

MOVAPO[®] and MOVAPO[®] PFS

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 MOVAPO or MOVAPO PFS?

MOVAPO or MOVAPO PFS contains the active ingredient apomorphine hydrochloride hemihydrate. MOVAPO and MOVAPO PFS are used in the treatment of Parkinson's disease to reduce the number and severity of bouts of freezing and stiffness (or "off" periods).

For more information, see Section [1. Why am I using MOVAPO or MOVAPO PFS?](#) in the full CMI.

2. What should I know before I use MOVAPO or MOVAPO PFS?

Do not use if you have ever had an allergic reaction to apomorphine hydrochloride hemihydrate, sodium metabisulfite or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use MOVAPO or MOVAPO PFS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MOVAPO or MOVAPO PFS 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 do I use MOVAPO or MOVAPO PFS?

- Your doctor will tell you how much to use.
- MOVAPO and MOVAPO PFS are designed for injection under the skin (subcutaneous).
- You will be trained to recognise when and how to inject. Follow the instructions given by your doctor or pharmacist.

More instructions can be found in Section [4. How do I use MOVAPO and MOVAPO PFS?](#) in the full CMI.

5. What should I know while using MOVAPO or MOVAPO PFS?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using MOVAPO or MOVAPO PFS.• If you become pregnant while you are using this medicine, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• 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.• Do not stop MOVAPO or MOVAPO PFS abruptly or change the dose, without speaking to your doctor to discuss a taper treatment plan.
Driving or using machines	<ul style="list-style-type: none">• MOVAPO or MOVAPO PFS 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.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C. Store in the medicine in its original carton to protect from light. Do not freeze.• Once opened, the solution should be used immediately. Discard any unused solution.

For more information, see Section [5. What should I know while using MOVAPO or MOVAPO PFS?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some side effects can be serious and you need to know what symptoms to look out for. MOVAPO and MOVAPO PFS can cause allergic reactions which may be very serious. If you develop symptoms of allergic reaction, you may need urgent medical attention or hospitalisation.

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.

MOVAPO[®] and MOVAPO[®] PFS

Active ingredient(s): *apomorphine (a-poe-MOR-feen) hydrochloride hemihydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MOVAPO and MOVAPO Pre-Filled Syringe (PFS).

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 MOVAPO and MOVAPO PFS.

Where to find information in this leaflet:

- [1. Why am I using MOVAPO or MOVAPO PFS?](#)
- [2. What should I know before I use MOVAPO or MOVAPO PFS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use MOVAPO or MOVAPO PFS?](#)
- [5. What should I know while using MOVAPO or MOVAPO PFS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using MOVAPO or MOVAPO PFS?

MOVAPO and MOVAPO PFS contains the active ingredient **apomorphine hydrochloride hemihydrate**. Apomorphine 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.

2. What should I know before I use MOVAPO or MOVAPO PFS?

Warnings

Do not use MOVAPO 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 symptoms of 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.

Do not use MOVAPO or MOVAPO PFS 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 use MOVAPO or MOVAPO PFS if:

- the packaging is torn or shows signs of tampering
- the expiry date printed on the pack has passed
- the solution has turned green or if the solution is cloudy or you can see particles in it.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes
- you have or have had any of the following medical conditions:
 - a history of 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 or MOVAPO PFS, your doctor will obtain an ECG (electrocardiogram) and will ask for a list of all 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. Your doctor will also ask you about other diseases you have, in particular concerning your heart. Some 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 too.

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

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Children and adolescents

MOVAPO and MOVAPO PFS should not be used in children and adolescents under the age of 18 years.

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 MOVAPO or MOVAPO PFS and affect how it works.

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
- ondansetron, a medicine used to treat nausea and vomiting. This may result in a severe drop in blood pressure or loss of consciousness.

MOVAPO and MOVAPO PFS may affect these medicines and how well they work. You may need different amounts of your medicines, or 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 MOVAPO or MOVAPO PFS.

4. How do I use MOVAPO and MOVAPO PFS?

How much to use

- Your doctor will tell you what dose to use. This depends on your initial response to MOVAPO or MOVAPO PFS.
- Follow the instructions provided and use MOVAPO or MOVAPO PFS until your doctor tells you to stop.

When to use MOVAPO or MOVAPO PFS

- You and/or your carer will be trained by hospital staff to recognise when to use MOVAPO or MOVAPO PFS.

How to use MOVAPO or MOVAPO PFS

You will usually be in hospital when you start using this medicine. It is recommended you are given an anti-nausea drug (domperidone) for a few days, and that you will

temporarily stop all other anti-Parkinsonian medication so that the correct dose of MOVAPO or MOVAPO PFS can be determined.

- MOVAPO and MOVAPO PFS is to be given as an injection under the skin (subcutaneously), usually in your lower abdomen or outer thigh. MOVAPO is either injected several times a day (intermittent injection) or continuously as an infusion (i.e. slow injection via a pump). MOVAPO PFS is injected continuously as an infusion.
- You and/or your carer will be trained by hospital staff on how to give the injections. **If you do not understand the instructions, ask your doctor, nurse or pharmacist to help.**
- It is advisable to change the site of injection every time you insert the needle to avoid getting lumps under the skin.
- When using MOVAPO ampoules for 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, there is no need to dilute prior to use.
- When using MOVAPO PFS for continuous infusion, there is no need to dilute prior to use.
- This medicine is for individual patient use only.

