

MOVAPO[®] PEN

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 PEN?

MOVAPO PEN contains the active ingredient apomorphine hydrochloride hemihydrate. MOVAPO PEN is 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 PEN?](#) in the full CMI.

2. What should I know before I use MOVAPO PEN?

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 PEN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MOVAPO PEN 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 PEN?

- Your doctor will tell you how much to use.
- MOVAPO PEN 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 PEN?](#) in the full CMI.

5. What should I know while using MOVAPO PEN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using MOVAPO PEN.• 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 PEN 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 PEN 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 PEN 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.• Store at the same conditions after opening and between withdrawals.• Discard after 48 hours of first use.

For more information, see Section [5. What should I know while using MOVAPO PEN?](#) 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 PEN 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[®] PEN

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

Consumer Medicine Information (CMI)

This leaflet provides important information about using MOVAPO PEN.

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 PEN.

Where to find information in this leaflet:

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

1. Why am I using MOVAPO PEN?

MOVAPO PEN 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 PEN?

Warnings

Do not use MOVAPO PEN 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 PEN 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 PEN 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 PEN, 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 PEN 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 PEN 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 PEN 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 PEN.

4. How do I use MOVAPO PEN?

How much to use

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

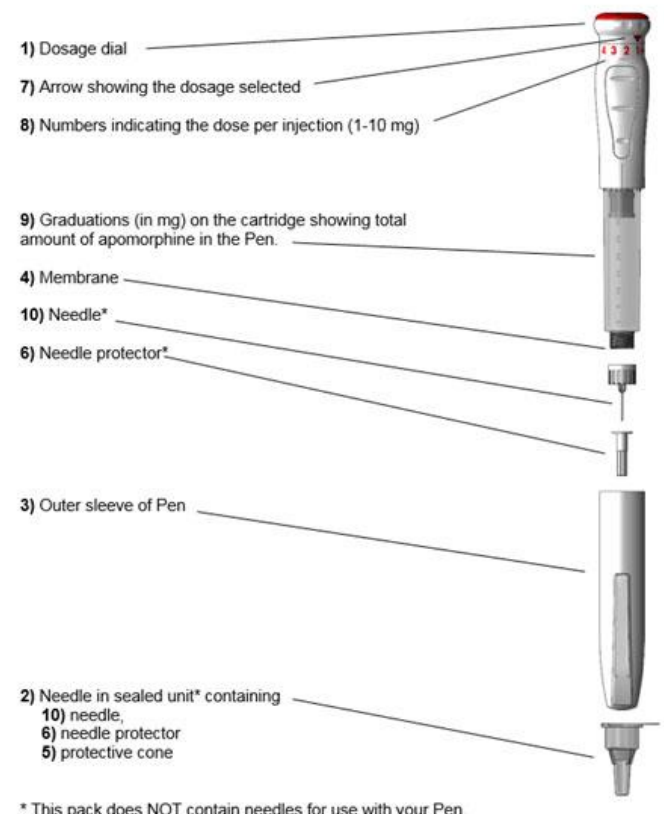
When to use MOVAPO PEN

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

How to use MOVAPO PEN

- 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 can be determined.
- You and/or your carer will be trained by hospital staff on how to give the injections. Instructions are also included in this CMI. **If you do not understand the instructions, ask your doctor, nurse or pharmacist to help.**

- MOVAPO PEN is to be given as an injection under the skin (subcutaneously), usually in your lower abdomen or outer thigh. It is injected several times a day.
- It is advisable to change the site of injection every time you insert the needle to avoid getting lumps under the skin.
- MOVAPO PEN is a cartridge contained in a Pen injector. The product is for individual patient use only.
- Before using MOVAPO PEN, study the diagram below to familiarise yourself with the medicine.
- **IMPORTANT: Do not pull the red capped dosage dial (see 1) before you have set the dosage (see "Selecting the correct dosage").**



* This pack does NOT contain needles for use with your Pen.

Attaching the needle

- Before using MOVAPO PEN you will need some surgical wipes and one needle in its protective cone (see 2).
- Take the pen out of its box and remove the outer sleeve (see 3).



- Wipe the membrane of the Pen (see 4) with a surgical wipe.



