

Paraldehyde Injection

Paraldehyde Injection BP 5 mL vial

Consumer Medicine Information

What is in this leaflet

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

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Paraldehyde Injection against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor.

Keep this leaflet in a safe place.

You may need to read it again.

What Paraldehyde Injection is used for

Paraldehyde Injection is used to treat convulsions, seizures and fits. It is also used as a sedative or to induce sleep.

It is only recommended for use when other treatments do not work or are not appropriate for the condition to be treated.

This medicine belongs to a group of medicines called sedatives and hypnotics.

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 addictive.

Before you are given Paraldehyde Injection

When you must not be given it

You should not be given Paraldehyde Injection if you have an allergy to:

- any medicine containing paraldehyde
- any of the ingredients listed at the end of this leaflet
- any other similar medicines.

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 should not be given this medicine if you have severe liver disease.

You should not be given this medicine if you have lung disease.

You should not be given this medicine if you are pregnant.

It may affect your developing baby if you are given it during pregnancy.

Do not breast-feed if you are being given this medicine.

The active ingredient in Paraldehyde Injection passes into breast milk and there is a possibility that your baby may be affected.

You should not be given this medicine if the solution is discoloured, cloudy, turbid, or a precipitate is present.

The solution is normally a clear, colourless to pale yellow liquid.

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

If you are given this medicine after the expiry date has passed, it may not work as well.

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

Before you are given it

Tell your doctor if you have ever received Paraldehyde Injection before.

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 disease
- asthma
- liver disease.

If you have not told your doctor about any of the above, tell them before you are given Paraldehyde Injection.

Taking other medicines

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

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

- alcohol
- barbiturates, medicines used for sedation or to treat seizures
- disulfiram, a medicine used to treat alcohol withdrawal.

These medicines may be affected by Paraldehyde Injection 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 given this medicine.

How Paraldehyde Injection is given

Paraldehyde Injection must only be given by a doctor, nurse or other trained person.

Paraldehyde Injection is given by injection into a muscle usually the buttocks. No more than 5 mL should be injected into the same spot.

Your doctor will decide what dose of Paraldehyde Injection you will receive and for how long you will receive it. This depends on your medical condition and other factors, such as your weight.

If you are given too much (overdose)

Paraldehyde Injection must only be given by a doctor, nurse or other trained person so an overdose is not likely to occur.

Immediately telephone your doctor or go to the Emergency Department at the nearest hospital if you think that too much Paraldehyde Injection has been given.

Symptoms of an overdose may include:

- rapid breathing
- cloudy urine, decreased urination
- slow heartbeat
- general weakness.

Contact the Poisons information centre on 13 11 26 for further advice on overdose management.

While you are being given Paraldehyde Injection

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you have been given Paraldehyde Injection.

Tell any other doctors, dentists, and pharmacists who treat you that you have been given this medicine.

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

It may affect other medicines used during surgery.

If you become pregnant while being given this medicine, tell your doctor immediately.

Things you must not do

Do not drive or operate machinery after being given Paraldehyde Injection.

This medicine causes drowsiness. Do not drive, operate machinery or do anything else that could be dangerous.

Do not drink alcohol after being given this medicine.

If you drink alcohol, the effects of this medicine may be worse.

Things to be careful of

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 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.

This medicine should not be stopped suddenly.

If this medicine is stopped suddenly it may have unwanted side effects such as hallucinations, sweating, tremors, restlessness and mental confusion. If possible your doctor will gradually reduce the amount you are given before stopping the medicine completely.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Paraldehyde Injection.

This medicine helps most people with seizures 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.

Ask your doctor to answer any questions you may have.

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

- skin rashes
- dizziness
- muscle cramps or tremors
- unusual sweating.

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

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

- pain, blistering or swelling at the injection site
- numbness at or near the injection site
- swelling and redness along a vein
- breathlessness, which may be very severe and usually worsens on lying down
- bluish discolouration of the skin
- nausea
- swelling or oedema
- severe stomach cramps
- confusion or agitation
- symptoms of hepatitis
 - nausea, vomiting, loss of appetite
 - yellowing of the skin and eyes
 - itching
 - fever
 - dark coloured urine.

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

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

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

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

After being given Paraldehyde Injection

Storage

Paraldehyde Injection will be stored in the surgery, pharmacy or ward of a hospital. The injection is kept in a dry place where the temperature stays below 25°C. It is protected from light.

Paraldehyde Injection should not be kept in the refrigerator. If crystallised, Paraldehyde Injection should be warmed gently.

Paraldehyde Injection will be opened for use on you. It will be used only once and then it will be discarded. It will never be stored after it is opened, nor used for more than one person.

Product description

What it looks like

Paraldehyde Injection is a clear, colourless to pale yellow solution in a clear glass vial.

Paraldehyde Injection is available in a 5 mL vial.

Ingredients

Paraldehyde Injection contains 100% paraldehyde as the active ingredient.

It also contains:

- hydroquinine as an antioxidant.

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

Manufacturer

Paraldehyde Injection is made and supplied in Australia by:

Phebra Pty Ltd
19 Orion Road
Lane Cove West, NSW 2066
Australia

Distributor

Paraldehyde Injection is distributed in New Zealand by:

AFT Pharmaceuticals Ltd
PO Box 33-203 Takapuna
Auckland, New Zealand

Paraldehyde Injection 5 mL vial AUST R 160612
Phebra product code-INJ153

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