# SALKALLI- retatrutide lyophilized powder 2.5mg injection, powder, lyophilized, for solution

**Guangzhou Yixin Cross-border E-commerce Co., Ltd.** 

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## Active ingredients (in each kit)

Retatrutide 2.5 mg (lyophilized powder) Sterile Water for Injection 0.25 mL

## **Purpose**

Antidiabetic / Weight management agent

Diluent

## Uses

Helps control blood sugar in adults with type 2 diabetes (when prescribed). Intended to assist adults with weight loss as directed by a healthcare provider.

## Warnings — Read carefully and tell your doctor if any apply to you.

Pancreatitis: Cases of pancreatitis have been reported. If you have severe abdominal pain (that may spread to the back), persistent vomiting, or signs of pancreatitis — stop using and contact your healthcare provider immediately.

Allergic reaction: Serious allergic reactions have been reported. Stop use and seek emergency care if you have hives, swelling of face/lips/tongue/throat, or trouble breathing.

Serious gastrointestinal disease: May cause GI adverse reactions. Not recommended for patients with severe GI disease (not studied).

Acute gallbladder disease: Cases (e.g., gallstones) have been reported. If you experience severe right-upper-abdominal pain or jaundice, seek medical evaluation.

Hypoglycemia warning: Do not use RETATRUTIDE if you have a history of recurrent or severe hypoglycemia. RETATRUTIDE may further lower blood glucose levels. Use is contraindicated in individuals with baseline hypoglycemia or conditions predisposing to hypoglycemia.

Pregnancy or breastfeeding: Do not use.

Children: Do not use.

Drug Interactions / Precautions

Other antidiabetic medications: Retatrutide lowers blood glucose. Using it with insulin or sulfonylureas may increase the risk of hypoglycemia. Blood glucose should be closely monitored; doses of other antidiabetic drugs may need adjustment.

Drugs affecting gastrointestinal motility: Retatrutide may delay gastric emptying. Coadministration with prokinetic agents (e.g., domperidone) or antacids may alter absorption or worsen GI discomfort. Cardiovascular medications: Caution with statins, digoxin, or warfarin.

Statins: absorption may be affected; monitor lipid levels.

Warfarin: changes in metabolism may alter anticoagulant effects; monitor INR levels.

General precautions: Retatrutide should be used only under medical supervision. Inform your healthcare provider about all medications, including prescription, over-the-counter, and herbal products.

Possible side effects

Nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia (indigestion), abdominal pain. If side effects are severe or persistent, contact your healthcare provider.

When to stop and call your doctor

If you develop severe abdominal pain (possible pancreatitis), severe allergic reaction, jaundice, or other serious symptoms.

## **Directions — Preparation & Dosing (basic patient summary)**

Concentration after reconstitution (calculation):

 $10 \text{ mg} \div 1 \text{ mL} = 10 \text{ mg/mL}.$ 

Therefore: 0.25 mL = 2.5 mg; 0.5 mL = 5 mg; 0.75 mL = 7.5 mg; 1 mL = 10 mg.

Typical weekly dosing schedule (example shown — follow your prescriber):

Weeks 1-4: 0.25 mL (2.5 mg) once weekly (subcutaneous)

Weeks 5-8: 0.5 mL (5 mg) once weekly

Weeks 9-12: 0.75 mL (7.5 mg) once weekly

Week 13 and onward: 1 mL (10 mg) once weekly

One carton (4 kits) provides 4 weekly doses.

How to prepare and inject (patient summary):

Wash hands with soap and water. Inspect vials for damage.

Using aseptic technique, withdraw the prescribed volume (in mL) of Sterile Water for Injection into a sterile syringe. Inject the diluent into the vial containing the lyophilized powder.

Gently swirl the vial until the powder fully dissolves. Do not shake vigorously. Solution should be clear; do not use if cloudy or particulate present.

Withdraw the prescribed volume (e.g., 0.25, 0.5, 0.75 or 1 mL) into a sterile syringe and inject subcutaneously in the abdomen, thigh, or upper arm after cleaning the site with alcohol. Rotate injection sites.

Dispose of syringe/needle in an appropriate sharps container.

## Do not use

Other antidiabetic medications: Retatrutide lowers blood glucose. Using it with insulin or sulfonylureas may increase the risk of hypoglycemia. Blood glucose should be closely monitored; doses of other antidiabetic drugs may need adjustment.

