PACKAGE LEAFLET: INFORMATION FOR THE USER

Secretine Iberoinvesa Pharma S.L. 100 E, poeder en oplosmiddel voor oplossing voor injectie/infusie

Secretin pentahydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. WHAT SECRETIN IBEROINVESA PHARMA IS AND WHAT IT IS USED FOR

Secretin Iberoinvesa Pharma is for diagnostic use.
It helps to diagnose if the pancrease is able to produce a sufficient amount of secretions to enable digestion (diagnosis of exocrine pancreatic dysfunction) and it also helps to diagnose a malignant condition (tumor) called Zollinger-Ellison syndrome in adults.

Your doctor decides how and when Secretin Iberoinvesa Pharma will be used.

2. WHAT YOU NEED TO KNOW YOU USE SECRETIN IBEROINVESA PHARMA

Do not use Secretin Iberoinvesa Pharma:
- if you are allergic to Secretin pentahydrochloride or any of the other ingredients of this medicine (listed in section 6).

If you suffer from acute pancreatitis or an acute episode of chronic pancreatitis the investigation with Secretin Iberoinvesa Pharma should be performed at least 2 weeks after complete resolution of the acute symptoms.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before Secretin Iberoinvesa Pharma is administered to you.

Renal or hepatic impairment
Secretin may exert affect your kidney, and may affect patients with electrolyte and water disturbances
Please tell your doctor if you suffer from liver or kidney disease or if you are known to have imbalances in water or salts in your blood.

Vasovagal reactions and transient increase of heart rate
Vasovagal reactions encompassing transiently reduced blood pressure and transient increase of heart rate have been observed with intravenous infusion and bolus injection of secretin.
Please tell your doctor if you suffer or have suffered from low blood pressure and fainting.

Secretin affects the blood levels of other hormones such as insulin, which may cause nausea or dizziness during treatment with secretin.
Please tell your doctor if you suffer from diabetes.

Other medicines and Secretin Iberoinvesa Pharma
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Please tell your doctor if you take any of the following:
- Carbonic anhydrase inhibitors,
- peripherally acting synthetic anticholinergics,
- Hormones such as ACTH, corti-costeroids, thyroxine, oestrogens, progesterone, prolactin, glucagon, prostaglandins, and morphine reduce the effect of secretin.

Influencing diagnostic tests:
Please tell your doctor if you are taking medicines that suppress the acid secretion in your stomach, such as omeprazole (so called proton-pump-inhibitors). These could influence the outcome of the test.

Pregnancy, breast-feeding and fertility

Your doctor will decide if it is necessary for you to be given Secretin Iberoinvesa Pharma.
There are no data on the use of Secretin Iberoinvesa Pharma in pregnant or breast-feeding women. If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice.

3. HOW TO USE SECRETIN IBEROINVESA PHARMA

In general Secretin Iberoinvesa Pharma will be applied only once by your doctor during a diagnostic procedure. Secretin is normally not self-applied.
The examination may be repeated after 2 - 3 days if required.

There is no experience for the use of Secretin Iberoinvesa Pharma in children. Until relevant experience is available, use of Secretin Iberoinvesa Pharma in children cannot be recommended.

Posology:
This medicine will always be administered by healthcare professional. It is not intended to be used by patients.
For the diagnosis of exocrine pancreatic dysfunction:
1 CU secretin/kg body weight is injected intravenously over 1 to 2 minutes or infused intravenously over up to 1 hour.

For the diagnosis of Zollinger-Ellison-Syndrome:
2 CU secretin/kg body weight is injected intravenously.

Before the test you will not be allowed to eat for at least 10-12 hours. Your doctor will have to undertake certain procedures with you in order to collect the secretions from the pancreas or repeatedly withdraw blood. Please ask your doctor for details.

