

DBL™ Papaverine Hydrochloride Injection

Papaverine Hydrochloride (pa-PAV-er-een)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Papaverine Hydrochloride 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 weighed the risks of you using papaverine 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™ Papaverine Hydrochloride Injection is used for

This medicine is used to produce erections in impotent men.

It belongs to a group of medicines called vasodilators.

When papaverine is injected into the penis (called 'intracavernosal' injection) it works by increasing blood flow to the penis, which results in an erection.

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children and newborn babies.

Before you use DBL™ Papaverine Hydrochloride Injection

When you must not use it

Do not use DBL™ Papaverine Hydrochloride Injection if you have an allergy to:

- any medicine containing papaverine
- any of the ingredients listed at the end of this leaflet.

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.

Do not use this medicine if you have any of the following medical conditions:

- complete atrioventricular block (a heart condition characterised by a slow or irregular heart beat)
- sickle cell anaemia (a disease in which the amount of oxygen-carrying pigment in the blood is below normal and the red blood cells become distorted)
- leukaemia (cancer of the blood)

- multiple myeloma (cancer of the bone)
- an implant in your penis
- any deformities of the penis
- abnormal thickening of the tissue of the penis
- any condition where sexual activity is inadvisable.

Do 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 start using 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:

- heart problems
- liver disease
- any disease that may be transmitted by contact with blood.

Tell your doctor if you are taking any oral medications used to treat impotence in men.

If you have not told your doctor about any of the above, tell him/her before you start to use papaverine.

Taking other medicines

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

Some medicines and papaverine may interfere with each other. These include:

- levodopa, a medicine used in the treatment of Parkinson's disease
- medicines to strong relieve pain, such as morphine, or other medicines which cause sleepiness
- medicines used to prevent blood clots, such as warfarin and heparin
- ioxaglate, a dye used when taking x-rays of the penis.

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

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

How DBL™ Papaverine Hydrochloride Injection is given

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

They may differ from the information contained in this leaflet.

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

How much is given

Your doctor will decide what dose of papaverine you will receive. This depends on your medical condition and whether or not you are taking any other medicines.

How it is given

A doctor or nurse will show you how to do the injection for at least the first time. If you will be self-administering papaverine your doctor will provide you with proper training and instruction to ensure that administration related injuries do not occur.

It is important that you follow your doctor's instructions at all times. If you are not certain about the way this medicine is given please contact your doctor; this leaflet is only intended to remind you about the instructions your doctor has already given you.

Always use a new syringe and needle for each injection. A 13 mm 27 to 30 gauge needle is recommended.

If the needle is bent at any time, do not use it for injecting papaverine and do not attempt to straighten it before injecting papaverine. A bent or restraightened needle may be more likely to break. Needle breakage with a portion of the needle remaining in the penis has been reported and in some cases requires hospitalisation and surgical removal.

Do not use papaverine if the ampoule is damaged or if the solution looks cloudy, coloured, or has particles in it.

Stretch the penis out across the thigh. If you are uncircumcised the foreskin must be pulled back before you inject papaverine. Clean the injection area with an alcohol swab.

Papaverine is injected directly into the base of the penis on the left or right-hand side. It is given as a slow injection over 1 to 2 minutes. Papaverine should not be injected just under the skin or into the midline or lower part of the penis.

After you have completed the injection, put pressure on the place of injection to prevent bruising. Then massage your penis as instructed by your doctor. This helps the medicine spread to all parts of the penis, so that it will work better.

Do not re-use or share needles or syringes.

Papaverine normally begins to work in about 10 minutes and the erection may persist for one to several hours.

If you use too much (overdose)

In case of overdose, immediately contact the Poisons Information Centre for advice (in Australia, call 13 11 26; in New Zealand call 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have used too much papaverine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include nausea, vomiting, weakness, drowsiness, double vision, rapid uncontrollable movements of the eyes, sweating, flushing, dizziness increased heart rate or priapism (a persistent painful erection of the penis that does not reverse within four hours).

While you are using DBL™ Papaverine Hydrochloride Injection

Things you must do

Do not injection this medicine under the skin or into the midline or lower part of the penis.

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

Tell any other doctors, dentists, and pharmacists who are treating 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.

If you are about to have any blood tests, tell your doctor that you are using this medicine.

It may interfere with the results of some tests.

Contact your doctor immediately if the erection lasts for longer than 4 hours, or if it becomes painful.

This may be a sign of priapism and must be treated immediately to prevent permanent damage.

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

Examine your penis regularly and contact your doctor if you notice changes or experience bleeding that does not stop despite applying pressure on the site.

Things to look out for include a lump where papaverine has been injected, or your penis becoming curved.

These may be signs of fibrosis (abnormal thickening of tissue).

Things you must not do

Do not use papaverine to treat any other complaint.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not increase the dosage of your medicine or use it more frequently than your doctor has instructed.

If too much is used, the erection may become so strong that it lasts too long and does not reverse when it should.

Do not use any solution left in the ampoule for a second injection, it should be used on one occasion only.

Discard any solution that is left over.

Do not use the needle to inject if it is bent.

Things to be careful of

Be careful driving or operating machinery until you know how papaverine affects you.

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

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using papaverine.

This medicine helps most people with impotence, but it may have unwanted side effects in a few people. 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.

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

- dizziness, headache or flushing
- mild discomfort in the penis during injection
- bruising or bleeding at injection site
- blood appearing at the end of the penis
- tingling at the tip of the penis
- difficulty in ejaculating.

The above list of side effects are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- pain or burning along penis
- redness and swelling at the injection site
- fibrosis (lumps) in the penis
- bending of the penis
- blister or ulcer at injection site
- swelling of the penis or foreskin.

The above list includes serious side effects which may require medical attention.

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

- increase in heart rate
- erection that lasts for more than 4 hours
- painful erection
- yellowing of the eyes and/or skin (jaundice).

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

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

Other side effects not listed above may occur in some patients.

After using DBL™ Papaverine Hydrochloride 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.

Keep your medicine in a cool dry place where the temperature stays below 25°C. Protect from light.

Do not store papaverine 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.

- 120 mg/10 mL ampoules (packs of 5) - AUST R 16277

This leaflet was updated in February 2015.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is leftover.

Product description

What it looks like

DBL™ Papaverine Hydrochloride Injection is a clear colourless to pale yellow solution in a glass ampoule.

Ingredients

Active ingredients:

- papaverine hydrochloride

Other ingredients:

- water for injections.

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

Supplier/Sponsor

Australian Sponsor:

Hospira Australia Pty Ltd
ABN 58 097 064 330
Level 3
500 Collins Street
Melbourne VIC 3000
Australia

New Zealand Sponsor:

Hospira NZ Limited
23 Haining Street
Te Aro
Wellington
New Zealand

DBL™ Papaverine Hydrochloride Injection is available in the following strengths and pack sizes:

- 30 mg/1 mL ampoules (packs of 5) - AUST R 16258