施他寧 STILMIN®
3 mg - 250 mg
本藥物由施貴寶公司製造。

稅號: TIL10107

製藥商: Merck Serono SA, Aubonne Branch
地點: Zone Industrielle de l'Ourtet, 1170 Aubonne Switzerland

May 2013

施他寧 STILMIN®

藥理作用

Somatostatin在體內的虛憤作用，特別是對胃酸、胃蛋白酶、胰蛋白酶的抑制效果，是其抗消化性胃炎及胃癌的標誌。其藥效主要通過以下途徑實現:

1. 抑制胃酸和胃蛋白酶的分泌，特別是對胃酸的抑制作用最強。
2. 抑制胃蛋白酶、胰蛋白酶和膽汁酸的分泌。
3. 抑制胃液中的黏液和蛋白酶的分泌。
4. 抑制胃腸蠕動，特別是對胃腸蠕動的抑制作用最強。
5. 抑制胃液中的胃蛋白酶、胰蛋白酶和膽汁酸的分泌。
6. 抑制胃液中的黏液和蛋白酶的分泌。
7. 抑制胃液中的黏液和蛋白酶的分泌。
8. 抑制胃液中的黏液和蛋白酶的分泌。
9. 抑制胃液中的黏液和蛋白酶的分泌。
10. 抑制胃液中的黏液和蛋白酶的分泌。

注意事項

某些藥物可能與施他寧相互作用，包括:

1. 抗酸藥：可能會減少施他寧的吸收，從而影響其藥效。
2. 抗生素：可能會影響施他寧的吸收，從而影響其藥效。
3. 抗病毒藥：可能會影響施他寧的吸收，從而影響其藥效。
4. 抗腫瘤藥：可能會影響施他寧的吸收，從而影響其藥效。
5. 抗糖尿病藥：可能會影響施他寧的吸收，從而影響其藥效。
6. 抗凝血藥：可能會影響施他寧的吸收，從而影響其藥效。
7. 抗胃酸藥：可能會影響施他寧的吸收，從而影響其藥效。
8. 抗胃腸蠕動藥：可能會影響施他寧的吸收，從而影響其藥效。
9. 抗胃腸蠕動藥：可能會影響施他寧的吸收，從而影響其藥效。
10. 抗胃腸蠕動藥：可能會影響施他寧的吸收，從而影響其藥效。

標記及包裝

標記:

1. 施他寧的標記主要包括藥物名稱、製藥商名稱、製藥日期。
2. 施他寧的標記主要包括藥物名稱、製藥商名稱、製藥日期。
3. 施他寧的標記主要包括藥物名稱、製藥商名稱、製藥日期。
4. 施他寧的標記主要包括藥物名稱、製藥商名稱、製藥日期。
5. 施他寧的標記主要包括藥物名稱、製藥商名稱、製藥日期。
6. 施他寧的標記主要包括藥物名稱、製藥商名稱、製藥日期。
7. 施他寧的標記主要包括藥物名稱、製藥商名稱、製藥日期。
8. 施他寧的標記主要包括藥物名稱、製藥商名稱、製藥日期。
9. 施他寧的標記主要包括藥物名稱、製藥商名稱、製藥日期。
10. 施他寧的標記主要包括藥物名稱、製藥商名稱、製藥日期。

包裝:

1. 施他寧的包裝主要包括有機玻璃容器、藥管、藥片、藥膏等。
2. 施他寧的包裝主要包括有機玻璃容器、藥管、藥片、藥膏等。
3. 施他寧的包裝主要包括有機玻璃容器、藥管、藥片、藥膏等。
4. 施他寧的包裝主要包括有機玻璃容器、藥管、藥片、藥膏等。
5. 施他寧的包裝主要包括有機玻璃容器、藥管、藥片、藥膏等。
6. 施他寧的包裝主要包括有機玻璃容器、藥管、藥片、藥膏等。
7. 施他寧的包裝主要包括有機玻璃容器、藥管、藥片、藥膏等。
8. 施他寧的包裝主要包括有機玻璃容器、藥管、藥片、藥膏等。
9. 施他寧的包裝主要包括有機玻璃容器、藥管、藥片、藥膏等。
10. 施他寧的包裝主要包括有機玻璃容器、藥管、藥片、藥膏等。

