

Pr **MOVAPO**[®]

Apomorphine Hydrochloride Injection

Supplied as pre-filled pen

Pr **MOVAPO**[®]

Chlorhydrate d'apomorphine injection

Fourni en stylo pré-rempli



**READ THIS FOR SAFE AND
EFFECTIVE USE OF YOUR MEDICINE**

PATIENT MEDICATION INFORMATION

**LISEZ CE DOCUMENT POUR ASSURER UNE
UTILISATION SÉCURITAIRE ET EFFICACE DE
VOTRE MÉDICAMENT.**

**RENSEIGNEMENTS POUR LES PATIENTS
SUR LES MÉDICAMENTS**

Read this carefully before you start taking MOVAPO and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about MOVAPO.

Serious Warnings and Precautions

You can suddenly fall asleep without any warning while taking MOVAPO. You should not:

- drive
- use machines or
- take part in activities that require you to be alert

You may put yourself and others at risk for serious injury or death.

If this happens to you, contact your doctor right away.

Falling asleep suddenly without warning has also been reported in patients taking other similar drugs to treat Parkinson's disease.

What is MOVAPO used for?

MOVAPO is used, as needed, to treat the sudden loss of control of body movements in people with advanced Parkinson's disease. This condition is called hypomobility or an 'off episode'.

It is an injection that is taken along with other oral drugs used for the treatment of Parkinson's disease.

How does MOVAPO work?

MOVAPO belongs to a group of drugs called dopamine agonists. It is not known exactly how it works. It seems to improve some of the chemical imbalance in the part of the brain affected by Parkinson's disease.

What are the ingredients in MOVAPO?

Medicinal ingredient: Apomorphine hydrochloride.

Non-medicinal ingredients: Sodium bisulfite and water for injection. It also contains hydrochloric

acid for pH adjustment.

MOVAPO comes in the following dosage forms:

Injection (supplied as pre-filled pen): 10 mg/mL

Do not use MOVAPO if you:

- are allergic to any of the ingredients in MOVAPO
 - the solution in the pre-filled pen contains a sulfite called sodium bisulfite. This can cause severe, life-threatening allergic reactions and asthma attacks in some people. If you have an allergic reaction to MOVAPO you should not take it again.
- are allergic to the components of the container
- are taking certain drugs used to treat nausea or vomiting called 5HT₃ antagonists such as:
 - ondansetron
 - granisetron
 - palonosetron

People taking these drugs with MOVAPO may experience very low blood pressure and loss of consciousness.

- are taking certain medicines to lower your blood pressure such as:
 - antihypertensive drugs or
 - vasodilators
- have severe liver disease
- have severe kidney disease

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MOVAPO. Talk about any health conditions or problems you may have, including if you:

- drive or do unsafe activities as part of your daily work
- have asthma
- have a condition in which your blood pressure falls drastically when you stand up quickly
- have ever become unconscious due to a fall in your blood pressure
- have a history of heart problems such as:

- your heart does not get as much blood as it needs because of a blockage in one or more of your arteries
- heart attack
- irregular heart rhythm
- have a history of fibrosis
- if you have allergies to sulfites
- have severe sudden uncontrolled jerky movements called dyskinesia
- have neuroleptic malignant syndrome. A disorder that causes you to have high fever and stiffness in your muscles
- if you have a history of feeling sleepy or drowsy
- have a condition where you do not have the usual amount of pigment (melanin) in your body. This is known as albinism
- have any unusual conditions related to your eyes or eyesight
- suffer from any mental disorders or have seen or heard things that are not there (hallucinations)
- have experienced any unusual urges and/or behaviours such as excessive:
 - gambling
 - sexual behaviour
 - eating
 - spending

There have been reports of people becoming addicted to dopamine replacement therapy. This can occur in some people taking dopamine drugs for a long time. This happens very rarely and it may be difficult for you to recognize. You or your caregiver should tell the doctor if either of you notice that you have new behaviour or changes to your behaviour.