Drugs affecting gastrointestinal motility: Retatrutide may delay gastric emptying. Co-

administration with prokinetic agents (e.g., domperidone) or antacids may alter absorption or worsen GI discomfort.

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Children: Do not use.

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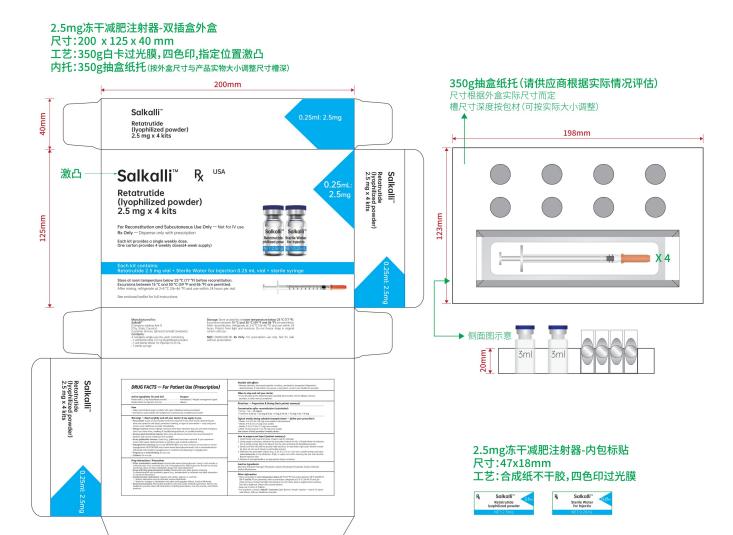
# Keep out of reach of children.

Not for use in children.

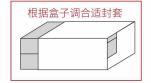
## **Inactive Ingredients:**

Mannitol, Disodium Hydrogen Phosphate, Sodium Dihydrogen Phosphate, Sodium Chloride, Sodium Bicarbonate.

## PRINCIPAL DISPLAY PANEL









## Saikaiii

## Retatrutide (lyophilized powder)

1 set containing 2 cartons (each carton contains 4 kits) 0.25ml: 2.5mg

0.25mL:

2.5mg

# Salkalli™ R



**USA** 

## Retatrutide (lyophilized powder)

1 set containing 2 cartons (each carton contains 4 kits)

For Reconstitution and Subcutaneous Use Only — Not for IV use Rx Only — Dispense only with prescription

Each kit provides a single weekly dose. One carton provides 4 weekly doses(4-week supply)

Salkalli™ Salkalli™ Retatrutide Sterile Water philized pow for Injectio

Each kit contains: Retatrutide 2.5 mg vial + Sterile Water for Injection 0.25 mL vial + sterile syringe

Store at room temperature below 25 °C (77 °F) before reconstitution. Excursions between 15 °C and 30 °C (59 °F and 86 °F) are permitted. After mixing, refrigerate at 2–8  $^{\circ}$ C (36–46  $^{\circ}$ F) and use within 24 hours per vial.

See enclosed leaflet for full instructions.



Solitality

Company address line 1]

(Company address line 1]

(City, State, Country)

Customer Service: [phone] | [email] | [website]

Contents:

1 set containing 2 cartons,
each corton containing 4 complete single-use kits, each kit containing:
1 vial Retartutied 2.3 mg (lyophilized powder)
1 sterile syringe

Storage: Store unused kits at room temperature below 25 °C (77 °F). Excursions between 15 °C and 30 °C (59 °F and 86 °F) are permitted. After reconstitution, refrigerate of 2-8° ( $^{\circ}$ 63-64 °F) and use within 24 hours. Protect from light and moisture. Do not freeze. Keep in original corton until use.

NDC: 00000-000-00. Rx Only. For prescription use only. Not for sale

0.25ml: 2.5mg

## DRUG FACTS — For Patient Use (Prescription)

Active ingredients (in each kit)
Retatrutide 2.5 mg (lyophilized powder)
Sterile Water for Injection 0.25 mL

**Purpose**- Antidiabetic / Weight management agent
- Diluent

Uses

- Helps control blood sugar in adults with type 2 diabetes (when prescribed).
- Intended to assist adults with weight loss as directed by a healthcare provider.

## Warnings — Read carefully and tell your doctor if any apply to you.

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  Children Do not use.

