

SOMATOSTATINA SERVYCAL
SOMATOSTATIN 250 mcg/ 3 mg
Lyophilized Powder for Injection
Made in Italy
Sale under prescription

QUALI-QUANTITATIVE COMPOSITION:

Each vial of Somatostatina Servycal 250 mcg contains:

Cyclic somatostatin acetate (Equiv. to cyclic somatostatin base)	250.00 mcg
Mannitol	20.00 mg

Each vial of Somatostatina Servycal 3 mg contains:

Cyclic somatostatin acetate (Equiv. to cyclic somatostatin base)	3.00 mcg
Mannitol	20.00 mg

Each ampoule of solvent contains:

Sodium chloride	18.00 mg
Water for injection q.s. to	2.00 mL

DRUG CATEGORY AND ACTION: ATC classification: H01C B01

This hormone inhibits:

The secretion of hydrochloric acid and pepsin, and gastrin release.

The pancreatic exocrine secretion.

The stimulated release of secretin and pancreozymin.

Besides, somatostatin infusion has shown to produce a maximum splanchnic flow decrease of 30% with no considerable decrease or variation of systemic blood pressure.

INDICACIONES:

This hormone is indicated for the treatment of:

- Severe acute bleeding of the upper gastrointestinal tract (bleedings due to gastric, duodenal, gastrointestinal ulcerations; bleeding gastritis; esophageal varices).
- Pancreatic fistula and acute pancreatitis.

PHARMACOLOGY:

Pharmacodynamics:

The structure of the active ingredient, chemical properties, and biological properties of somatostatin are analogous to those of the hypothalamic cyclic tetradecapeptide. Somatostatin is an inhibitor of growth hormone.

Somatostatin has an inhibitory action on:

- Intestinal motility.
- The secretion of hydrochloric acid and pepsin, and gastrin release.

- The pancreatic exocrine and endocrine secretion (basal and stimulated insulin and glucagon secretion).
- The stimulated release of secretin and pancreozymin.
- Somatostatin infusion has shown to produce a maximum splanchnic flow decrease of 30% with no considerable variation of systemic blood pressure.

Pharmacokinetics:

Following intravenous administration, somatostatin levels decline very rapidly, mainly because of the enzyme degradation it undergoes (aminopeptidase and endopeptidase action). The plasma half-life of somatostatin is about 2 minutes (1.1 to 3 minutes); therefore, somatostatin should be administered by continuous infusion at a steady rate. Levels stabilize in not more than 15 minutes; mean concentrations obtained depend on the infusion rate. When the recommended usual dose (250 mcg/hour) is administered, these levels range from 300 to 3000 pg/mL.

Hepatic impairment does not appear to substantially influence the metabolic clearance of somatostatin, while renal impairment does.

The pharmacokinetics in non-obese insulin-independent diabetic patients are similar to those in healthy volunteers.

Subcutaneous administration produces very low blood levels of somatostatin.

DOSAGE AND ADMINISTRATION:

Due to its short half-life (1 to 2 minutes), somatostatin should be administered by IV continuous infusion at a steady rate to maintain plasma levels.

This drug should be reconstituted with physiological saline immediately before use and the resulting solution should be added to the infusion fluid.

The recommended dose is 3.5 mcg/kg/h (250 mcg/h for a 75-kg person) of somatostatin, diluted in sterile pyrogen-free isotonic physiological saline and administered by continuous infusion.

In the treatment of gastrointestinal bleeding and esophageal variceal rupture, a dose of 250 mcg should be administered, immediately after starting the continuous infusion, by slow IV injection over approximately 3 minutes to avoid nausea and heat sensation. Blood pressure should be carefully monitored during somatostatin administration. The minimum duration of therapy is 48 to 72 hours to prevent new bleeding, and the maximum duration of therapy is 5 days because the usefulness of longer infusion times has not been confirmed yet.

In the case of pancreatic fistula and acute pancreatitis, 3.5 mcg/kg/h of somatostatin should be administered by continuous infusion for 7 to 10 days. On the basis of severity and at physician's discretion, treatment with somatostatin may be extended to 15 running days.

CONTRAINDICATIONS:

Hypersensitivity to the components of somatostatin or other substances closely related from the chemical point of view. Pregnancy, postpartum period, breastfeeding.

WARNINGS AND PRECAUTIONS:

Somatostatin is meant for hospital use; patients treated with somatostatin should be kept under strict medical observation. Infusion should be slow and continuous (over 3 minutes).

