

APOMINE® Solution for Infusion

apomorphine hydrochloride hemihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about APOMINE Solution for Infusion. 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 APOMINE Solution for Infusion 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 in a safe place. You may need to read it again.

For further information on APOMINE Solution for Infusion please contact your doctor or pharmacist, or your ANSSER nurse (1800 276 646).

What APOMINE Solution for Infusion is used for

APOMINE Solution for Infusion contains apomorphine which belongs to a group of medicines called dopaminergic compounds.

Apomorphine is used in the treatment of Parkinson's disease to reduce the number and severity of bouts of freezing and stiffness (or "off" periods).

This medicine works by acting on dopamine receptors. These receptors help control movement by the body.

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.

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

Before you use APOMINE Solution for Infusion

When you must not use it

Do not use APOMINE Solution for Infusion if you have an allergy to:

- apomorphine
- sodium metabisulfite or sulfites
- certain types of pain killers such as morphine or other opioid analgesics.

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.

The amount of sodium contained in APOMINE solution for infusion is 3.4 mg per mL, which should be taken into consideration by patients on a controlled sodium diet.

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

- certain forms of dementia eg. Alzheimer's Disease
- severe kidney or liver disease

- problems with circulation of blood in the brain (cerebrovascular disease)
- breathing problems (respiratory depression).

Do not give this medicine to a child under the age of 18 years.

Do not use this medicine in combination with anti-vomiting medicines (antiemetics) known as 5HT3 antagonists, such as ondansetron, granisetron or palonosetron.

People taking ondansetron together with apomorphine, the active ingredient in APOMINE Solution for Infusion, have had very low blood pressure and lost consciousness or "blacked out".

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 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:

- a history of severe nausea and vomiting
- heart disease
- kidney disease
- liver disease
- lung disease
- problem gambling

- any addictive behaviour (eg. sex, shopping or eating)

APOMINE can cause impulse control disorders, including addictive behaviour and cravings for more APOMINE, even when you don't have "off" symptoms to treat.

Before you use APOMINE Solution for Infusion, your doctor may obtain an ECG (electrocardiogram), do blood tests and ask for a list of all other medicines you take.

The ECG and blood tests will be repeated in the first days of your treatment and at any point if your doctor thinks this is needed. He or she will also ask you about other diseases you may have, in particular, concerning your heart. Some of the questions and investigations may be repeated at each medical visit. If you experience symptoms which may come from the heart, eg. palpitations, fainting, or near-fainting, you should report this to your doctor immediately.

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

Your doctor will discuss the possible risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start using APOMINE Solution for Infusion.

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 APOMINE Solution for Infusion may interfere with each other. These include:

- ondansetron, granisetron or palonosetron, anti-vomiting medicines (antiemetics)
- tetrabenazine, a medicine used to treat movement disorders

- metoclopramide, a medicine used to treat nausea
- medicines used to treat some psychiatric (mental) conditions (eg. phenothiazines, haloperidol, flupenthixol)
- papaverine, a medicine which expands blood vessels
- amphetamines.

These medicines may be affected by APOMINE Solution for Infusion or may affect how well they work. You may need different amounts of your medicine, or you may need to use different medicines.

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

How to use APOMINE Solution for Infusion

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

They may differ from the information contained in this leaflet.

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

Do not use APOMINE Solution for Infusion if the solution has turned green, or if the solution is cloudy or you can see particles in it.

How much is given

Your doctor will decide what dose you will receive. This depends on your initial response to APOMINE Solution for Infusion.

How it is given

You will usually be in hospital when you start using APOMINE Solution for Infusion. It is recommended that you are given anti-nausea tablets (domperidone) for a few days before starting APOMINE® Solution for Infusion and that you stop all your other anti-Parkinsonian medication before you

start using APOMINE® Solution for Infusion. This medicine is given as an infusion under the skin (subcutaneously), usually into your lower abdomen or outer thigh. It is given as a continuous infusion (ie, slow injection via a pump).