If you use more Secretin Iberoinvesa Pharma than you should
If too high doses are administered, the symptoms occuring may be lowering of blood pressure and disturbances of your water and acid base balance. Acute poisoning has not been reported yet.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Frequencies are defined as follows:
very common: may affect more than 1 in 10 people
common: may affect up to 1 in 10 people
uncommon: may affect up to 1 in 100 people
rare: may affect up to 1 in 1,000 people
very rare: may affect up to 1 in 10,000 people
not known: frequency cannot be estimated from the available data

Frequencies	**System Organ Class**	**Undesirable effects**
Common	Investigations	Pancreas enzymes increased (amylase, lipase, trypsin) in blood
Uncommon	Metabolism and nutrition disorders	Electrolyte disturbance
Rare	Gastrointestinal disorders	Diarrhea, sometimes in conjunction with abdominal cramps or nausea and retching
Not known (cannot be estimated from the available data)	Immune systeme disorders	Hypersensitivity reactions against the peptide, that can express in headache, increase of blood pressure, fast heartbeat, itching, exanthema, as well as hives
	Metabolism and nutrition disorders	Acidosis, low electrolytes such as calcium and sodium
	Nervous system disorders	Vertigo (if injected too fast)
	Gastrointestinal disorders	Increased volume of gastric fluid (during infusion of Secretin Iberoinvesa Pharma)
	Renal and urinary disorders	Micturition urgency (during infusion of Secretin Iberoinvesa Pharma)
	General disorders	Hot flush (if injected too fast)
	Investigations	Decreased blood pressure. Short-term decrease of blood sugar in diabetics
	Cardiac disorders	Fast or slow heartbeat, faintness,

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SECRETIN IBEROINVESA PHARMA

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
Do not use this medicine if you notice any visible particle after reconstituation.
Use the freshly prepared solution immediately.

Store and transport refrigerated (2 °C – 8°C).
Do not freeze.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Secretin Iberoinvesa Pharma contains

The active substance is: secretin pentahydrochloride. One vial with 24.4 mg powder contains 0.029 mg secretin pentahydrochloride, equivalent to the effect of 100 clinical units (CU).

The other ingredients are: Glycine hydrochloride, glycine, polygelin

What Secretin Iberoinvesa Pharma looks like and contents of the pack

The powder and solvent are filled into 15R clear glass vials (Ph.Eur., Type I) The vials are closed with bromobutyl rubber stoppers. The primary packaging material is sealed with aluminium Snap Caps with polypropylene (PP) plastic disc.

One single pack contains:
Active substance: One vial with 24.4 mg powder (white to off-white freeze-dried pellet that may break into powder) contains 0.029 mg secretin pentahydrochloride, equivalent to the effect of 100 clinical units (CU).
Solvent: 1 vial with 10 ml sodium chloride 9 mg/ml (0.9 %) solution for injection (clear colourless solution).

5er-bundle packs (5 × 1) contain:
5 single packs

5er-bulk packs (5 + 5) contain:
5 vials, each containing 24.4 mg of powder and
5 vials, each containing 10 ml of solvent.

5er-combi packs (2 × 5) contain:
one pack with 5 vials each containing 24.4 mg of powder and
one pack of 5 vials each containing 10 ml of solvent.

Not all pack sizes may be marketed.

Marketing authorisation holder
Iberoinvesa Pharma S.L.
Calle Zurbaran 18, 6°
28010 Madrid
Spanje

Manufacturer
Sanochemia Pharmazeutika AG
Landeggerstrasse 7
2491 Neufeld/Leitha, Austria

Dit middel is in het register ingeschreven onder:
RVG 111527

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	Secretin Iberoinvesa Pharma S.L., 100 CU, Pulver und Lösungsmittel zur Herstellung einer Injektions- bzw. Infusionslösung
Belgium:	Secretin Iberoinvesa Pharma 100 UC (unités cliniques) poudre et solvant pour solution injectable/pour perfusion
Germany:	Secretin Iberoinvesa Pharma S.L., 100 CU, Pulver und Lösungsmittel zur Herstellung einer Injektions- bzw. Infusionslösung

Spain:	Secretin Iberoinvesa Pharma S.L., 100 CU, Polvo y disolvente para solución inyectable y para perfusión
Italy:	Secretina Iberoinvesa Pharma, 100 CU, Polvere e solvente per soluzione iniettabile/ per infusione
The Netherlands:	Secretine Iberoinvesa Pharma S.L. 100 E, poeder en oplosmiddel voor oplossing voor injectie/infusie

Deze bijsluiter is voor het laatst goedgekeurd in maart 2015.

The following information is intended for medical or healthcare professionals only: The complete SmPC of Secretin Iberoinvesa is provided as a tear-off section at the end of the printed leaflet, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use.