Package leaflet: Information for the user

[Nationally approved name] 10 mg/ml solution for injection in cartridge

Apomorphine hydrochloride hemihydrate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor<, nurse> or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor<, nurse> or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is [Nationally approved name] 10 mg/ml solution for injection in cartridge, which will be referred to as [Nationally approved name] throughout this leaflet.

What is in this leaflet

1. What [Nationally approved name] is and what it is used for

[Nationally approved name] contains apomorphine solution for injection. It is injected into the area under the skin (subcutaneously) by using only the dedicated D-mine-Pen. The active ingredient in [Nationally approved name] is apomorphine hydrochloride hemihydrate. There is 10 mg of apomorphine hydrochloride hemihydrate in each millilitre of solution.

Apomorphine hydrochloride hemihydrate belongs to a group of medicines known as dopamine agonists. [Nationally approved name] is used to treat Parkinson's disease. Apomorphine helps to reduce the amount of time spent in an 'off' or immobile state in people who have previously been treated for Parkinson's disease with levodopa (another treatment for Parkinson's disease) and/or other dopamine agonists.
Your doctor <or nurse> will help you to recognise the signs of when to use your medicine.

Despite the name, apomorphine does not contain morphine.

2. What you need to know before you use [Nationally approved name]

Do NOT use [Nationally approved name]
- if you are allergic to apomorphine or any of the other ingredients of this medicine (listed in section 6).
- if you are under 18 years of age
- if you have breathing difficulties
- if you have dementia or Alzheimer's disease
- if you suffer from a mental illness with symptoms such as hallucinations, delusions, disordered thoughts, loss of contact with reality
- if you have liver problems

- if you have severe dyskinesia (involuntary movements) or severe dystonia (inability to move) despite taking levodopa
- if you or someone in your family are known to have an abnormality of electrocardiogram (ECG) called "long QT syndrome". Tell your doctor.
- if you use the antiemetic ondansetrone

Warnings and precautions
Before you use [Nationally approved name]:, 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.

Talk to your doctor<, nurse> or pharmacist before using [Nationally approved name]:
- if you have kidney problems
- if you have lung problems
- if you have heart problems
- if you have low blood pressure or feel faint and dizzy when you stand
- if you are taking any medicines to treat high blood pressure
- if you feel sick or suffer from being sick
- if your Parkinson's disease causes certain mental problems such as hallucinations and confusion
- if you are elderly or frail

Tell your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings. **Your doctor may need to adjust or stop your dose.**

Some patients develop addiction-like symptoms leading to craving for large doses of [Nationally approved name] and other medicines used to treat Parkinson`s disease.

Children and adolescents
[Nationally approved name] must not be used in children and adolescents under 18 years of age.

Other medicines and [Nationally approved name]
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Check with your doctor or pharmacist before taking your medicine
if you are using medicines that are known to affect the way your heart beats. This includes medicines used for heart rhythm problems (such as quinidine and amiodarone), for depression (including tricyclic antidepressants such as amitriptyline and imipramine) and for bacterial infections ('macrolide' antibiotics such as erythromycin, azithromycin and clarithromycin) and domperidone.

~~**Other medicines and [Nationally approved name]**~~
~~Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.~~

If you use [Nationally approved name] with other medicines the effect of those medicines may be altered.
This is especially true for:
- Medicines such as clozapine to treat some mental disorders

- Medicines to lower your blood pressure
- Other medicines for Parkinson‘s disease

Your doctor will tell you if you need to change the dose of your apomorphine or any of your other medicines.

If you are taking levodopa (another medicine for Parkinson’s disease) as well as apomorphine your doctor should check your blood regularly.

[Nationally approved name] with food and drink
Food and drink do not affect the way [Nationally approved name] will work.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor<, nurse> or pharmacist for advice before taking this medicine.
[Nationally approved name] should not be used during pregnancy unless clearly necessary.

It is not known whether [Nationally approved name] is transferred to breast milk. Talk to your doctor if you are breast-feeding or intend to breast-feed. Your doctor will explain to you, whether you should continue/discontinue breast-feeding or continue/discontinue taking this medicine.

Driving and using machines
[Nationally approved name] can cause drowsiness and a strong desire to sleep. Do not drive or use any tools or machinery if [Nationally approved name] affects you in this way.

[Nationally approved name] contains sodium metabisulphite
Sodium metabisulphite can rarely cause a severe allergic reaction with symptoms such as rash or itchy skin, difficulty breathing, puffiness of the eyelids, face or lips, swelling or redness of the tongue. If you experience these side effects, immediately go to the nearest hospital casualty department.

[Nationally approved name] contains less than 1 mmol ~~(23mg) of~~ sodium (23mg) per 10 ml, that is to say essentially ‘sodium-free’~~i.e. essentially sodium-free.~~

3. How to use [Nationally approved name]

Always use [Nationally approved name] exactly as your doctor has told you. Check with your doctor<, nurse> or pharmacist if you are not sure.