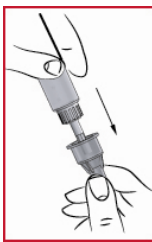
- Peel off the paper from the needle cone (see 2).



- It is important to bring the needle to the Pen in a straight line, as shown below. If the needle is presented at an angle, it may cause the Pen to leak.



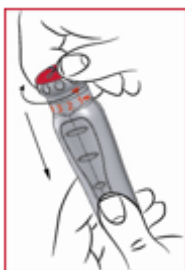
- Screw the cone (see 2) clockwise onto the membrane until it is tight. This securely attaches the needle.
- Remove the protective cone (see 5), but do not throw it away. Do not remove the needle protector (see 6) at this stage.



- Replace the Pen's outer sleeve (see 3).

Selecting the correct dose

- Press the red capped dosage dial (see 1) and whilst holding it down, turn the dial clockwise until the arrow points to the dose your doctor chose for you



(see 7 & 8). Release the downward pressure on the red capped dial. The dose is now set and you do not need to redial for subsequent injections.

- IMPORTANT: If you pass your prescribed dose while turning the dial, just continue pressing and turning in the same direction until the arrow points to the dose your doctor chose for you.**
- Never pull and turn the red capped dosage dial at the same time.**
- If your dose is 1 mg, start by emptying a 1 mg dose onto a paper tissue and discarding it. This is called 'priming' and is important because it ensures you get the full dose the first time you use your Pen. Then, set the dose you require for injection and inject it the usual way (see "Injecting").
- If the first dose required is more than 1 mg, you do not need to prime the Pen.

Injecting

- Once you have set the dose, gently pull out the red capped dosage dial as far as it will go. Check the red scale on the plunger (see 9) and inject only if the line that is just visible matches the intended dose.



- Using a surgical wipe, clean the area of skin where you plan to inject the medicine and around it.
- Remove the Pen's outer sleeve (see 3).
- Remove the needle protector (see 6).
- Inset the needle (see 10) into the skin as shown by your doctor.
- To inject, press the red capped dosage dial (see 1) down as far as it will go, using your thumb if possible. Once the red capped dosage dial is fully depressed, count to three before withdrawing the needle.



- Replace the protective cone (see 5) and push gently into place. Once secure, turn the needle anticlockwise



to unscrew it. Keep the needle in its protective cone and discard it in a “Sharps” container.

Preparing for the next injection

- Remove the outer sleeve of the Pen and check there is enough apomorphine left in the cartridge for your next injection. If there is, put a new needle in place in the same way as before.
- If there is not enough apomorphine left for another injection, prepare another Pen.
- Finally, replace the outer sleeve of your Pen.



If you use too much MOVAPO PEN

If you think that you have used too much MOVAPO PEN, 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 PEN?

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 PEN.

Things you should not do

- Do not use MOVAPO PEN 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 PEN 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 PEN, 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 PEN affects you.

MOVAPO PEN 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 PEN below 25°C.

- Do not freeze.
- Keep in the original carton to protect from light.
- Store at the same conditions after opening and between withdrawals.

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

When you start using a new MOVAPO PEN, it can be used for up to 48 hours. Do not re-use MOVAPO PEN after this time. Use a new Pen.

Getting rid of any unwanted medicine

To dispose of your pens safely, always remove the needle from the pen before discarding it in a “Sharps” container.

Ask your doctor, nurse or pharmacist where you can dispose of the container when it is full.

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal. If the pen is completely empty, you may dispose of it in your household waste.

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 PEN contains

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

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

What MOVAP0 PEN look like

MOVAP0 PEN is supplied as a disposable multiple dose pen injector system incorporating a clear glass cartridge. Each glass cartridge contains 3 mL of a sterile, clear, colourless solution (10 mg/mL), practically free from visible particles.

MOVAP0 PEN 30 mg/3 mL is supplied in a box of 5 disposable pens (AUST R 275694).

Who distributes MOVAP0 PEN

In Australia:

STADA Pharmaceuticals Australia Pty Ltd

Suite 2.04, 26 Rodborough Road

Frenchs Forest NSW 2086

Australia

www.stada.com.au

MOVAP0® is a registered trademark of Britannia Pharmaceuticals Limited.

This leaflet was prepared in January 2024.