製藥廠:

1. Merck Serono SA, Aubonne Branch
2. Zone Industrielle de l'Ourtet, 1170 Aubonne Switzerland
3. 比利時安德萊赫特
4. 比利時安德萊赫特
5. 比利時安德萊赫特
6. 比利時安德萊赫特
7. 比利時安德萊赫特
8. 比利時安德萊赫特
9. 比利時安德萊赫特
10. 比利時安德萊赫特

電話:

1. (02) 2162-1111 N00001 B
2. (02) 2162-1111 N00001 B
3. (02) 2162-1111 N00001 B
4. (02) 2162-1111 N00001 B
5. (02) 2162-1111 N00001 B
6. (02) 2162-1111 N00001 B
7. (02) 2162-1111 N00001 B
8. (02) 2162-1111 N00001 B
9. (02) 2162-1111 N00001 B
10. (02) 2162-1111 N00001 B
Stilamin®

FOR INTRAVENOUS INFUSION ONLY

Presentation
Ampoules of Stilamin (Somatostatin) contain synthetic somatostatin (as the acetate) as a white, freeze-dried, sterile and pyrogen-free powder. Two strengths are available: 250 μg and 3 mg.

Each ampoule of Stilamin contains:
Somatostatin 250 μg or 3.0 mg
D-Mannitol (excipient) 5.0 mg
* Corresponding to 300 μg and 3.6 mg of somatostatin acetate respectively.

Each ampoule of the strength 250 μg is accompanied by a solvent ampoule containing 1 ml of isotonic, sterile and pyrogen-free Sodium Chloride injection solution.

Indication and use
Stilamin is indicated for:
• Severe acute haemorrhage from oesophageal varices.
• Severe acute haemorrhage from gastric or duodenal ulcers, or accompanying acute erosive or haemorrhagic gastritis.
• Adjunct treatment of pancreatic, biliary and intestinal fistulae.
• Prophylaxis and treatment of postoperative complications following pancreatic surgery.

Pharmacodynamic properties
Stilamin is a synthetic cyclic 14-amino-acid peptide, which is identical in structure and action to natural somatostatin. By intravenous infusion in humans, somatostatin causes inhibition of growth hormone, thyroid stimulating hormone, insulin and glucagon secretion as well as inhibition of gastric acid secretion. It also affects the absorption, motility, splanchnic blood flow and trophic functions of the gastrointestinal tract. Physiologically, somatostatin is found mainly in the gastrointestinal tract and in the hypothalamus. Somatostatin inhibits the release of gastrin, gastric acid, and pepsin which supports its indication in the treatment of upper gastrointestinal haemorrhage. Furthermore, somatostatin is capable of reducing markedly splanchnic blood flow without causing significant variations in the systemic arterial pressure, which proves to be valuable for the management of oesophageal varical haemorrhage. Somatostatin reduces both pancreatic endocrine and exocrine secretion which makes it effective in the prophylaxis and treatment of postoperative complications of pancreatic surgery.

The positive effect of somatostatin in the management of diabetic streptococcal cellulitis can be ascribed to its suppression activity of glucagon secretion.

Pharmacokinetics
In healthy persons, the plasma level of endogenous somatostatin is low, generally well under 175 ng/L.

Following intravenous administration, somatostatin shows a very short plasma half-life which, as measured by radioimmunoassay, lies between 1.1 and 3 minutes in normal subjects, between 1.2 and 4.8 minutes in subjects with liver disease, between 2.6 and 4.9 minutes in subjects with chronic renal failure.

Following an intravenous infusion at a rate of 75 μg/h, the plateau level was obtained within 15 minutes and reached 1250 ng/L. The metabolic clearance rate was around 11/ min. and the half-life around 2.7 minutes.

