Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Trazogastro

2. Qualitative and quantitative composition

Each ml contains:
Diatrizoate Meglumine 660 mg.
Diatrizoate Sodium 100 mg.

Iodine content 370 mg

For a full list of excipients, see section 6.1

3. Pharmaceutical form

Oral solution
Clear, pale yellow to slightly brown viscous liquid, free from foreign matter.

4. Clinical particulars

4.1 Therapeutic indications

This medicinal product is for diagnostic use by oral or rectal administration only.
Trazogastro is a contrast medium for the radiological examination of the gastrointestinal tract (also in combination with barium sulphate).
Trazogastro may be of particular value in the following instances:

1. Suspected partial or complete stenosis.
2. Acute haemorrhage.
3. Threatening perforation (peptic, ulcer, diverticulum).
4. Other acute conditions which are likely to require surgery.
5. After resection of the stomach or intestine (danger of perforation or leak).
6. Megacolon.
7. Visualization of a foreign body or tumour before endoscopy.
8. Visualization of a gastrointestinal fistula.
9. Before endoscopy

Further indications:

- Early diagnosis of a radiologically undetectable perforation or anastomotic defect in the oesophagus.
- The treatment of uncomplicated meconium ileus.
- Computerized tomography in the abdominal region.

4.2 Posology and method of administration

Dosage for oral use
The dosage is dependent on the type of examination and the age of the patient.
Adults and children of 10 years of age or over.
Visualization of the stomach: 60ml

Follow-through examination of the gastrointestinal tract: a maximum of 100ml

Computerized tomography (CT)

0.5 – 1.5 litres of approximately 3% Trazogastro solution (30ml Trazogastro / 1 litre of water).

Older and cachectic patients: Dilution with an equal volume of water is recommended.

Children

Children (up to 10 years of age): 15-30ml (can be diluted with twice its volume of water)

Infants and young children; 15-30ml (diluted with 3 times its volume of water)

Dosage for rectal use (including therapy of uncomplicated meconium ileus)

Adults

Up to 500ml Trazogastro dilution (diluted with 3-4 times its volume of water)

Children

Children (over 5 years of age): up to 500ml Trazogastro dilution (diluted with 4-5 times its volume of water)

Children (up to 5 years of age): up to 500ml Trazogastro dilution (diluted with 5 times its volume of water)

Therapy of uncomplicated meconium ileus

Trazogastro can be given by enema for non-operative treatment of uncomplicated meconium ileus. Advantage is taken of the high osmotic pressure of the contrast medium: the surrounding tissue is forced to release considerable amounts of fluid, which then flows into the gut and dissolves the inspissated meconium.

The procedure must be carried out slowly and only under fluoroscopic control. Injection should stop as soon as Trazogastro is seen to enter the ileum. Owing to its high osmolarity, Trazogastro may cause the loss of a large amount of fluid into the intestines. An intravenous drip must therefore be set up before the enema is given and fluid should be infused as required. If the Trazogastro is not expelled during the first hour after removal of the rectal catheter, and X-ray should be taken to ensure that overdistension of the bowel as a result of the high osmolarity of Trazogastro has not occurred.

Dosage for Trazogastro in combination with barium sulphate: Oral and rectal administration.

Adults

In adult patients, addition of approximately 30ml Trazogastro to the usual dose of barium should be adequate.

Children

Children from 5-10 years of age: 10ml Trazogastro to 100ml barium sulphate suspension. Children up to 5 years of age: 2-5ml Trazogastro to 100ml barium sulphate suspension. If necessary (in cases of pylorospasm or pyloric stenosis), the portion of Trazogastro in the suspension may be further increased, this does not affect the contrast.

For the early diagnosis of a perforation or investigation of an anastomosis in the oesophagus or gastrointestinal tract, the patient should drink up to 100ml Trazogastro. After 30-60 minutes (later, if the defect is suspected of being in the distal gut), a urine specimen should be taken and 5ml mixed with 5 drops of concentrated hydrochloric acid. The contrast medium which has undergone renal excretion will appear within two hours as a typical crystal formation in the precipitate.

4.3 Contraindications

Hypersensitivity to iodine-containing contrast media. Manifest hyperthyroidism.
Trazogastro must not be administered undiluted in patients with low plasma volume, as for example in newborns, infants, children and in dehydrated patients, since hypovolaemic complications can be particularly serious in these patients.
Trazogastro must not be administered undiluted in patients with suspected possibility of aspiration or broncho-oesophageal fistula, since hyperosmolarity may cause acute pulmonary oedema, chemical pneumonia, respiratory collapse and death.

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

The following risks are higher in the case of intravascular administration of iodinated contrast media but are also relevant for the enteral use of Trazogastro.
<u>Hypersensitivity</u>
As with other contrast agents, Trazogastro can be associated with anaphylactoid / hypersensitivity or other idiosyncratic reactions, characterized by cardiovascular, respiratory or cutaneous manifestations, and ranging to severe reactions including shock. Delayed reactions may occur (hours later or up to several days).
Medication for the treatment of hypersensitivity reactions as well as readiness for institution of emergency measures are necessary.
The risk of anaphylactoid / hypersensitivity reactions is higher in case of:

- Any history of allergic disorders,
- History of bronchial asthma,
- A previous anaphylactoid / hypersensitivity reaction to iodinated contrast media. Patients with cardiovascular disorders are more susceptible to serious or even fatal outcomes of severe anaphylactoid / hypersensitivity reactions.

<u>Thyroid dysfunction</u>

In neonates, especially preterm infants, who have been exposed to Trazogastro, either through the mother during pregnancy or in the neonatal period, it is recommended to monitor thyroid function, as an exposure to excess iodine may cause hypothyroidism, possibility requiring treatment.

