

DBL™ Papaverine Hydrochloride Injection

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using DBL Papaverine Hydrochloride Injection?

DBL Papaverine Hydrochloride Injection contains the active ingredient papaverine hydrochloride. DBL Papaverine Hydrochloride Injection is used to produce erections in impotent men.

For more information, see Section [1. Why am I using DBL Papaverine Hydrochloride Injection?](#) in the full CMI.

2. What should I know before I use DBL Papaverine Hydrochloride Injection?

Do not use if you have ever had an allergic reaction to papaverine hydrochloride or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions and/or take any other medicines.

For more information, see Section [2. What should I know before I use DBL Papaverine Hydrochloride Injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Papaverine Hydrochloride Injection and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is DBL Papaverine Hydrochloride Injection 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. A doctor or trained nurse will give you the first injection. If you will be self-administering papaverine your doctor will provide you with proper training and instruction.

More instructions can be found in Section [4. How is DBL Papaverine Hydrochloride Injection given?](#) in the full CMI.

5. What should I know while using DBL Papaverine Hydrochloride Injection?

| | |
|------------------------------------|--|
| Things you must do | <ul style="list-style-type: none">• Call your doctor straight away if the erection lasts for longer than 4 hours, or if it becomes painful.• Remind any doctor, nurse, pharmacist or dentist you visit that you are using DBL Papaverine Injection.• 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 you must not do | <ul style="list-style-type: none">• Do not injection this medicine under the skin or into the midline or lower part of the penis.• Do not increase the dosage of your medicine or use it more frequently than your doctor has instructed.• Do not use any solution left in the ampoule for a second injection. Do not use if the needle is bent. |
| Driving or using machines | <ul style="list-style-type: none">• 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. If this problem continues or gets worse, talk to your doctor. |
| Looking after your medicine | <ul style="list-style-type: none">• Store it in a cool dry place (where the temperature stays below 25°C) away from moisture, heat or sunlight• Keep it where young children cannot reach it. |

For more information, see Section [5. What should I know while using DBL Papaverine Hydrochloride Injection?](#) in the full CMI.

6. Are there any side effects?

Side effects include: 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; Serious side effects include: pain or burning along penis; redness, swelling, blister or ulcer at the injection site; fibrosis (lumps) in the penis; bending of the penis; swelling of the penis or foreskin. Very serious side effects include: increase in heart rate; erection that lasts longer than 4 hours; painful erection; yellowing of the eyes and/or skin.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

DBL™ Papaverine Hydrochloride Injection

Active ingredient(s): *Papaverine Hydrochloride* (pa-PAV-er-een)

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Papaverine Hydrochloride Injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DBL Papaverine Hydrochloride Injection.**

Where to find information in this leaflet:

- [1. Why am I using DBL Papaverine Hydrochloride Injection?](#)
- [2. What should I know before I use DBL Papaverine Hydrochloride Injection?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is DBL Papaverine Hydrochloride Injection given?](#)
- [5. What should I know while using DBL Papaverine Hydrochloride Injection?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using DBL Papaverine Hydrochloride Injection?

DBL Papaverine Hydrochloride Injection contains the active ingredient **papaverine hydrochloride**. DBL Papaverine Hydrochloride Injection is used to produce erections in impotent men.

DBL Papaverine Hydrochloride Injection 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.

2. What should I know before I use DBL Papaverine Hydrochloride Injection?

Warnings

Do not use DBL Papaverine Hydrochloride Injection if:

- you are allergic to papaverine hydrochloride, or 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.

Always check the ingredients to make sure you can use this medicine.
- 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.
- the expiry date printed on the pack has passed 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.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have or have had any other medical conditions, especially the following:
 - heart problems
 - liver disease
 - any disease that may be transmitted by contact with blood.
- take any medicines for any other condition especially 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

DBL Papaverine Hydrochloride Injection is not intended for use by women.

3. What if I am taking other medicines?

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

Some medicines may interfere with DBL Papaverine Hydrochloride Injection and affect how it works.

These include:

- levodopa, a medicine used in the treatment of Parkinson's disease
- medicines to strongly 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Papaverine Hydrochloride Injection.

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

4. How is DBL Papaverine Hydrochloride Injection given?

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 DBL Papaverine Hydrochloride Injection 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 DBL Papaverine Hydrochloride Injection

If you think that you have used too much DBL Papaverine Hydrochloride Injection, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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).

5. What should I know while using DBL Papaverine Hydrochloride 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 Papaverine Hydrochloride Injection.**
- **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.

- **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).**

Call your doctor straight away 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.

Things you must not do

- **Do not inject this medicine under the skin or into the midline or lower part of the penis.**
- **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.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DBL Papaverine Hydrochloride Injection affects you.

DBL Papaverine Hydrochloride Injection 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.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

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 it in a cool dry place (where the temperature stays below 25°C) away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

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

When to discard your medicine

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or your doctor tells you to stop using this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

| Side effects | What to do |
|---|---|
| General <ul style="list-style-type: none">• dizziness, headache or flushing Genital and administration site related | Speak to your doctor if you have any of these side effects and they worry you. |

| Side effects | What to do |
|---|--|
| <ul style="list-style-type: none">• 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 | These side effects are usually mild and short-lived. |

Serious side effects

| Serious side effects | What to do |
|---|--|
| Genital and administration site related <ul style="list-style-type: none">• 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 | Call your doctor straight away if you notice any of these serious side effects. You may require medical attention. |

Very serious side effects

| Very serious side effects | What to do |
|--|---|
| Heart related <ul style="list-style-type: none">• increase in heart rate Genital <ul style="list-style-type: none">• erection that lasts for more than 4 hours• painful erection Liver related <ul style="list-style-type: none">• yellowing of the eyes and/or skin (jaundice). | Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects. You may need urgent medical attention or hospitalisation. |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What DBL Papaverine Hydrochloride Injection contains

| | |
|---|--------------------------|
| Active ingredient (main ingredient) | papaverine hydrochloride |
| Other ingredients (inactive ingredients) | water for injections |

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

Do not use this medicine if you are allergic to any of these ingredients.

What DBL Papaverine Hydrochloride Injection looks like

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

DBL Papaverine Hydrochloride Injection is available in 120 mg/10 mL ampoules (packs of 5) (Aust R 16277).

Who distributes DBL Papaverine Hydrochloride Injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedinfo.com.au

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