- have suspicious, undiagnosed cuts in your skin or a history of skin cancer called melanoma
- are pregnant or planning on becoming pregnant. You should not take MOVAPO if you are pregnant
- are breastfeeding. You should not take MOVAPO if you are breastfeeding

- have severe liver problems
- have severe kidney problems

Other warnings you should know about:

- **MOVAPO taken with L-dopa (also called levodopa):** MOVAPO may increase the side effects of L-dopa. This may cause or worsen pre-existing uncontrolled jerky movements (dyskinesia). Tell your doctor if this happens. Your doctor may need to change the dose of the medicines you are taking.
- **Injection site reactions:** Bruising, swelling, and itchiness can happen at the site where you inject MOVAPO. Changing the place where you inject MOVAPO every time you take a dose and putting some ice on the injection site before and after injections may help.
- **Prolonged painful erections (priapism):** MOVAPO may cause prolonged, painful erections in some men. If you have an erection that lasts more than 4 hours you should call your doctor or go to the nearest hospital emergency room right away.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with MOVAPO

- Other medicines used to treat Parkinson's disease, including levodopa
- Drugs used to treat nausea or vomiting called 5HT₃ antagonists such as:
 - ondansetron
 - granisetron
 - palonosetron
- Drugs to lower your blood pressure such as:
 - antihypertensive drugs or
 - vasodilators
- Anti-psychotic drugs (such as chlorpromazine and haloperidol)
- Alcohol. You should avoid alcohol when using MOVAPO. It can worsen your side effects.

- Drugs that have sedative effects (such as benzodiazepines and antidepressants)
- Certain drugs that have an effect on your heart rate. These include:
 - antiarrhythmics (such as flecainide and propafenone)
 - antipsychotics
 - antidepressants (such as fluoxetine and amitriptyline)
 - opioids (such as methadone)
 - some antibiotics (such as erythromycin, clarithromycin and ciprofloxacin)
 - antimalarials (such as quinone and chloroquine)
 - antifungals (such as ketoconazole)
 - tyrosine kinase inhibitors (such as sunitinib)
 - histone deacetylase inhibitors (such as vorinostat)
 - beta-2 adrenoceptor agonists (such as salmeterol)

How to take MOVAPO:

MOVAPO may affect your ability to remain alert while doing normal everyday activities. You should avoid doing activities such as driving a car, doing physical tasks or using hazardous machinery until you know how it affects you.

Before you use MOVAPO, make sure your healthcare professional goes through the important information with you and your caregiver and shows you how to use it properly.

You or your caregiver should keep a record after each injection of how much MOVAPO you have taken or been given.

Your doctor will usually prescribe another medicine called an “antiemetic”, to take at least 2 days before you start taking MOVAPO and while you are taking MOVAPO. This will help lessen the symptoms of nausea and vomiting which can happen with MOVAPO.

MOVAPO is to be injected under the skin (subcutaneous) only. Do not inject MOVAPO into a vein.

Usual Adult Dose:

Your doctor will determine the right dose for you and how often you need to take it. Take it exactly as your doctor has told you to.

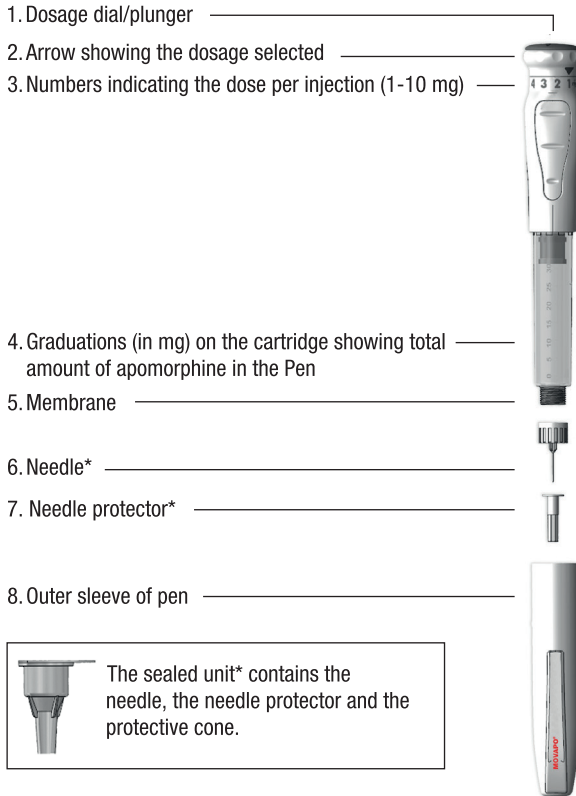
Your doctor or another healthcare professional will give you the first dose.