There is no need to dilute APOMINE Solution for Infusion prior to use.

APOMINE Solution for Infusion is a pre-diluted solution in a vial, intended for use as a continuous infusion with a suitable pump/syringe driver.

You and/or your carers will be trained by hospital staff to recognise when and how to give the infusions.

It is advisable to change the infusion site every time you insert the needle, to avoid getting lumps under the skin.

This medicine is for individual patient use only.

If you use too much (Overdose)

Immediately notify your doctor or nurse, or if you are not in hospital, telephone the Poisons Information Centre 13 11 26 (Australia) or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have used too much APOMINE Solution for Infusion. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include severe nausea and vomiting, slow or troubled breathing, restlessness, hallucinations or unconsciousness.

While you are using APOMINE Solution for Infusion

Things you must do

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

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

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

It may affect other medicines used during surgery.

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

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

Things you must not do

Do not use APOMINE Solution for Infusion to treat any other complaints unless your doctor tells you to.

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

Things to be careful of

Be careful driving or operating machinery until you know how APOMINE Solution for Infusion affects you.

This medicine may cause drowsiness, dizziness or light-headedness in some people. It could also make you fall asleep without warning. 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 using APOMINE Solution for Infusion.

APOMINE Solution for Infusion helps most people with Parkinson's Disease but 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.

If you are over 65 years of age you may have an increased chance of experiencing side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor, nurse 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:

- nausea or vomiting, particularly when starting this medicine
- lumps under the skin, rashes or ulcers at the site of injection, which are sore, troublesome and may be red and itchy
- drowsiness, yawning or suddenly falling asleep, weight loss
- confusion
- dizziness or light-headedness when standing up, fainting
- headache
- unpleasant metallic taste, sore mouth
- runny nose, watery eyes
- reduced facial hair growth
- spontaneous penile erection
- decreased sex drive
- infertility, or inability to get pregnant
- absent, irregular or infrequent periods
- breast milk leakage in people who are not pregnant
- loss of interest in sex, painful or uncomfortable intercourse, or vaginal dryness

- acne or excess body and facial hair growth
- hot flashes.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

- increased involuntary movements or increased shakiness during 'on' periods
- aggression and agitation
- swelling of your arms and hands, or legs and ankles (peripheral oedema)
- pale or yellow skin, yellow eyes or mouth, dark coloured urine
- fever, weakness, dizziness, confusion, breathlessness, inability to handle physical activity, increased heart rate
- pain in the upper abdomen and bloating, or feeling full in the stomach early after eating, loss of appetite, unexplained weight loss
- bleeding or bruising
- lack of impulse control - an inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which includes an increased need to gamble, compulsive eating, shopping or medication use, or a highly increased sex drive.

The above list includes serious side effects that may require medical attention. Serious side effects are rare or uncommon.

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

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face lips, tongue or other parts of the body
- hallucinations (seeing, hearing or feeling things that are not there)

- severe nausea and vomiting

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

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.

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

After using APOMINE Solution for Infusion

Storage

Store the APOMINE Solution for Infusion below 25°C.

Store in original package to protect it from light and do not refrigerate or put in the freezer.

APOMINE Solution for Infusion is for single use only. The contents should be used within 24 hours of puncturing the vial. Discard any unused solution.

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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

APOMINE Solution for Infusion is supplied as a clear and colourless to slightly yellow solution that comes in a 20 mL glass vial in packs of 5.

Do not use APOMINE Solution for Infusion if it looks cloudy or develops a green colour.

Ingredients

APOMINE Solution for Infusion contains

- apomorphine hydrochloride hemihydrate
- sodium metabisulfite (E223)
- sodium chloride
- hydrochloric acid
- water for injections

APOMINE Solution for Infusion does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Strength

20 mL glass vial containing apomorphine hydrochloride hemihydrate 5 mg/mL

Sponsor

Interpharma Pty Ltd
Suite 103,
39 East Esplanade
Manly NSW 2095, Australia
Ph: 1300 308 213

Glass vials - AUST R 260149

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