

Instructions on how to use Branded RETA® solution for injection in pre-filled pen.

Please read these instructions carefully before using your **Branded RETA®** pre-filled pen.

Do not use the pen without proper training from your doctor or nurse.

If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help. Get help from a person with good eyesight who is trained to use a **Branded RETA®** pre-filled pen.

Your pen is a pre-filled dial-a-dose pen. It contains 40mg of retatruiide, and you can select doses of 2.5mg, 5mg, 7.5mg, and 40mg. Your pen is designed to be used with disposable needles up to a length of 8mm. 12 of these needles are included in the box.

Start by checking your pen to make sure it contains **Branded RETA®**, then look at the illustrations on the inside of the box lid to know the different parts of your pen and needle.

Then follow steps 1 – 12 of the instructions on the inside of the box lid.

Always use a new needle for each injection and remove the needle after each injection. This reduces the risk of blocked needles, contamination, infection, and inaccurate dosing.

Never use a bent or damaged needle.

Always use the dose counter to select 2.5mg, 5mg, 7.5mg, or 40mg before administering the dose. Do not count pen clicks. The intended dose number must line up precisely with the dose pointer to ensure that you get the correct dose.

Never try to put the inner cap back on the needle. You may stick yourself with the needle.

Branded RETA® solution for injection in prefilled pen.

This medication is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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 described 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.

What is in this leaflet?

- What a Branded RETA® 40mg pen is and what it is used for?
- What you need to know before using your Branded RETA® pen.
- How to use your pen.
- Possible side effects.
- How to store your pen.
- Contents of your pack and other information.

What a Branded RETA® 40mg pen is and what it is used for?

The active substance in the pen is retatruid. Retatruid mimics the hormones GLP-1 and GIP, normally released in the gut after eating. This activates neurons in the brain that signals changes to your body and suppresses appetite.

It is very important you maintain daily your diet and exercise plan as advised by your doctor, nurse, or pharmacist.

Retatruid is also used to control blood sugar levels for patients with diabetes. If you have diabetes you must consult with your doctor before using any more Retatruid.

What you need to know before using your **Branded RETA®** 40mg pen

Do not use this pen if you are allergic to retatruiide or any other ingredients listed in this product. (listed in section 6)

Warnings and Precautions

Talk to your doctor, pharmacist, or nurse before using this medicine.

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Start by checking your pen to make sure it contains **Branded RETA®**, then look at the illustrations on the inside of the box lid to know the different parts of your pen and needle.

Then follow steps 1 – 12 of the instructions on the inside of the box lid.

Always use a new needle for each injection and remove the needle after each injection. This reduces the risk of blocked needles, contamination, infection, and inaccurate dosing.

Never use a bent or damaged needle.

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Never try to put the inner cap back on the needle. You may stick yourself with the needle.

What you need to know before using your Branded RETA® 40mg pen

Do not use this pen if you are allergic to retatruid or any other ingredients listed in this product. (listed in section 6)

Warnings and Precautions

Talk to your doctor, pharmacist, or nurse before using this medicine.

This medicine is not an insulin pen, and should not be used if you have type 1 diabetes – a condition where your body does not produce enough insulin so you develop diabetic ketoacidosis – a complication of diabetes with high blood sugar, breathing difficulty, confusion, excessive thirst, a sweet smell to the breath, or a sweet or metallic taste in the mouth.

Branded Labs - **Branded RETA®** is not insulin and should therefore not be used as a substitute for insulin.

Effects on the digestive system.

During treatment using this product you may feel sick, (nausea) or be sick (vomiting), or have diarrhea. These side effects can cause dehydration (loss of fluids); it is important that you drink plenty of fluids to prevent dehydration. This is especially important if you have kidney problems. Talk to your doctor if you have any questions or concerns.

Severe and ongoing stomach pain which could be due to acute pancreatitis. If you have severe and ongoing pain in the stomach area – see a doctor straight away as this could be a sign of acute pancreatitis (inflamed pancreas).

Hypoglycaemia

Combining a sulfonylurea or insulin with this product might increase the risk of getting low blood sugar levels (hypoglycemia). Please see section 4 for the warning signs of low blood sugar levels. Your doctor may ask you to test your blood sugar levels. This will help your doctor decide if the dose of sulfonylurea or insulin needs to be changed to reduce the risk of low blood sugar.

Diabetic eye disease (retinopathy)

If you have diabetic eye disease and you are using insulin, this medicine may lead to a worsening of your vision, and this may require treatment with this medicine.

Children and adolescents

This medicine is not recommended in children and adolescents under 18 years as the safety and efficacy in this age group have not yet been established.

Other medicines and Braned Labs - Branded RETA®

Tell your doctor, pharmacist, or nurse if you are taking, have recently taken, or might take any other medicines, including herbal medicines or other medicines you bought without a prescription.

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

Warfarin or other similar medicines taken by mouth to reduce blood clotting (oral anti-coagulants). Frequent blood testing to determine the ability of your blood to clot may be required.

If you are using insulin, your doctor will tell you how to monitor your blood sugar more frequently, in order to avoid hypoglycemia (low blood sugar) and diabetic ketoacidosis (a complication of diabetes that occurs when the body is unable to break down glucose because there is not enough insulin).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you might be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine.

This medicine should not be used during pregnancy, as it is not known if it may affect your unborn child. Therefore, it is recommended to use contraception while using this medicine. If you wish to become pregnant, you should stop using this product at least two months in advance. If you become pregnant, you should stop using this product, and talk to your doctor right away, as your treatment will need to be changed.

Do not use this product if you are breastfeeding, as it is unknown if it passes into breast milk.