Before you use <apomorphine>, your doctor will ensure that you tolerate the medicine and an antiemetic medicine that you need to use simultaneously.

Domperidone should be taken at least 2 days before [Nationally approved name] is started to stop you feeling or being sick.

Do not use [Nationally approved name] if
- the solution has turned green.
- the solution is cloudy or you can see particles in it.

How much to use
The amount of [Nationally approved name] you should use and the number of injections required each day will depend upon your personal needs. Your doctor will discuss this with you and tell you how much of your medicine you should inject and how often.

The amount that will work best for you will have been determined during your visit to the specialist clinic.

- The usual daily dose is between 3 mg and 30 mg.
- You may need as much as 100 mg per day.
- Typically, you will need between 1 and 10 injections each day.
- Each single injection should not be more than 10 mg.

The D-*mine* Pen that is required for the application of [Nationally approved name] solution for injection in cartridge is not suitable for patients needing doses above 6 mg per injection.
For these patients, other products have to be used.

There is no need to dilute [Nationally approved name] before use. In addition, it must not be mixed with other medicines.

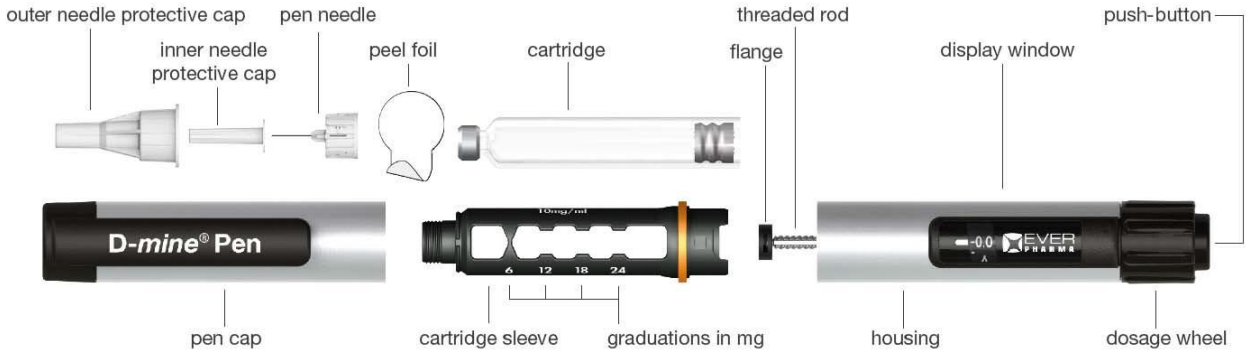
- Your doctor will tell you what dose of [Nationally approved name] to use and how often you should use it. Your doctor will also tell you how to change your dose of [Nationally approved name], if needed. Do not change your dose of [Nationally approved name] or use it more often unless your doctor has told you to.
- You and your caregivers will receive detailed instructions in the preparation and injection of doses from your doctor, with particular attention paid to the correct use of the required dosing pen.

Before using [Nationally approved name]

Note: This pack does NOT include the pen or pen needles.

[Nationally approved name] cartridges are designed to be used only with the dedicated D-*mine* Pen and disposable pen-needles as specified in the Instructions for Use of the pen.

Description of the pen



- Always use a new needle for each injection to prevent contamination.
- Needles and pen must not be shared.
- Before using [Nationally approved name], study your pen and the pen manual to familiarise yourself with the correct handling. If your pen is damaged or not working properly (due to mechanical defects), please refer to the Instructions for Use of the pen.

Where and how to inject [Nationally approved name]

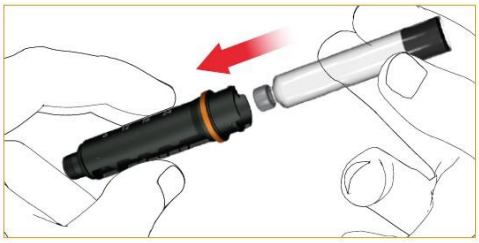
- First wash your hands.
- Before using the pen you will need some surgical wipes and one needle in its protective cone.
- Follow the instructions in your pen manual.

Pen preparation / changing cartridge

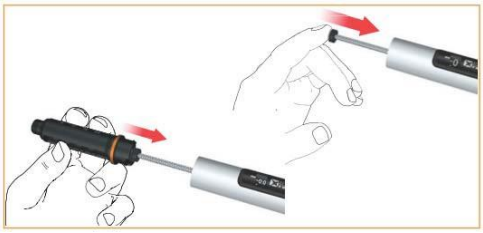
Take your pen out of its case and remove the pen cap.

Remove the cartridge sleeve by twisting it clockwise.

Insert the new cartridge into the cartridge sleeve.