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## Possible side effects

When to stop and call your doctor

• If you develop severe abdominal pain (possible pancreatitis), severe allergic reaction, jaundice, or other serious symptoms.

## Directions — Preparation & Dosing (basic patient summary)

Concentration after reconstitution (calculation):

• 10 mg + 1 mL = 10 mg/mL.

• Therefore: 0.25 mL = 2.5 mg; 0.5 mL = 5 mg; 0.75 mL = 7.5 mg; 1 mL = 10 mg.

Typical weekly dosing schedule (example shown — follow your prescriber):

• Weeks 1-4: 0.25 mL (25 mg) once weekly (subcutaneous)

- One cortion (4 kHz) provides 4 weekly doses.

  New to propore and inject (potient summary):

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  2. Wosh hinds with soop and water, inspect viols for damage.

  2. Living agestic featuring, withdraws the prescribed violance for mil. of Sterick Water for Injection

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  6. Dispose of syntynginesdie in an appropriate sharps container.

Inactive Ingredients:
Mannitol, Disodium Hydrogen Phosphate, Sodium Dihydrogen Phosphate, Sodium Chloride,
Sodium Bicarbonate.

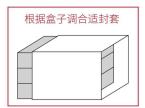
Other information

- Store unnest kits at tom temperature below 25 °C (77 °F). Excursions between 15 °C and 30 °C

97 °G and 68 °P) are permitted. After reconstitution, refrigerate at 2-8°C (164-46 °P) and use width 27 shours. Protect from kight and moistate. Do not feetac. Resp. in original continual use. Proceedings of the control o

2.5mg冻干减肥注射器-3件套封套 尺寸:200 x 127 x 122 mm

工艺:350g白卡过光膜,四色印



200mm

## Salkalli™

Retatrutide (lyophilized powder)

1 set containing 3 cartons (each carton contains 4 kits) 0.25ml: 2.5mg

# Salkalli™

**USA** 

# Retatrutide (lyophilized powder)

1 set containing 3 cartons (each carton contains 4 kits)

For Reconstitution and Subcutaneous Use Only — Not for IV use Rx Only — Dispense only with prescription

Each kit provides a single weekly dose. One carton provides 4 weekly doses(4-week supply)



0.25mL: 2.5mg

Each kit contains: Retatrutide 2.5 mg vial + Sterile Water for Injection 0.25 mL vial + sterile syringe

Store at room temperature below 25 °C (77 °F) before reconstitution. Excursions between 15 °C and 30 °C (59 °F and 86 °F) are permitted. After mixing, refrigerate at 2–8 °C (36–46 °F) and use within 24 hours per vial.

See enclosed leaflet for full instructions.



## Manufactured for: Salkalli™

Salkalli\*\*
[Company address line 1]
[City, State, Country]
Customer Service: [phone] | [email] | [website]

- Customer Service: [phone] [ [email] ] [website]
  Contents:
  1 set containing 3 caratons,
  each carato containing 4 complete single-use kits, each kit containing:
  -1 vial Returtutide 2.5 mg (lyophillized powder)
  -1 vial Sterile kareter for injection 0.25 ml.
  -1 sterile syringe

Storage: Store unused kits at room temperature below 25 °C (77 °F). Excursions between 15 °C and 30 °C (59 °F and 86 °F) are permitted. After reconstitution, refrigerate at 2-8 °C (35-46 °F) and use within 24 hours. Protect from light and moisture. Do not freeze. Keep in original corton until use

NDC: 00000-000-00. Rx Only. For prescription use only. Not for sale without prescription.

0.25ml: 2.5mg

## DRUG FACTS — For Patient Use (Prescription)

Active ingredients (in each kit) Retatrutide 2.5 mg (lyophilized powde

Purpose
Antidiabetic / Weight management agent
Diluent

Uses

- Helps control blood sugar in adults with type 2 dilabetes (when prescribed).

- Intended to assist adults with weight loss as directed by a healthcare proving the control of the

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  \*Annecentitis closes of paraceutils have been reported. If you have severe abdominal pain and contact you healthcore provider immediately.

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  \*Hypoglycemilia warning. Do not use RETABUTIOE froy farther lover blood glaces elved. Use is controllected in individuals with baseline hypoglycemical recommendation or conditions predisposing to hypoglycemia.

  \*Pergenory or breatfeeding: Do not use.

  \*Children\* Do not use.

- \*\*Chaldere Do not use.