Do not change your dose of MOVAPO or stop taking it unless your doctor has told you to.

Instruction for Use:

Figure 1 shows the different parts of the pen. You should familiarise yourself with its parts.

Figure 1:



What you need:

- 1 pre-filled pen
- 1 Pen needle. [Note: the pack does not contain needles. You can use the same needles that are used for insulin pens to use with your MOVAPEN Pen].
- 2 alcohol swabs
- 1 hard-walled plastic container such as a “Sharps” bin to throw away used needles. This is available from your pharmacy. Alternatively, you can use any other suitable container.

The disposable pen needles should be used **only once** and then properly thrown away. **DO NOT SHARE YOUR NEEDLES.**

Read these instructions carefully.

Important: Do not pull the dosage dial/plunger (see **1** in **Figure 1**) before you have set the dose you need.

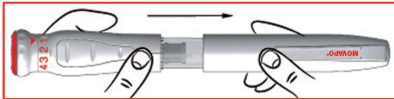
Step 1: Attach the pen needle

Do not use the pen if the solution in the cartridge is cloudy, green or contains particles.

Do not use after the expiry date on the label.

- Before you attach the pen needle to the Pen you will need an alcohol swab and one pen needle. Do not remove the needle from its protective cone (see **Figure 1**). Take the Pen out of its box and remove the outer sleeve (see **Figure 2**).

Figure 2:



- Wipe the membrane (see **Figure 3**) with an alcohol swab.

Figure 3:



- Peel off the paper from the protective cone (see **Figure 4**). Screw the cone onto the membrane by turning it to the right (clockwise). This will attach the needle securely to the Pen (see **Figure 5**).

Figure 4:



Figure 5:



PLEASE NOTE

It is important to bring the needle protective

cone to the Pen in a straight line, as shown in **Figure 5**. This will attach the needle securely. If the protective cone is brought in and attached at an angle it may cause the Pen to leak.

- Remove the protective cone (see **Figure 6**). Do not throw it away. Do not remove the needle protector at this stage (see **7** in **Figure 1**).

Figure 6:



- Put back the Pen's outer sleeve.

Step 2: Select your dose

- Press the dosage dial and turn it to the right (clockwise) until the arrow points to the dose your doctor told you to take (see **Figure 7**).
- Let go of the dial. The dose is now set. You do not have to set the dial again for subsequent doses.
- Never pull and turn the dial at the same time.

Important: If you pass the dose you need while turning the dial, just continue pressing and turning the dial to the right until you arrive at it again.

Figure 7:



If your dose is 1 mg: it is necessary to “prime” the Pen before injecting the first dose. First load the dose (see **Step 3**). Then remove the needle protector from the needle (see **Figure 10**). Finally, press the dosage dial down as far as it will go and empty the first 1 mg dose onto a paper tissue.

If your first dose is more than 1 mg: you do not need to “prime” the pen.

Step 3: Load your dose

- Load your dose by pulling the dosage dial out (see **Figure 8**) as far as it will go.
- When the dosage dial is pulled as far as it will go, you should see a number scale on the plunger. The highest number that you see on the plunger must match the dose you have set on the dosage dial. This ensures that the correct dose has been loaded. **Only inject your dose if the number on the plunger scale is the same as the number on the dosage dial.**
- Never try to change the dose when the Pen is in the “loaded” position. If the wrong dose has been selected, you will have to discard the incorrect dose into a paper towel and reset the dosage dial to the correct dose. Follow the instructions under “**Step 2: How to select your dose**” again.

Figure 8:

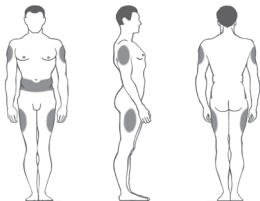


Step 4: Inject your dose

Remember:

- Your doctor will show you or your caregiver how to inject your dose properly
- You will have to change the place where you inject MOVAPRO **every time** you take a dose to help avoid injection site reactions
- Choose a place on your: (see **Figure 9**)
 - stomach
 - upper arm (right or left side)
 - upper thigh (right or left side)

Figure 9:



Hard to inject areas: There may be some areas on your body that may be hard for you to inject the drug yourself. You should ask your doctor for instructions on how to inject MOVAPRO into these areas.