If you use too much MOVAPO or MOVAPO PFS

If you think that you have used too much MOVAPO or MOVAPO PFS, you may need urgent medical attention. Symptoms of overdose may include severe nausea and vomiting, slow or troubled breathing, restlessness, hallucinations or unconsciousness.

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.

5. What should I know while using MOVAPO or MOVAPO PFS?

Things you should do

- If you plan to have surgery, tell the surgeon or anaesthetist you are taking this medicine. It may affect any medicines used during surgery.
- Keep all your doctor's appointments so that your progress can be checked.

Call your doctor straight away if you:

- are about to start on any new medication
- become pregnant
- have any symptoms which may come from your heart, e.g. palpitations, fainting, or near-fainting
- experience diarrhoea

Remind any doctor, dentist or pharmacist you visit that you are using MOVAPO or MOVAPO PFS.

Things you should 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.
- Do not stop MOVAPO or MOVAPO PFS abruptly or change the dose, without speaking to your doctor to discuss a taper treatment plan.
- It is important not to suddenly stop taking your MOVAPO or MOVAPO PFS, unless advised to do so by your doctor. If you stop taking it suddenly, your condition may worsen, or you may have unwanted side effects. The dose will normally be reduced gradually over several days.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MOVAPO or MOVAPO PFS affects you.

MOVAPO or MOVAPO PFS 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.

Looking after your medicine

Store MOVAPO and MOVAPO PFS below 25°C.

- Do not freeze.
- Keep in the original carton to protect from light.

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

Store it in a cool dry place 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.

Keep it where young children cannot reach it.

When to discard your medicine

This medicine is for single use only. Once opened, the contents of the ampoule or pre-filled syringe should be used immediately. Discard any unused solution.

Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date.

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.

Less serious side effects

Less serious side effects	What to do
<p>Gut related:</p> <ul style="list-style-type: none"> • Nausea or vomiting particularly when starting this medicine <p>Skin and Hair related:</p> <ul style="list-style-type: none"> • Lumps under the skin, rashes or ulcers at the site of injection which are sore, troublesome and may be red and itchy • Reduced facial hair <p>Nervous system related:</p> <ul style="list-style-type: none"> • Drowsiness or suddenly falling asleep • Confusion • Dizziness or light-headedness when standing up, fainting • Headache <p>Eyes, nose and mouth related:</p> <ul style="list-style-type: none"> • Unpleasant metallic taste, sore mouth • Runny nose • Watery eyes <p>Other:</p> <ul style="list-style-type: none"> • Weight loss • Spontaneous penile erection • Yawning 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Nervous system or behaviour related:</p> <ul style="list-style-type: none"> • Increased involuntary movements or increased shakiness during “on” periods • Aggression, agitation • Inability to resist impulse, drive or temptation to perform an action that could be harmful to you or others, which may include: <ul style="list-style-type: none"> - decreased or increased sexual arousal - increased need to gamble - compulsive eating, shopping or medication use <p>Blood related:</p> <ul style="list-style-type: none"> • Reduction in blood platelets which can lead to bleeding or bruising • Reduction in red blood cells which can lead to pale yellow skin, weakness or breathlessness 	<p>Call your doctor straight away if you notice any of these serious side effects.</p>

Very serious side effects

Serious side effects	What to do
<p>Allergy related:</p> <ul style="list-style-type: none">• Shortness of breath• Wheezing or difficulty breathing• Swelling of the face, lips, tongue or other parts of the body• Rash, itching or hives of the skin <p>Nervous system or behaviour related:</p> <ul style="list-style-type: none">• Hallucinations (seeing, hearing or feeling things that are not there)• High fever, muscle cramps or stiffness, dizziness, severe headache, fast heartbeat, confusion, agitation, hallucinations, or if you are sweating a lot (symptoms relating to neuroleptic malignant syndrome)	<p>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.</p>

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 MOVAPO and MOVAPO PFS contains

Active ingredient (main ingredient)	Apomorphine hydrochloride hemihydrate
Other ingredients (inactive ingredients)	Sodium metabisulfite Water for injections Hydrochloric acid Sodium hydroxide (MOVAPO only)
Potential allergens	Sodium metabisulfite

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

What MOVAPO and MOVAPO PFS look like

MOVAPO 50 mg/5 mL is a clear, colourless, sterile solution, supplied in a box of 5 ampoules (AUST R 142093).

MOVAPO PFS 50 mg/10 mL is a clear, colourless, sterile solution, is supplied in a box of 5 pre-filled syringes (AUST R 129948).

Who distributes MOVAPO and MOVAPO PFS

In Australia:

STADA Pharmaceuticals Australia Pty Ltd
Suite 2.04, 26 Rodborough Road
Frenchs Forest NSW 2086
Australia
www.stada.com.au

In New Zealand:

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

MOVAPO® is a registered trademark of Britannia Pharmaceuticals Limited.

This leaflet was prepared in January 2024.