  \*\*Drug Interaction\*\* Precuration\*\*

  \*\*Other antidabetic medications Retarratise lowers blood glucose. Using it with insulin or authorise the antidabetic medications Retarratise lowers blood glucose should be closely monitored, dose of other antidabetic drugs may need adjustment.

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  \*\*Cardiovisuation medications: Custon with statist, algosist, or variorin.

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## Possible side effects

When to stop and call your doctor

If you develop severe abdominal pain (possible pancreatitis), severe allergic reaction, jaundice, or other serious symptoms.

## Directions — Preparation & Dosing (basic patient summary)

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- New to praper and inject (patient summary):

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  2. Using agestic textural, withdraw the prescribed volume (in mit.) of Sterile Water for Injection

  and a safety syringe. When the falsent first the vide containing the lyophilized provider.

  Into a safety syringe, when the safety is the safety of the s

Inactive Ingredients:
Mannitol, Disodium Hydrogen Phosphate, Sodium Dihydrogen Phosphate, Sodium Chloride,
Sodium Bicarbonate.

- Other information

  Store unwald sits of come temperature below 25 °C (77 °F). Excursions between 15 °C and 30 °C
  (97 °F and 65 °F) are permitted. After reconstitution, refrigerate at 2-6 °C (56-46 °F) and use
  (56-1) its single-use Discard any unused solution.

  Seep and of reconstruction of children.

  For questions, contact. Solution! "Customer Care: [phone / email / website insent. To report
  side effects, (and your healthcase provider).

2.5mg冻干减肥注射器-4件套封套 尺寸:200 x 127 x 162 mm 工艺:350g白卡过光膜,四色印



200mm

# Salkalli™

## Retatrutide (lyophilized powder)

1 set containing 4 cartons (each carton contains 4 kits)

0.25ml: 2.5mg

# Salkalli<sup>™</sup> <sup>R</sup><sub>x</sub>



**USA** 

# Retatrutide (lyophilized powder)

1 set containing 4 cartons (each carton contains 4 kits)

For Reconstitution and Subcutaneous Use Only — Not for IV use **Rx Only** — Dispense only with prescription

Each kit provides a single weekly dose. One carton provides 4 weekly doses(4-week supply)



0.25mL: 2.5mg

# Each kit contains: Retatrutide 2.5 mg vial + Sterile Water for Injection 0.25 mL vial + sterile syringe

Store at room temperature below 25 °C (77 °F) before reconstitution. Excursions between 15 °C and 30 °C (59 °F and 86 °F) are permitted. After mixing, refrigerate at 2–8 °C (36–46 °F) and use within 24 hours per vial.

See enclosed leaflet for full instructions.



Manufactured for:
Salkalli\*
[Company address line 1]
[City, State, Country]
Customer Service: [phone] | [email] | [website]
Contents:
1 set containing 4 carrons,
each corton containing 4 complete single-use kits, each kit containing:
1 vial Returturble 2.5 mg (tyophilized powder)
1 vial Sterile Water for injection 0.25 mL
1 sterile symrage

Storage: Store unused kits at room temperature below 25 °C (77 °F). Excursions between 15 °C and 30 °C (59 °F and 86 °F) are permitted. After reconstitution, refrigerate at 2-8 °C (36-46 °F) and use within 24 hours. Protect from light and moisture. Do not freeze. Keep in original corton until use

NDC: 00000-000-00. Rx Only. For prescription use only. Not for sale without prescription.