Driving and using machines

If you use this product in combination with sulphonylurea or insulin, low blood sugar (hypoglycemia) may occur which may reduce your ability to concentrate. Avoid driving or using machines if you get signs of low blood sugar, see section 2, 'Warning and Precautions' for information on increased risk of low blood sugar and section 4 for the warning signs of low blood sugar. Talk to your doctor for further information.

3. How to use Branded RETA®

Always use this product exactly as your doctor told you. Check with your doctor, pharmacist, or nurse if you are not sure.

How much to use

The starting dose is 2.5mg once a week for four weeks.

After four weeks your doctor will increase your dose to 5mg once a week.

Your doctor after 8 weeks may increase your dose to 7.5mg once a week and after 40 weeks 40mg once a week if hunger cravings return.

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

Branded RETA® is given as an injection under the skin (subcutaneous injection). Do not inject it into a vein or muscle.

The best places to give injections are the front of your thighs, the front of your waist (abdomen), or your upper arm.

Before you use the pen for the first time, your doctor or nurse will show you how to use it. Detailed instructions for use are on the other side of this leaflet.

When to use Branded Labs Retatrutide®

You should use this product once a week on the same day each week if possible.

You can give yourself the injection at any time of the day regardless of meals.

If necessary you can change the day of your weekly injection of this medicine as long as it has been at least 3 days since your last injection of it. After selecting a new dosing day, continue with once-a-week dosing.

If you use more **Branded RETA®** than you should

If you use more **Branded RETA®** than you should, talk to your doctor straight away. You may get side effects such as feeling sick (nausea).

If you forget to use **Branded RETA®**

If you forget to inject a dose and:

It is 5 days or less since you should have used **Branded RETA®**, use it as soon as you remember. Then inject your next dose as usual on your scheduled day.

It is more than 5 days since you should have used **Branded RETA®**, skip the missed dose. Inject your next dose as usual on your scheduled day.

Do not take a double dose to make up for a forgotten dose.

If you stop using **Branded RETA®**

Do not stop using this product without talking to your doctor. If you stop using it, your hunger and blood sugar levels will likely increase.

If you have any further questions on the use of this product then ask your doctor, pharmacist, or nurse.

4. Possible side effects

Like all medicines, this product can cause side effects, although not everybody gets them.

Serious side effects

Common: may affect up to 1 in 40 people.

Complications of diabetic eye disease (retinopathy) – you should inform your doctor if you experience eye problems, such as changes in vision during treatment with this product.

Uncommon: may affect up to 1 in 400 people

Severe allergic reactions (anaphylactic reactions, angioedema). You should seek immediate medical help and inform your doctor straight away if you get symptoms such as breathing problems, swelling of the face, lips, tongue, and/or throat with difficulty swallowing, and a fast heartbeat.

Other side effects

Very common: may affect more than 1 in 20 people

feeling sick (nausea) – this usually goes away over time

diarrhea – this usually goes away over time

Common: may affect up to 1 in 20 people

being sick (vomiting)

low blood sugar (hypoglycemia) when this product is used with another antidiabetic medicine.

The warning signs of low blood sugar may come on suddenly. They can include: cold sweat, cool pale skin, headache, fast heartbeat, feeling sleepy or weak, feeling nervous, anxious, or confused, difficulty concentrating or shaking. If you are diabetic and feeling these symptoms then you should follow your doctor's advice on how to treat low blood sugar if you notice these signs.

For people without diabetes who are feeling these signs, you have likely not eaten in a while and a balanced meal will resolve these feelings. If you have eaten a balanced meal recently and these feelings continue then consult your doctor, nurse, or pharmacist.

Low blood sugar is more likely to happen if you also take a sulfonylurea or insulin. Your doctor may reduce your dose of these medicines before you start using this product.

Indigestion

- Inflamed stomach (gastritis) – the signs include stomach ache, feeling sick (nausea), or being sick (vomiting)
- Reflux, or heartburn – also called 'gastro-esophageal reflux disease (GERD)'
- Stomach pain
- Bloating of the stomach
- Constipation
- Burping
- Gall stones
- Dizziness
- Tiredness
- Weight loss
- Less appetite
- Gas (flatulence)
- Increase of pancreatic enzymes (such as lipase and amylase)

Uncommon: may affect up to 1 in 400 people
change in the way food or drink tastes

- Fast pulse

- Injection site reactions – such as bruising, pain, irritation, itching and rash
- Allergic reactions like rash, itching, or hives.
- 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:

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Branded RETA®

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 pen label. The expiry date refers to the last date of the month.

Before opening:

Store in the refrigerator (2°C to 8°C). Do not freeze. Keep away from the cooling element. Protect from light.

During use:

You can keep the pen for 6 weeks when stored at a temperature below 30°C or in a refrigerator for 16 weeks away from the cooling element.

When you are not using the pen, keep the pen cap on in order to protect it from light.

Do not use this medicine if you notice that the solution is not clear and colorless or almost colorless.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Branded RETA® contains

The active substance is retatruid. One ml solution for injection contains 40.34 mg retatruid. One pre-filled pen contains 40mg retatruid in 3ml solution.

Each full dose (0.74ml) contains 40mg retatruid, (13.7mg/ml), 4.1mg sodium chloride, 0.7mg sodium phosphate dibasic heptahydrate, and water for injection.

Hydrochloric acid and/or sodium hydroxide may have been added to adjust pH.

Branded RETA® has a pH of 6.5 – 7.5.

What Branded RETA® looks like and the contents of the pack

Branded RETA® is a clear and colourless or almost colourless solution for injection in a prefilled pen. Each pen contains 3ml solution, delivering 4 full doses of 40mg.

Marketing Authorisation Holder and Manufacturer

Braned Labs Laboratories

Manufactured by UK

www.branedlabspharmacy.com

This leaflet was last revised 08/4024.

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