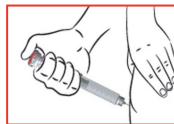
- Using an alcohol swab, clean the area of skin where you will be injecting the dose.
- Remove the Pen’s outer sleeve.
- Remove the needle protector (see **Figure 10**).

Figure 10:



- Insert the needle into the skin as your doctor has shown you or your caregiver to do. (see **Figure 11**).

Figure 11:



- Press the dosage dial down as far as it will go, using your thumb. Once the dosage dial is fully pressed, count to 3 before taking the needle out.
- Remove and throw away the needle:
 - attach the protective cone back onto the used needle, and push it gently into place
 - once it is secure, you can unscrew the needle by turning it to the **left** (counter clockwise) (see **Figure 12 and 13**)
 - throw away the needle in the hard walled plastic container.

Figure 12:

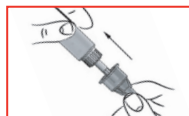


Figure 13:

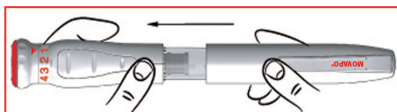


Step 5: Preparing the Pen for the next injection

Check that there is enough apomorphine left in the cartridge for the next injection (see 4 in **Figure 1**).

- If there is, follow **Step 1** and attach a new needle. Put back the outer sleeve of the Pen (see **Figure 14**). Remember do not throw away the protective cone.
- If there is not enough apomorphine left for another injection, prepare another Pen (follow **Step 1 and Step 2**).

Figure 14:



Overdose:

If you think you have taken too much MOVAPO, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you take too much MOVAPO, you may experience more side effects than usual and they may be stronger than usual. You may experience:

- a low heart rate
- excessive sickness
- excessive sleepiness
- difficulty breathing
- You may also feel faint or dizzy particularly when you stand up, due to low blood pressure.

Missed dose:

If you miss your dose, take the next one when you next require it. Do not take another dose of MOVAPO **sooner than 2 hours** after the last dose. Do not take a double dose to make up for the one you missed.

What are the possible side effects from using MOVAPO?

These are not all the possible side effects you may feel when taking MOVAPO. If you experience any side effects not listed here, contact your healthcare professional.

Side effects include:

- drowsiness or sleepiness
- sudden uncontrolled movements (dyskinesia)
- dizziness
- fainting
- nausea
- vomiting
- yawning
- confusion
- runny nose
- joint pain
- headache
- trouble sleeping
- swelling of your hands, arms, legs and feet
- bruising, swelling or itchy at the injection site
- prolonged and painful erection

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Dyskinesia: sudden uncontrolled movements		✓	
COMMON			
Syncope: fainting when standing up		✓	
Hallucinations: seeing or hearing things that are not there		✓	
Compulsive behavior: inability to resist the impulse to perform an action that could be harmful such as gambling too much, increased sexual urges, uncontrollable urge to eat or spend money, or repeating meaningless actions		✓	
UNCOMMON			
Excessive sleepiness or falling asleep while doing normal activities		✓	
Uneven (irregular) heart beat or palpitation		✓	
Changed patches of pigmented skin, including irritated or irregular moles, or moles in which you have noticed changes, skin cancer (melanoma)		✓	
RARE			
Allergic reactions: red, itchy swellings on the skin, swelling of the face, lips, mouth, tongue or throat, difficulty swallowing or breathing, rash or intense itching			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>)
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store:

- at 25°C (storage between 15°C to 30°C is acceptable)
 - store in the original box to protect from light
- When you start using a new MOVAP0 Pen, it can be used for up to 48 hours if kept at room temperature. Throw away the pen 48 hours after opening.

Do not use the solution if it is green, cloudy or if you see particles.

Do not use the pre-filled pen after the expiry date printed on the label. The expiry date refers to the last day of that month.

Keep out of reach and sight of children.

If you want more information about MOVAP0:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website www.paladinlabs.com, or by calling 1-888-867-7426.

This leaflet was prepared by Paladin Labs Inc.

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