0.25ml: 2.5mg

DRUG FACTS — For Patient Use (Prescription)	Possible side effects Nausea, diarrhe, decreased appetite, vomiting, constipation, dyspepsia (indigestion), abdominal pain. If side effects are severe or persistent, contact your healthcare provider.	
Active ingredients (in each kit)  Retatrutide 2.5 mg (tyophilized powder)  Antidiobetic / Weight management agent	When to stop and call your doctor  If you develop severe abdominal pain (possible pancreatitis), severe allergic reaction, joundate, or other serious symptoms.	
Sterile Water for Injection 0.25 mL Diluent	Directions — Preparation & Dosing (basic patient summary)	
Uses - Helps control blood sugar in adults with type 2 diabetes (when prescribed) Intended to assist adults with weight loss as directed by a healthcare provider.	Concentration after reconstitution (calculation): - 10 mg +1 mL = 10 mg/mL Therefore: 0.25 mL = 2.5 mg; 0.5 mL = 5 mg; 0.75 mL = 7.5 mg; 1 mL = 10 mg.	
Worning: — Read earyfully and fell your descrif for ye goly to you.  Procuratitis Come of proceeding this wheen inspired, all you have seen set declaration of procured the read of procuration from them to procure the read of the procuration	Typical weekly desing schedule (seample shown – follow your prescriber):  -treelect – 10.5 fm. (5.7mg) one weekly fudectionsoon)  - Weeks 5-6 0.5 m. (5.7mg) once weekly  - Weeks 5-7 0.7 m. (7.5mg) once weekly  - Week 15 and onwards 1 m. (10 mg) once weekly  - One cotton (6.4 kilds provides 4 weekly doses.	
	How to prepare and Inject (patient summary):  1. Wish homes with soop and water. Inspect vide for damage.  2. Using osepitic technique, withdrow the prescribed volume (n n.L) of Sterile Woter for injection into a sterile syrings, linject the duter into the volume (an n.L) of Sterile Woter for injection into a sterile syrings, linject the duter into the volume of the homes agroupdly. Sulfarion should be clear, do not use if cloudy or particulate present.  4. Windrow the prescribed volume (e.g., 0.25, 0.5, 0.75 or 1 m.L) into a sterile syringe and inject subcutaneously in the obdomen, thigh, or upper arm offer cleaning the site with olcohol.  5. Discusse of exmensioned in a no approprise sharps scottener.	
	Duspose of syringeneese in an appropriate sharps container.      Inactive Ingredients:     Mannitol, Disadium Hydragen Phosphate, Sodium Dihydragen Phosphate, Sodium Chloride, Sodium Bicarbonate.	
Co-daminisation with policitic grants (e.g., domperidonal or articulated may after charaption or versen of disconfirett.  Confedence and medication Caution with latter, disposit, or versation.  Confedence and medication Caution with latter, disposit, or versation.  Welforthis character in the confedence of the confed	Other Information Store amounts that committee below 26 °C (71°F). Excussion between 15 °C and 20 °C (27°F). Excussion between 15 °C and 20 °C (27°F). Excussion between 15 °C and 20 °C (26°F4. °F) and use with 24 °C (26°F4. °F) and use with 24 °C (26°F4. °F) and use with 24 °C (26°F4. °F) and use Each bit is single-use. Biccard any unused solding. Both of the committee of the c	

# SALKALLI

retatrutide lyophilized powder 2.5mg injection, powder, lyophilized, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:84778-116
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
RETATRUTIDE (UNII: NOP2Y096GV) (RETATRUTIDE - UNII:NOP2Y096GV)	RETATRUTIDE	2.5 mg in 0.25 mL	

Inactive Ingredients		
Ingredient Name	Strength	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)		
MANNITOL (UNII: 30WL53L36A)		
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)		
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)		

**SODIUM CHLORIDE** (UNII: 451W47IQ8X)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84778-116- 02	2 in 1 PACKAGE, COMBINATION	10/30/2025	
1		4 in 1 CARTON		
1		0.25 mL in 1 KIT; Type 1: Convenience Kit of Co-Package		
2	NDC:84778-116- 01	4 in 1 CARTON	10/30/2025	
2		0.25 mL in 1 KIT; Type 1: Convenience Kit of Co-Package		
3	NDC:84778-116- 03	3 in 1 PACKAGE, COMBINATION	10/30/2025	
3		4 in 1 CARTON		
3		0.25 mL in 1 KIT; Type 1: Convenience Kit of Co-Package		
4	NDC:84778-116- 04	4 in 1 PACKAGE, COMBINATION	10/30/2025	
4		4 in 1 CARTON		
4		0.25 mL in 1 KIT; Type 1: Convenience Kit of Co-Package		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		10/30/2025	

# **Labeler -** Guangzhou Yixin Cross-border E-commerce Co., Ltd. (455800881)

# **Registrant -** Guangzhou Yixin Cross-border E-commerce Co., Ltd. (455800881)

Establishment				
Na me	Address	ID/FEI	<b>Business Operations</b>	
Guangzhou Yixin Cross-border E-commerce Co., Ltd.		455800881	label(84778-116) , manufacture(84778- 116)	

Revised: 11/2025 Guangzhou Yixin Cross-border E-commerce Co., Ltd.