Somatostatin exerts an inhibitory action on glucagon and insulin release. Thus, blood glucose should be checked at 4-to-6-hour regular intervals. In addition, special attention should be paid to insulin-dependent patients during treatment. Somatostatin should not be administered concurrently with carbohydrates requiring insulin to be metabolized or infusion solutions containing glucose or fructose in order to avoid alterations in blood glucose levels. If deemed appropriate, additional doses of insulin may be given.

Endoscopically-demonstrated arterial bleeding resulting from ruptures of blood vessels should be treated with surgery.

Somatostatin inhibits the intestinal absorption of certain nutrients. Therefore, it should be administered concomitantly with parenteral nutrition in long treatments.

In the case of pancreatic and gastrointestinal fistula due to neoplastic disease or intestinal inflammation, the appropriate etiological treatment should be instituted.

Sudden or inadequate interruption of infusion may lead to a rebound secretory effect. During the 15 minutes following IV administration, patients should be placed in the supine position.

Somatostatin must not be used during pregnancy, postpartum period, or breastfeeding.

Drug-drug interactions:

Somatostatin should not be administered in conjunction with solutions containing glucose or fructose.

Besides, this drug increases barbiturates' ability to induce sleep and enhances the anticonvulsant action of pentetazol. Thus, somatostatin should not be administered concomitantly with these drugs until their effects have ceased.

ADVERSE REACTIONS:

Somatostatin administration may cause transient nausea, dizziness and heat in the face. This is particularly verified when IV infusion is administered too rapidly or infusion is not continuous. Orthostatic hypotension has rarely been reported and it may be avoided by placing patients in the supine position during injection. IV bolus administration of somatostatin may result in respiratory arrest.

The following reactions have been reported as a result of sudden treatment interruption: vomiting, diarrhea, abdominal pain, rebound hypersecretion of growth hormone and other hormones. Impaired glucose tolerance, arrhythmia, and hyponatremia have been less frequently reported.

Rebound effects are due to sudden interruption of infusion, especially in patients with fistulas.

It is not possible to exclude the possibility or risk of hypersensitivity to somatostatin during repeated treatment.

OVERDOSAGE:

No overdose has been reported. If necessary, the cessation of somatostatin effect may be obtained some minutes after interrupting infusion due to the short half-life of this drug.

In the case of acute poisoning, go to the nearest Hospital or contact Toxicology Centers:
Hospital de Niños Dr. Ricardo Gutiérrez: Ph: + 54 (11) 4962-6666 / 2247
Hospital Dr. Juan P. Garrahan: Ph: + 54 (11) 4941-6191 / 6012
Hospital Dr. Juan A. Fernández: Ph: + 54 (11) 4801-5555
Hospital A. Posadas: Ph: + 54 (11) 4654-6648 / 4658-7777

PRESENTATIONS:

SOMATOSTATINA SERVYCAL 250 mcg: 1 vial containing Lyophilized powder for injection + 1 ampoule containing solvent.

SOMATOSTATINA SERVYCAL 3 mg: 1 vial containing Lyophilized powder for injection + 1 ampoule containing solvent.

KEEP OUT OF THE REACH OF CHILDREN

STORE BETWEEN 10° C AND 25° C, PROTECTED FROM LIGHT.

**RECONSTITUTED SOLUTION CAN BE STORED UNDER THE SAME
CONDITIONS (10° C- 25° C) FOR UP TO 12 HOURS.**

Manufactured by:

ALFA WASSERMAN SPA, CONTRADA S. EMIDIO S.N.C., ALANNO (PE), ITALY
Via Tiburtina 1040 – 00156 Rome, Italy.

Imported, conditioned and distributed by:

SERVYCAL S.A.

José Ingenieros 2489 – (B1636EPS) – Olivos

Buenos Aires – Argentina

Ph/Fax: + 54 (11) 4794-9382

www.servycal.com

Under license of: PHT Via Ariosto 34 – Milan, Italy.

Medicinal Specialty Authorized by the Argentine Ministry of Health (A.N.M.A.T.)
Certificate No. 47553

Technical Director: Pamela Carla Marcuzzi – Pharmacist- Biochemist

Revision date: 09/2003

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SOMATOSTATIN 3 mg
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Each ampoule of solvent contains:

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Water for injection q.s. to	2.00 mL

Dosage and administration: see patient package insert.

Batch No.:

Expiration date:

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