After intravenous injection of 2 μg of 125-I tyrosine somatostatin, urinary excretion contained 40% of the radioactivity after 4 hours and 70% after 24 hours.

Somatostatin is rapidly metabolized in the liver through the action of endopeptidases and aminopeptidases, resulting in cleavage between the N-terminus and the cyclized portion of the molecule.

Dosage and administration
Stilamin is given intravenously, by slow bolus injection (3 to 5 minutes) of 250 μg or by continuous infusion at a rate of 250 μg/hour (equivalent of approximately 3.5 μg/kg body weight/hour).

The lyophilised powder should be reconstituted with the physiological sodium chloride solution immediately prior to use.

For continuous infusion one 3 mg of Stilamin ampoule should be used to prepare a 12 hours infusion. The solution may be either saline or 5% dextrose and should be adjusted to guarantee an outflow of 250 μg somatostatin/hour. The use of a perfusion syringe is recommended.

Treatment of severe acute bleeding from the upper gastrointestinal tract, including from oesophageal varices
It is recommended to start by a slow intravenous injection of 250 μg of Stilamin as loading dose, then immediately followed by an intravenous infusion at a rate of 250 μg/h.

In case of interruption of more than 3 to 5 minutes between two infusions, an additional slow intravenous injection of 250 μg is recommended to ensure a continuous treatment.

Once the haemorrhage has stopped (usually in less than 12 to 24 hours), treatment should be continued for 48 - 72 hours in order to avoid rebleeding.

Treatment up to 120 hours has been routinely performed in this indication.

Adjunct treatment in pancreatic, biliary and intestinal fistulae
A continuous infusion of Stilamin at a rate of 250 μg/h is recommended until closure of the fistulae (2-20 days). This infusion should be performed in addition to total parenteral nutrition. Once the fistula has been closed, treatment should be continued for 1 to 3 days and stopped progressively in order to avoid rebound effect.

Prophylactic treatment of postoperative complications following pancreatic surgery
Stilamin is administered at the beginning of the surgical intervention at a rate of 250 μg/h and treatment is continued for 5 days.

Precautionary statements
Contra-indications
Stilamin is contra-indicated:
• During pregnancy and the immediate post-partum period (puerperium) as well as during lactation. There is no evidence of the drug's safety in human pregnancy nor is there evidence from animal work that it is free from hazard.

Avoid in pregnancy unless there is no safer alternative.

b) In states of proven hypersensitivity to somatostatin

Warning
Due to its inhibitory effect on the secretion of insulin and glucagon, the administration of Stilamin can, at the outset of treatment, lead to a transient fall in blood glucose level. Caution is, therefore, called for in insulin-dependent diabetic patients in whom blood glucose should be measured every 3-4 hours.

Simultaneous administration of insulin-requiring sugars should, if possible, be avoided. If necessary, insulin should be administered.

Interaction with other drugs
Since somatostatin lengthens the time of hexobarbital-induced sleep and potentiates the action of pentetrazol, Stilamin should not be administered concomitantly with these drugs or with drugs exerting the same effects.

Side-effects
Nausea, vertigo, and flushing have been reported rarely. Nausea and vomiting have been reported when the infusion rate is greater than 50 μg/min.

Incompatibilities
Physical incompatibilities with other drugs have not been tested, therefore Stilamin should be administered alone in the syringe and in infusion solutions.

Stability and storage
Storage condition and expiry date are indicated on the box. Solutions of Stilamin in physiological sodium chloride are stable for 24 hours.

Package quantities
Ampoules of stilamin 250 μg are packed singly and in boxes of five. Each ampoule is accompanied by an ampoule of 1 ml of physiological Sodium Chloride injection as solvent.

Ampoules of stilamin 3 mg are packed singly.

Drugs should be stored out of reach of children.

Manufacturer:
Merk Serono SA Aubonne Branch Zone Industrielle de l'Ouatetaz, 1170 Aubonne Switzerland