

## MOVAPO® PEN

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

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about MOVAPO PEN. 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 PEN 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 PEN 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 PEN is used for

MOVAPO PEN 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 MOVAPO PEN

##### *When you must not use it*

**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 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 PEN.**

##### *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 MOVAPO PEN may interfere with each other. These include:

- tetraabenazine, 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 PEN, 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 PEN

**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.**

**Your doctor, nurse or pharmacist can provide further instructions on how to use MOVAPO PEN. The full instructions for using MOVAPO PEN are also provided in the leaflet in the pack.**

**Do not use MOVAPO PEN if the solution has turned green or if the solution is cloudy or you can see particles in it.**

##### *How much to use*

You will usually be in hospital when you start using MOVAPO PEN. 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 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.

**Instructions for how to use the MOVAPO PEN are provided at the end of this leaflet.**

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) or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have used too much MOVAPO PEN. 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 PEN

##### *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 PEN.**

**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 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 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.**

### Things to be careful of

**Be careful driving or operating machinery until you know how MOVAPO PEN 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 PEN.**

MOVAPO PEN 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 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 MOVAPO PEN
- 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 side effects which 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 PEN

#### Storage

**Keep your pens in a cool dry place where the temperature stays below 25°C. Do not freeze. Keep the container in the outer carton to protect from light. Store at the same conditions after opening and between withdrawals.**

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

**Do not store MOVAPO PEN 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

**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 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.**

If the pen is completely empty you may dispose of it in your household waste.

### Product description

#### What it looks like

MOVAPO PEN is supplied as a disposable multiple dose pen injector system incorporating a clear glass cartridge containing a clear solution for injection. Each glass cartridge contains 3 mL of solution for injection. Each MOVAPO PEN pack contains 5 disposable pens.

#### Ingredients

MOVAPO PEN contains 30 mg of apomorphine hydrochloride hemihydrate in 3 mL (10 mg/mL).

MOVAPO PEN also contains:

- sodium metabisulfite
- water for injections
- may contain hydrochloric acid for pH adjustment

MOVAPO PEN does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

#### Supplier

STADA Pharmaceuticals Australia Pty Ltd,  
Suite 2.04, 26 Rodborough Road,

Frenchs Forest NSW 2086  
Australia

MOVAPO® is a registered trademark of  
Britannia Pharmaceuticals Limited.

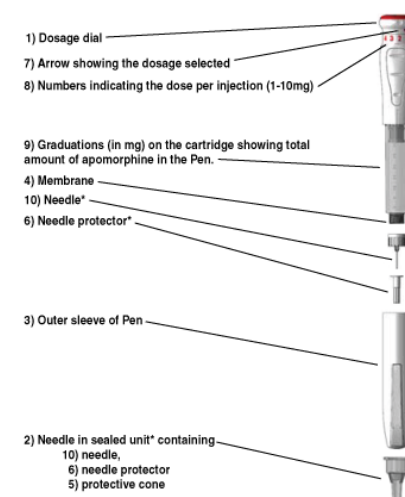
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### Instructions for using MOVAPO PEN

Before using MOVAPO PEN, study the diagram below and your pen to familiarise yourself with your medicine:



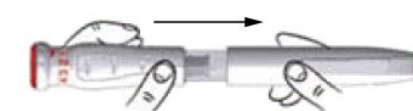
\*This pack does NOT contain needles for use with your Pen.

**IMPORTANT: Do not pull the red capped dosage dial (see 1) before you have set the dosage (see 'Selecting the correct dosage').**

#### Attaching the needle

(a) Before using MOVAPO PEN you will need some surgical wipes and one needle in its protective cone (see 2).

(b) Take the Pen out of its box and remove the outer sleeve (see 3).



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



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



(e) 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.



(f) Screw the cone (see 2) clockwise onto the membrane until it is tight. This securely attaches the needle.

(g) Remove the protective cone (see 5), but do not throw it away. Do not remove the needle protector (see 6) at this stage.



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

#### **Selecting the correct dose**

i) 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 a full dose the first time you use your Pen. Then, set the dose you require for injection and inject it in the usual way (see "Injecting"). If the first dose required is more than 1 mg, you do not need to prime the Pen.

#### **Injecting**

(j) 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.



(k) Using a surgical wipe, clean the area of skin where you plan to inject the medicine and around it.

(l) Remove the Pen's outer sleeve (see 3).

(m) Remove the needle protector (see 6).



(n) Insert the needle (see 10) into the skin as shown by your doctor.

(o) 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.



(p) Replace the protective cone (see 5) onto the used needle and push gently into place. Once secure, turn the needle anti-clockwise to unscrew it. Keep the needle in its protective cone and discard it in a "Sharps" container.



#### **Preparing for the next injection**

(q) 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.

(r) If there is not enough apomorphine left for another injection, prepare another pen.

(s) Finally, replace the outer sleeve of your Pen.

