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What Victoza® is used for

Victoza® is used to treat type 2 diabetes mellitus when diet and exercise alone are not enough to control your blood sugar levels.

How Victoza® works

Victoza® contains the active substance liraglutide. It helps your body reduce your blood sugar level only when blood sugar is too high. It also slows food passage through your stomach.

Victoza® can be used together with other diabetic medicines as metformin, a sulphonylurea (such as glimepiride or glibenclamide), metformin and a sulphonylurea (such as glimepiride or glibenclamide) as well as metformin and a glitazone (such as rosiglitazone or pioglitazone)

Before you use Victoza®

-When you must not use it

If you are allergic (hypersensitive) to liraglutide or any of the other ingredients of Victoza®.

Victoza® should not be used in children and adolescents under 18 years.

-Before you start to use it

- If you are also taking a sulphonylurea (such as glimepiride or glibenclamide), your doctor may tell you to test your blood sugar levels. This

will help your doctor to decide if the dose of the sulphonylurea needs to be changed.

- Victoza® should not be used if you have type 1 diabetes or diabetic ketoacidosis. Victoza® is not a substitute for insulin.
- The use of Victoza® is not recommended in patients with inflammatory bowel disease and/or diabetic gastroparesis (delayed gastric emptying).
- If you have symptoms of acute pancreatitis (inflammation of the pancreas), like persistent, severe abdominal pain, you should consult your doctor.
- When initiating treatment with Victoza®, you may in some cases experience loss of fluids/dehydration, e.g. in case of vomiting, nausea and diarrhea. It is important to avoid dehydration by drinking plenty of fluids. Contact your doctor if you have any questions or concerns.
- Please inform your doctor if you have thyroid disease.
- Victoza is not recommended for use during pregnancy and breast-feeding.

-Taking other medicines

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor, nurse or pharmacist if you are using medicines for diabetes containing any of the following active substances:

- insulin. Combination of Victoza® with insulin has not been evaluated.
- a sulphonylurea (such as glimepiride or glibenclamide). You may get hypoglycaemia (low blood sugar) when using Victoza® together with a

sulphonylurea as sulphonylurea increases the risk of hypoglycaemia. When you first start using these medicines together, your doctor may tell you to lower the dose of the sulphonylurea medicine.

How to use Victoza®

-How much to use

Always use Victoza® exactly as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure.

- The starting dose is **0.6 mg** once a day, for at least one week.
- Your doctor will tell you when to increase it to **1.2 mg** once a day.
- Your doctor may tell you to further increase the dose to **1.8 mg** once a day, if your blood glucose is not adequately controlled with a dose of 1.2 mg.
- Daily doses higher than 1.8 mg are not recommended.

Do not change your dose unless your doctor has told you to.

-When to use it

Victoza® is given as an injection under the skin (subcutaneous). Do not inject it into a vein or muscle. The best places to give yourself the injection are the front of your thighs, the front of your waist (abdomen), or your upper arm.

-How long to use it

Continue taking Victoza for as long as your doctor recommends.

Before you use the pen for the first time, your doctor or nurse will show you how to use it.

-If you forget to use it

If you forget a dose, use Victoza® as soon as you remember.

Then take your next dose as usual the following day.

Do not take an extra dose or increase the dose on the following day to make up for the missed dose. Consult your doctor or pharmacist on what you should do if you forget to use it.

-If you use too much (overdose)

If you use more Victoza[®] than you should, talk to your doctor straight away. You may need medical treatment. If you use too much Victoza[®], you may experience nausea or vomit.

While you are using it

-Things you must do

It is recommended that you measure your blood sugar regularly.

Tell all the doctors, dentists and pharmacists treating you that you are taking Victoza[®].

Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

-Do not take any insulin if you feel a hypo coming on.

-Do not share your Victoza[®] pen with anyone else.

-Do not try to repair your pen or pull it apart.

-Do not administer Victoza[®] into the vein or muscles.

-Things to be careful of

If you drive or use tools or machines, watch out for signs of a hypo. Your ability to concentrate or to react will be less during a hypo. Never drive or use machinery if you feel a hypo coming on. Discuss with your doctor whether you can drive or use machines at all, if you have a lot of hypos or if you find it hard to recognise hypos.

Side effects

Like all medicines, Victoza[®] can cause side effects although not everybody gets them.

Side effects may occur with certain frequencies, which are defined as follows:

- very common: affects more than 1 user in 10
- common: affects 1 to 9 users in 100
- uncommon: affects 1 to 9 users in 1,000
- rare: affects 1 to 9 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: frequency cannot be estimated from the available data

Very common side effects

- Nausea (feeling sick). This usually goes away over time.
- Diarrhoea. This usually goes away over time.

Common side effects

- Hypoglycaemia (low blood sugar). The warning signs of low blood sugar may come on suddenly and can include: cold sweat, cool pale skin, headache, fast heartbeat, feeling sick, feeling very hungry, changes in vision, feeling sleepy, feeling weak, nervous, anxious, confused, difficulty concentrating, shaking (tremor). Your doctor will tell you how to treat low blood sugar and what to do if you notice these warning signs. If you are already taking a sulphonylurea medicine when you start using Victoza[®], your doctor may tell you to reduce the dose of the sulphonylurea.
- Anorexia
- Decreased Appetite
- Headache
- Vomiting
- Dyspepsia (indigestion)
- Inflamed stomach (gastritis). The signs include stomach pain, nausea and vomiting.

- Gastro-oesophageal reflux disease (GORD). The signs include heartburn.
- Abdominal distension
- Abdominal pain upper
- Constipation
- Wind (flatulence)
- Eructation (burping)
- Upper respiratory tract infection

Uncommon side effects

- Pancreatitis (inflammation of the pancreas)
- Thyroid events - like nodules, increased blood calcitonin and goiters (swelling of the neck)

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Victoza[®]

-Storage

Before opening:

Store in a refrigerator (2°C - 8°C).

Keep away from the cooling element. Do not freeze.

During use:

You can keep the pen for 1 month when stored at a temperature below 30°C or in a refrigerator (2°C - 8°C), away from the cooling element. Do not freeze. When you are not using the pen, keep the pen cap on in order to protect from light.

Do not use Victoza[®] if the solution is not clear and colourless.

Keep out of the reach and sight of children.

-Disposal

Do not use Victoza® after the expiry date which is stated on the label and the carton after 'Expiry'. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

Victoza® is supplied as a clear, colourless solution for injection in pre-filled pen

-Ingredients

-Active ingredient
liraglutide

-Inactive ingredients
disodium phosphate dihydrate,
propylene glycol, phenol and water
for injections.

-MAL number:

MAL20102073A

Manufacturer

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
Denmark

Product Registration Holder

Novo Nordisk Pharma (M) Sdn Bhd
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