Barium sulphate

If Trazogastro is used together with barium sulfate preparations, attention must be drawn to the contraindications, warnings and possible side effects relevant to the preparation.

Trazogastro contains sodium

This medicinal product contains 3.8 mg of sodium. To be taken into consideration by patients on a controlled sodium.

Gastrointestinal

In case of prolonged retention of Trazogastro in the gastrointestinal tract (e.g. obstruction, stasis), tissue damage, bleeding, bowel necrosis and intestinal perforation may occur.

Hydration

Adequate hydration and electrolyte balance should be established and maintained in the patients, since the hyperosmolarity of Trazogastro may cause dehydration and electrolyte imbalance.

Because of the additives (flavourings and a wetting agent), Trazogastro must not be used intravascularly.

4.5 Interaction with other medicinal products and other forms of interaction

Hypersensitivity reactions can be aggravated in patients on beta-blockers.

Interleukin-2: Previous treatment (up to several weeks) with Interleukin-2 is associated with an increased risk of delayed reactions to Trazogastro.

Interference with diagnostic tests

Radioisotopes: Diagnosis and treatment of thyroid disorders with thyrotropic radioisotopes may be impeded for up to several weeks after administration of iodinated contrast agents due to reduced radioisotope uptake.

4.6 Pregnancy and Lactation

Pregnancy

Adequate and well-controlled studies in pregnant women have not been conducted. Animal studies do not indicate direct or indirect harmful effects with respect to embryonal / foetal development.

Caution should be exercised when using Trazogastro in pregnant women.

Breast-feeding

It is unknown whether sodium amidotrizoate or meglumine amidotrizoate are excreted in human breast milk. Intravascular use has shown that salts of the diatrizoic acid are excreted in breast milk. A decision on whether to continue / discontinue breast feeding or continue / discontinue therapy with Trazogastro should be made taking into account the benefit of breast-feeding to the child and the benefit of administering Trazogastro to the woman.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Undesirable effects in association with the use of iodinated contrast media are usually mild to moderate and transient in nature. However, severe and life-threatening reactions as well as deaths have been reported. Vomiting, nausea and diarrhea are the most frequently recorded reactions. The following undesirable effects have been recorded in association with the use of Trazogastro. The most appropriate MedDRA term is used to describe a certain reaction and its synonyms and related conditions.

Immune system disorders, anaphylactic reaction / hypersensitivity:

- Anaphylactoid shock, anaphylactoid / hypersensitivity reaction.
- Systemic hypersensitivity is mostly mild and occurs generally in the form of skin reactions. However, the possibility of a severe hypersensitivity reaction cannot be entirely excluded.

Endocrine disorders:

- Hyperthyroidism, hypothyroidism*
- (*Reported mostly in neonates, especially preterm neonates).

Metabolism and nutrition disorders:

- Fluid and electrolyte imbalance.

Nervous system disorders:

- Disturbances in consciousness, headache, dizziness.

Cardiac disorders:

- Cardiac arrest, tachycardia.

Vascular disorders:

- Shock, Hypotension.

Respiratory, thoracic and mediastinal disorders:

- Bronchospasm, dyspnea, medication aspiration, pulmonary oedema following aspiration, aspiration pneumonia.

Gastrointestinal disorders:

- The hypertonic Trazogastro solution may give rise to diarrhea, but this ceases as soon as the intestine has been emptied. Existing enteritis or colitis may be temporarily exacerbated. In case of obstruction, the prolonged contact with bowel mucosa can lead to erosions and to bowel necrosis.

- Other undesirable effects include vomiting, nausea, diarrhea, intestinal perforation, abdominal pain and oral mucosal blistering.

Skin and subcutaneous tissue disorders:

- Toxic epidermal necrolysis, urticarial, rash, pruritus, erythema, oedema face.

General disorders and administration site conditions:

- Pyrexia, sweating.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poison board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org.

4.9 Overdose

Disorders of water and electrolyte balance caused by overdose should be corrected.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: X-ray contrast media, iodinated and water-soluble, ATC code: V08AA01.

Trazogastro does not extent a pharmacological effect. It is an iodine containing contrast medium, iodine being radio-opaque.

5.2 Pharmacokinetic properties

Only 3% of amidotrizoic acid, the radio-opaque agent of Trazogastro, is absorbed following oral administration. If a perforation of the gastrointestinal tract is present, Trazogastro finds its way into the abdominal cavity or the surrounding tissue, where it is absorbed and finally excreted via the kidneys.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of systemic toxicity, genotoxicity, toxicity to reproduction, local tolerance and contactsensitizing potential.

6. Pharmaceutical Particulars

6.1 List of Excipients

Sodium Hydroxide BP, Edetate Disodium U.S.P, Polysorbate 80 (Tween 80) B.P, Sweet orange No-1 In-House, Sodium Dihydrogen O-Phosphate USP, Sucralose NF

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section Posology and method of administration.

6.3 Shelf-Life

3 Years

6.4 Special Precautions for storage

Store below 30°C. Do not freeze. Protect from light and secondary X-rays. Keep out of reach of children.

6.5 Nature and Content of container

30 ml amber coloured PET bottle
100 mL amber coloured PET bottle

6.6 Special precautions for disposal and other handling

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

7. Marketing Authorization Holder

UNIQUE PHARMACEUTICAL LABORATORIES
(A Div. Of J. B. Chemicals & Pharmaceuticals Ltd.)
Plot No. 128/1, G.I.D.C Industrial Area, Ankleshwar-393 002, Gujarat State, India.

8. Marketing Authorization Number

CTD10833

9. Date of first authorization/renewal of the authorization

30/07/2024

10. Date of revision of the text

16/05/2025