orspec pharma
part of uniphar

7 November 2023

Shortage of GASTROGRAFIN amidotrizoate meglumine/sodium amidotrizoate oral liquid bottle and alternative supply arrangement under Section 19A of the Therapeutic Goods Act

Dear Healthcare Professional,

This communication is sent by ORSPEC Pharma to notify your organisation that due to the shortage of **GASTROGRAFIN amidotrizoate meglumine/sodium amidotrizoate oral liquid bottle (AUST R 10684),** ORSPEC Pharma has arranged the supply of an alternative product on a temporary basis.

Gastrografin sodium amidotrizoate/ meglumine amidotrizoate gastroenteral solution bottles (UK) are NOT registered in Australia and supply is granted under an approval granted by the Therapeutic Goods Administration (TGA) under Section 19A of the Therapeutic Goods Act, 1989 until **31 March 2024** for the following indications:

> *Gastrografin is a contrast medium for the examination of the gastrointestinal tract. It can be administered orally and as an enema and is primarily indicated in cases in which the use of barium sulfate is unsatisfactory, undesirable or contraindicated. Among these are:*
> *- suspected partial or complete stenosis*
> *- acute haemorrhage*
> *- threatening perforation (peptic ulcer, diverticulum)*
> *- other acute conditions which are likely to require surgery*
> *- after resection of the stomach or the intestine (danger of perforation or leak)*
> *- megacolon*
> *- visualisation of a foreign body or tumour before endoscopy*
> *- visualisation of gastrointestinal fistula*
>
> *In addition to these conditions Gastrografin can generally be used for the same purposes as barium sulfate with the exception of the visualisation of mucosal diseases. Due to the insufficient coating properties of Gastrografin, barium sulfate should be used for single or double contrast techniques.*
>
> *- Early diagnosis of a radiologically undetectable perforation or anastomotic defect in the oesophagus or gastrointestinal tract.*
> *- Treatment of meconium ileus.*
> *- Computerised tomography in the abdominal region. The danger of false diagnoses is significantly reduced if the intestine is opacified with Gastrografin, especially for differential diagnoses in the minor pelvis. Gastrografin facilitates delimitation of the intestine from neighbouring organs and permits an assessment of changes in the shape of the pancreas.*

The s19A approved product is identical in active ingredient and strength to the Australian registered product. The two products differ in excipient ingredients and pack size. The differences are noted below:

	ARTG product GASTROGRAFIN amidotrizoate meglumine/sodium amidotrizoate oral liquid bottle (AUST R 10684)	**S19A product** Gastrografin sodium amidotrizoate/ meglumine amidotrizoate gastroenteral solution bottles (UK)
Excipient Ingredients	- disodium edetate - saccharin sodium - polysorbate 80 - star anise oil - purified water	- disodium edetate - sodium hydroxide - saccharin sodium - star anise oil - polysorbate 80 - purified water
Presentation	Pack of 1 x bottle	Pack of 10 x bottles

Gastrografin sodium amidotrizoate/ meglumine amidotrizoate gastroenteral solution bottles (UK) , are registered in the United Kingdom and are packaged in English. For dosing and administration information, please refer to the Australian Product Information for **GASTROGRAFIN amidotrizoate meglumine/sodium amidotrizoate oral liquid bottle (AUST R 10684)** available at https://www.ebs.tga.gov.au/

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **Gastrografin sodium amidotrizoate/ meglumine amidotrizoate gastroenteral solution bottles (UK) ,** should be reported by healthcare professionals and patients to ORSPEC Pharma on 024 339 4239 or email at customerservice@orspecpharma.com. Alternatively, this information can be reported to the TGA at https://www.tga.gov.au/reporting-problems

Please forward this information to relevant staff members in your organisation.

For further information, please contact ORSPEC Pharma on 024 339 4239 or email customerservice@orspecpharma.com.

Yours sincerely,

Deon Scheepers
Managing Director
ORSPEC Pharma