

Product Name: Ristaben 25, 50 & 100	Component: Patient Information Leaflet Date Approved: 20 March 2019
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PATIENT INFORMATION LEAFLET
Information for the patient about RISTABEN™

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

RISTABEN™ 25 tablet

RISTABEN™ 50 tablet

RISTABEN™ 100 tablet

Read all of this leaflet carefully before you start taking RISTABEN™

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

RISTABEN has been prescribed for you personally and you should not share RISTABEN with other people. It may harm them, even if their symptoms are the same as yours.

WHAT RISTABEN CONTAINS

The active substance is:

RISTABEN (sitagliptin phosphate) is a tablet that contains 25, 50 or 100 mg of sitagliptin as the active ingredient.

The other ingredients are:

Anhydrous dibasic calcium phosphate, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, and sodium stearyl fumarate.

Product Name: Ristaben 25, 50 & 100	Component: Patient Information Leaflet
	Date Approved: 20 March 2019

In addition, the film-coating contains the following inactive ingredients: Polyethylene glycol (macrogol), polyvinyl alcohol, red iron oxide, talc, titanium dioxide and yellow iron oxide.

WHAT RISTABEN IS USED FOR

RISTABEN belongs to a class of medicines that lowers blood sugar levels in patients with type 2 diabetes mellitus. Type 2 diabetes is also called non-insulin-dependent diabetes mellitus or NIDDM.

Your doctor has prescribed RISTABEN to help lower your blood sugar, which is too high because you have type 2 diabetes.

BEFORE YOU TAKE RISTABEN

Do not take RISTABEN:

If you are allergic to sitagliptin or any of the other ingredients in RISTABEN. A list of ingredients can be found at the beginning of this leaflet under “**WHAT RISTABEN CONTAINS**”.

If you have type 1 diabetes

Take special care with RISTABEN:

There are some things your doctor should know before you get the medicine.

Tell your doctor if you have or have had:

- any allergies

While taking RISTABEN

Cases of inflammation of the pancreas (pancreatitis) have been reported in patients receiving RISTABEN. Pancreatitis can be a serious, potentially life-threatening medical condition. Stop taking RISTABEN and call your doctor if you experience severe and persistent stomach pain, with or without vomiting, because you could have pancreatitis.

Product Name: Ristaben 25, 50 & 100	Component: Patient Information Leaflet
	Date Approved: 20 March 2019

Taking RISTABEN with food and drink:

RISTABEN can be taken with or without food.

Pregnancy and Breastfeeding

RISTABEN is not recommended for use during pregnancy.

If you are pregnant, planning to become pregnant or breastfeeding your baby while taking RISTABEN, please contact your doctor, pharmacist or other health-care professional for advice.

It is not known if RISTABEN passes into breast milk.

If you are taking RISTABEN you should not breastfeed your baby.

Driving and using machinery:

There is no information to suggest that RISTABEN affects your ability to drive a car or operate machinery.

Taking other medicines with RISTABEN:

RISTABEN may be taken with most medicines.

If you are taking other medicines on a regular basis (prescription or non-prescription), including complementary or traditional medicines, the use of RISTABEN with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

HOW TO TAKE RISTABEN

Do not share RISTABEN prescribed for you with others.

Product Name: Ristaben 25, 50 & 100	Component: Patient Information Leaflet Date Approved: 20 March 2019
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Always take RISTABEN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The recommended dose is to take:

One 100 mg tablet once a day by mouth, with or without food

If you have the impression that the effect of RISTABEN is too strong or too weak, talk to your doctor or pharmacist.

If you have kidney problems, your doctor may prescribe lower doses.

Your doctor may prescribe RISTABEN along with certain other medicines that lower blood sugar.

Diet and exercise can help your body use its blood sugar better. It is important to stay on your doctor recommended diet, exercise and weight loss program while taking RISTABEN.

Use in Children

RISTABEN has not been studied in children under 18 years of age.

