

DBL™ Octreotide Injection

Octreotide (ok-tree-oh-tide) acetate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL Octreotide Injection. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using DBL Octreotide Injection against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What DBL Octreotide Injection is used for

This medicine is used to treat:

- **Acromegaly:**
In people with acromegaly the body makes too much growth hormone, which controls the growth of tissues, organs and bones. This leads to enlargement of the bones, especially of the hands and feet. Other symptoms include headaches, increased sweating, tiredness, numbness of the hands and feet, pain and stiffness in the joints and loss of sexual function. By blocking the excess growth hormone, octreotide can relieve many of these symptoms.
- **Symptoms of certain types of cancer such as carcinoid syndrome and VIPoma:**

By blocking hormones that are over-produced in these conditions, octreotide can relieve symptoms such as flushing of the skin and severe diarrhoea.

- **People who are having surgery on the pancreas.**

This medicine helps to lower the chance of complications after the surgery.

Octreotide is a man-made medicine derived from somatostatin (so-MAT-oh-STAT-in), a substance found in the human body.

Octreotide is used instead of somatostatin because its effects are stronger and last longer so that it needs to be given only 2 or 3 times a day.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

There is very little information on the use of this medicine in children.

Before you use DBL Octreotide Injection

When you must not use it

You must not use Octreotide Injection if you have an allergy to:

- any medicine containing Octreotide

- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

You must not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should use this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have, or have had, any of the following medical conditions:

- gallstones
- problems with your blood sugar levels, either too high (diabetes) or too low (hypoglycaemia)
- problems with your liver
- problems with your thyroid
- a history of vitamin B12 deprivation.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you use DBL Octreotide Injection.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Octreotide may interfere with each other.

These include:

- bromocriptine, a medicine used to treat acromegaly
- medicines used to treat diabetes
- cimetidine, a medicine for ulcers
- ciclosporin, a medicine used to suppress the immune system
- quinidine, a medicine used to prevent irregular heartbeats
- terfenadine, a medicine used to treat allergies.

Tell your doctor if you are taking any medicine:

- to control blood pressure (e.g. beta blockers or calcium channel blockers)
- to control fluid or electrolyte balance.

These medicines may be affected by octreotide or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being treated with this medicine.

How to use DBL Octreotide Injection

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much is given

The dose of DBL Octreotide Injection depends on the condition being treated.

Acromegaly:

treatment is usually started with injections of 0.05 to 0.1 mg every 8 or 12 hours. The dose can then be adjusted depending on how well it blocks growth hormone and relieves symptoms such as tiredness, sweating and headache.

Carcinoid syndrome and VIPoma:

treatment is usually started with injections of 0.05 mg once or twice a day. The dose can be increased if symptoms such as diarrhoea are not relieved.

Surgery on the pancreas:

injections of 0.1 mg are usually given three times a day for one week, starting about an hour before the operation.

How it is given

DBL Octreotide Injection is given as a subcutaneous injection. That means that it is injected into the fat layer just under the skin.

If you are giving the injections yourself

If you will be giving the injections yourself, your doctor or nurse will teach you how to do the injection.

Before using the injection, check the liquid for particles or a change in colour. If you notice anything unusual, do not use the vial.

Once a vial is opened, use it immediately and throw out any liquid that remains.

The vial does not contain any preservative.

Give the injections between meals or at bedtime. Avoid having meals around the time of the injections.

This will help to reduce the chance of stomach upset.

To help prevent irritation or pain at the injection site:

- **choose a new site for each injection. The upper arms, thighs and abdomen are good areas for injection.**
- **make sure the vial is at room temperature before you use it. If it has been in the fridge, take it out half an hour before using it. You can warm it up in your hand but do not try to heat it.**

If you notice pain, stinging, tingling, burning, redness or swelling at the injection site after the injection, gently rub the site for a few seconds.

These side effects rarely last more than 15 minutes after an injection.

If you forget to use it

Inject the dose as soon as you remember, and then go back to using it as you would normally.

It will not do any harm if you miss a dose but some of your symptoms may come back temporarily until you get back on schedule.

Do not use a double dose to make up for the one that you missed.

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that an overdose has happened. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Some of the symptoms of an overdose may include slow heartbeat, flushing of the face, cramps in the abdomen, diarrhoea,

an empty feeling in the stomach and nausea (feeling sick).

Ask your doctor or pharmacist if you have any concerns.

While you are using DBL Octreotide Injection

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using DBL Octreotide Injection.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.

It may affect other medicines used during surgery.

Women of child-bearing age should use an effective contraceptive method during treatment with DBL Octreotide Injection.

If you become pregnant while you are being treated with this medicine, tell your doctor immediately.

DBL Octreotide Injection should only be used during pregnancy if clearly needed.

Do not breast-feed while using DBL Octreotide Injection.

It is not known whether octreotide passes into breast milk.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem to be the same as yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how DBL Octreotide Injection affects you.

This medicine may cause dizziness, light-headedness, tiredness, drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being treated with DBL Octreotide Injection.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- irritation, pain, redness, rash or swelling at the injection site
- loss of appetite
- indigestion, nausea or vomiting
- cramps
- feeling of bloating or wind
- constipation, diarrhoea or other change in bowel motions
- stomach pain or tenderness
- discoloured stools
- fatty stools
- headache
- dizziness or light headedness

- swelling of hands or feet due to excess fluid
- tiredness or weakness
- flushing of the skin
- temporary hair loss
- changes in the rhythm of your heart beat
- shortness of breath.

The above list includes the more common side effects of your medicine.

If any of the following happen, tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital:

- symptoms of an allergic reaction including shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.
- severe pain, tenderness or swelling in the stomach or abdomen, which may be accompanied by fever, nausea and vomiting, yellowing of the skin and eyes, loss of appetite, feeling unwell, itching, light coloured urine (symptoms of a possible problem with your liver, pancreas or gall bladder)
- symptoms of low blood glucose (hypoglycaemia), including sweating, trembling, dizziness, weakness, hunger, palpitations (feeling of fast or irregular heartbeat) and fatigue
- symptoms of high blood glucose (hyperglycaemia), including lethargy or tiredness, headache, thirst, passing large amounts of urine, and blurred vision
- symptoms of an underactive thyroid gland (hypothyroidism) causing changes in heart rate, appetite or weight, tiredness, feeling cold, or swelling at the front of the neck
- unusually slow heartbeat
- increased bleeding or bruising (could be low levels of platelets in the blood).

The above list includes very serious side effects. You may need urgent medical attention

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using DBL Octreotide Injection

Storage

Keep your medicine in the original pack until it is time to use it.

If you take your medicine out of the pack it may not keep well.

Store your medicine in the refrigerator. Do not freeze them.

Do not store DBL Octreotide Injection or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or you find that the expiry date has passed or the vials have been left out of the fridge for too long, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

DBL Octreotide Injection comes in 1 mL glass vials containing a clear colourless liquid free of foreign matter. It is available in packs of 5.

Ingredients

DBL Octreotide Injection contains 0.05 mg, 0.1 mg or 0.5 mg of octreotide (as octreotide acetate) as the active ingredient. It also contains:

- glacial acetic acid
- sodium acetate trihydrate
- sodium chloride
- water for injections.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

DBL™ Octreotide Injection is supplied by:

Pfizer Australia Pty Ltd
Sydney NSW

Toll Free Number: 1800 675 229
www.pfizer.com.au

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Australian Registration Numbers:

0.05 mg/ 1 mL AUST R 120734

0.1 mg/ 1 mL AUST R 120735

0.5 mg/1 mL AUST R 120736