

MOVAPO® and MOVAPO® PFS

apomorphine (a-poe-MOR-feen) hydrochloride hemihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MOVAPO and MOVAPO Pre-Filled Syringe (PFS). 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 MOVAPO or MOVAPO PFS 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 with the medicine.

You may need to read it again.

For further information on MOVAPO or MOVAPO PFS please refer to “A guide to the use of apomorphine in the treatment of Parkinson’s Disease for patients and carers” which is available from STADA Pharmaceuticals Australia Pty Ltd.

What MOVAPO and MOVAPO PFS are used for

MOVAPO and MOVAPO PFS contain 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 MOVAPO or MOVAPO PFS

When you must not use it

Do not use MOVAPO Injection or MOVAPO PFS if you have an allergy to:

- any medicine containing apomorphine or sodium metabisulfite
- any of the ingredients listed at the end of this leaflet
- 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.

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

- certain forms of dementia e.g. 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 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 or pharmacist 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 (e.g. sex, shopping or eating)

Before you use MOVAPO PEN, your doctor will obtain an ECG (electrocardiogram) and will ask for a list of all other medicines you take.

This ECG 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, e.g. palpitations, fainting, or near-fainting, you should report this to your doctor immediately. Also, if you experience diarrhoea or start a new medication, this should be reported to your doctor.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor will discuss with you the possible risks and benefits involved.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using MOVAPO or MOVAPO PFS.

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, MOVAPO Injection and MOVAPO PFS may interfere with each other. These include:

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

These medicines may be affected by MOVAPO and MOVAPO PFS, or may affect how well they work. You may need different amounts of

your medicines, or you may need to use different medicines.

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

How to use MOVAPO and MOVAPO PFS

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 MOVAPO or MOVAPO PFS if the solution has turned green or if the solution is cloudy or you can see particles in it.

How much to use

Your doctor will decide what dose you will receive. This depends on your initial response to MOVAPO.

How to use it

You will usually be in hospital when you start using MOVAPO. It is recommended that you are given an anti-nausea drug (domperidone) and that you stop all your other anti-Parkinsonian medication before you start using MOVAPO. This medicine is given as an injection under the skin (subcutaneously), usually into your lower abdomen or outer thigh. It is either injected several times a day or continuously as an infusion (i.e. slow injection via a pump).

MOVAPO PFS is a pre-diluted, pre-filled syringe intended for use as a continuous infusion with a suitable pump/syringe driver. There is no need to dilute MOVAPO PFS prior to use.

When using MOVAPO ampoules to prepare a continuous infusion, it is

recommended that MOVAPO is first diluted with an equal volume of sodium chloride 0.9% (normal saline). When using MOVAPO ampoules for intermittent injections, it is not necessary to dilute the MOVAPO.

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

The medicine is for individual patient use only.

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

If you use too much (overdose)

Immediately notify your doctor or nurse, or if you are not in hospital, telephone the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 POISON or 0800 764 766 in New Zealand) or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have used too much MOVAPO or MOVAPO PFS. 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 MOVAPO and MOVAPO PFS

Things you must do

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

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 you are 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 MOVAPO or MOVAPO PFS 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 MOVAPO or MOVAPO PFS affects you.

This medicine may cause drowsiness, sudden onset of sleepiness, dizziness or light-headedness 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 using MOVAPO or MOVAPO PFS.

MOVAPO and MOVAPO PFS helps most people with Parkinson's disease, 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.

If you are over 65 years of age you may have an increased chance of getting 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 or suddenly falling asleep
- 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
- weight loss
- yawning.

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, agitation
- pale yellow skin, weakness or breathlessness
- bleeding or bruising
- inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may

include:

- decreased or increased sexual arousal
- increased need to gamble
- compulsive eating, shopping or medication use

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
- rash, itching or hives on the skin
- hallucinations (seeing, hearing or feeling things that are not there)

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

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

Other side effects not listed above may 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:

- increase in some white blood cells
- high prolactin level in blood.

After using MOVAPO or MOVAPO PFS

Storage

Storage for MOVAPO:

Keep MOVAPO 2 mL and 5 mL ampoules in a cool dry place where the temperature stays below 25°C.

Storage for the Pre-Filled Syringe:

Keep MOVAPO PFS in a cool dry place where the temperature stays

below 25°C. Keep unused pre-filled syringes in the outer cardboard carton.

Store in original package in order to protect from light and do not put in the freezer.

MOVAP0 and MOVAP0 PFS are for single use only. Once opened, the contents of the ampoule or pre-filled syringe should be used immediately. Discard any unused solution.

Do not store MOVAP0, MOVAP0 PFS 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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

MOVAP0:

MOVAP0 is supplied as a clear, colourless, sterile solution that comes in 2 mL or 5 mL glass ampoules in packs of 5.

MOVAP0 PFS:

MOVAP0 PFS is supplied as a clear, colourless, sterile solution that comes in 10 mL pre-filled glass syringe in packs of 5.

Ingredients

MOVAP0 contains 20 mg of apomorphine hydrochloride hemihydrate in 2 mL or 50 mg apomorphine hydrochloride hemihydrate in 5 mL.

MOVAP0 PFS contains 50 mg apomorphine hydrochloride hemihydrate in 10 mL.

MOVAP0 and MOVAP0 PFS also contain:

- sodium metabisulfite
- water for injection
- may contain hydrochloric acid and MOVAP0 may contain sodium hydroxide to adjust the pH

MOVAP0 and MOVAP0 PFS do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Australia

STADA Pharmaceuticals Australia Pty Ltd,
Suite 2.04,
26 Rodborough Road,
Frenchs Forest NSW 2086,
Australia

New Zealand

CARSL Consulting,
Clinical and Regulatory Services,
24 Side Road, Parkhill Farm, RD10,
Hastings
PO Box 766 Hastings
New Zealand

MOVAP0® is a registered trademark of Britannia Pharmaceuticals Limited.

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Australian Register Numbers

MOVAP0 ampoules:

20 mg/2 mL AUST R 142086

50 mg/5 mL AUST R 142093

MOVAP0 PFS pre-filled syringe:

50 mg/10 mL AUST R 129948