Use in the Elderly

No dosage adjustment is necessary based on age.

If you take more RISTABEN than you should:

In the event of overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take RISTABEN:



Product Name: Ristaben 25, 50 & 100	Component: Patient Information Leaflet
	Date Approved: 20 March 2019

If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not take a double dose of RISTABEN.

POSSIBLE SIDE EFFECTS

RISTABEN may cause side effects

Not all side effects reported for RISTABEN are included in this leaflet. Should your general health worsen while taking RISTABEN, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happen, stop taking RISTABEN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions which may be serious including rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing. If you have an allergic reaction, stop taking RISTABEN and call your doctor right away. Your doctor may prescribe a medication to treat your allergic reaction and a different medication for your diabetes.
- Severe and persistent stomach pain, often with nausea and vomiting. These may be symptoms of pancreatitis. Pancreatitis can be a serious, potentially life-threatening medical condition. Stop taking RISTABEN and call your doctor right away if you experience these symptoms.

These are very serious side effects. You may need urgent medical attention or hospitalization.

Some patients have experienced kidney problems (sometimes requiring dialysis) while taking RISTABEN

The following are side effects of RISTABEN that are seen frequently.



Tell your doctor if you notice any of the following:

- low blood sugar; signs and symptoms of low blood sugar may include: headache, drowsiness, irritability, hunger, dizziness, confusion, sweating, feeling jittery, weakness and fast heart beat
- nausea
- flatulence
- foot swelling
- headache
- upper respiratory infection
- stuffy or runny nose and sore throat
- arm or leg pain
- painful joint disease, most frequently affecting the hips, knees and spine
- flu-like symptoms
- swelling of the arms and legs

The following are side effects of RISTABEN that are seen less frequently.

Tell your doctor if you notice any of the following:

- abdominal pain
- diarrhoea
- constipation
- vomiting
- drowsiness
- dizziness
- runny nose
- dry mouth

Product Name: Ristaben 25, 50 & 100	Component: Patient Information Leaflet
	Date Approved: 20 March 2019

- upper respiratory infection
- stuffy or runny nose and sore throat
- constipation
- vomiting
- headache
- joint pain
- muscle aches
- arm or leg pain
- back pain

Tell your doctor or pharmacist if you develop any unusual side effect or if any known side effect does not go away, or gets worse.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF RISTABEN

Store at or below 30 °C.

Do not use RISTABEN after the month and year shown following Exp./Verv.: on the container.

Keep all medicines out of reach and sight of children.

Protect from moisture

The blister should be kept in the carton until required for use.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF RISTABEN



Product Name: Ristaben 25, 50 & 100	Component: Patient Information Leaflet
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RISTABEN 25, 50 and 100 will be packaged in opaque PVDC/PE/PVC push-through blisters (referred to as PVDC blister) with push-through aluminium lidding. Packs contain 10, 14, 28 or 30 tablets with blisters of 10 or 14 tablets. The blisters are opened by pushing the tablets through the foil. 1 or 3 blisters of 10's or 2 blisters of 14's are placed in a carton, with a package insert, to make packs of 10's, 30's or 28's respectively.

IDENTIFICATION OF RISTABEN

RISTABEN 25: A pink, round, biconvex, film-coated tablet with "221" on one side and plain on the other.

RISTABEN 50: A light beige, round, biconvex, film-coated tablet with "112" on one side and plain on the other.

RISTABEN 100: A beige, round, biconvex, film-coated tablet with "277" on one side and plain on the other.

REGISTRATION NUMBERS

RISTABEN 25: 48/21.2/1349

RISTABEN 50: 48/21.2/1350

RISTABEN 100: 42/21.2/1351

NAME ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

MSD (Pty) Ltd

117 16th Road

Halfway House

South Africa



BP20190320

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DATE OF PUBLICATION OF PATIENT INFORMATION LEAFLET

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