face oedema.
- Fever, sweating.

Frequency not known:
Underactive thyroid (hypothyroidism)

Allergy-like reactions may occur, including severe reactions (shock) that may need immediate medical intervention. Mild swelling of the face, lips, tongue or throat, coughing, itching, runny nose, sneezing and hives (nettle-type rash) may be the first signs that a severe reaction is happening.

Delayed reactions, hours to days after the administration of GASTROGRAFIN may occur.
- **Tell the department staff immediately if you experience any of these signs or have difficulty in breathing.**
  Disorders of the stomach or bowels.
  GASTROGRAFIN may give rise to diarrhoea, but this stops as soon as the bowels have been emptied. An existing inflammation of the bowels may temporarily worsen. If an obstruction exists, it may hinder the passage of GASTROGRAFIN and lead to tissue damage of the bowel.

- **If any of the side effects gets serious,** or if you notice any side effects not listed in this leaflet, please tell your doctor or radiologist.

6. STORING AND DISPOSING OF GASTROGRAFIN:

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.
Until required for use, GASTROGRAFIN must be stored in the original outer carton below 30 °C. Protect from light, heat and secondary X-rays. Contents should be discarded within 72 hours of first opening the bottle.

At temperatures below 7 °C GASTROGRAFIN tends to crystallise, but this can be reversed by gently warming and shaking the bottle. This phenomenon has no effect on the effectiveness or stability of the preparation.
Do not use after expiry date stated on the carton and the bottle.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF GASTROGRAFIN:

Amber glass bottles of 100 ml with a high-density polyethylene cap.

8. IDENTIFICATION OF GASTROGRAFIN:

A clear, colourless to faintly yellowish solution with a faint odour of anise oil.

9. REGISTRATION NUMBER:

H/28/2842

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Bayer (Pty) Ltd
Reg. No.: 1968/011192/07
27 Wrench Road
ISANDO
1609

11. DATE OF PUBLICATION:

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