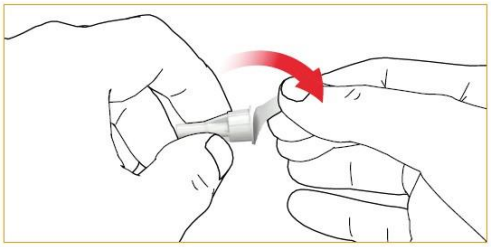
Push the threaded rod back completely. This is best performed using your finger tip.



Push the cartridge sleeve into the housing and turn anti-clockwise to lock.

Attachment of pen needle

Follow the instructions for use of your pen needle. Pull off the peel foil.



Click on / twist on the pen needle to the cartridge sleeve.

Remove the outer needle protective cap. Keep the outer needle protective cap to safely remove and dispose of the pen needle after use.

Remove and dispose the inner needle protective cap.

Priming / function check

Remove any remaining air in your cartridge before use. Dial the test dose forward by turning the dosage wheel. Check the dialed dose by looking vertically from above and not at an angle onto the display, so that the symbol "♦" is clearly displayed. This is called "priming" and is important because it ensures you get a full dose when you use your pen.

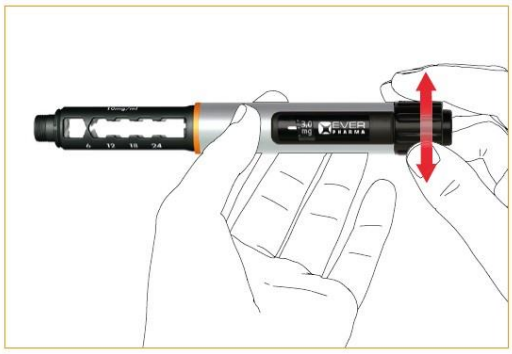
For the function check, hold your pen pointing upwards and gently tap the cartridge sleeve, so that the air can rise to the top.

Press the push-button.

A few drops of medicine will emerge from the pen needle tip. If no drops emerge, repeat the step.

Setting the dose

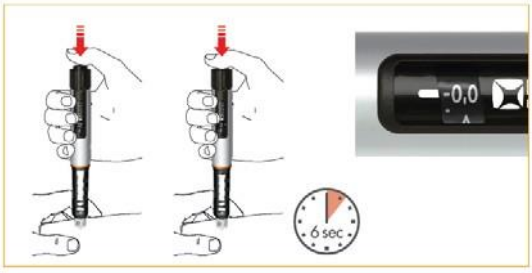
Dial your required dose by turning the dosage wheel clockwise. Correct your dose by turning in anti-clockwise direction.



Injection

- Using a surgical wipe, clean the area of skin where you plan to inject the medicine and around it.
- Inject [Nationally approved name] into an injection site on the front of your waist (abdomen) or your outer thighs under the skin (subcutaneously) as shown by your doctor <or nurse>.

Press the push-button in fully for injection. Hold the push-button fully down during medication discharge. After your medication has been completely discharged, wait for 6 seconds and then pull out your pen needle slowly. You may either keep the push-button pressed or release it during the 6 seconds. Check that the display is at the "0,0" position to confirm full dose delivery.

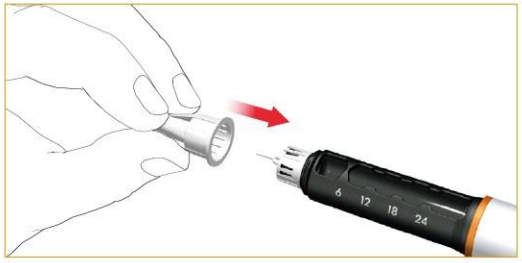


- Change the injection site each time [Nationally approved name] is used. This will lower your chances of having a skin reaction at the site where you inject [Nationally approved name]. Do not inject [Nationally approved name] into an area of skin that is sore, red, infected or damaged.
- You must never inject yourself directly into a vein (intravenously) or muscle (intramuscularly).

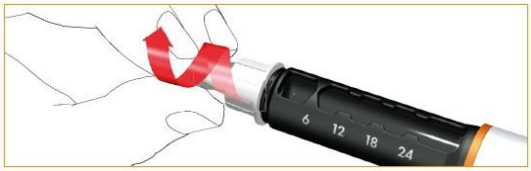
After using [Nationally approved name]
Remove and discard the needle after each injection (for safe disposal see section 5).

Removal of pen needle after each injection

Carefully attach the outer needle protective cap on the pen needle.

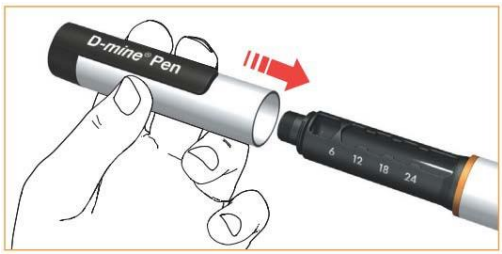


Twist off the pen needle by turning the outer shield clockwise and dispose it correctly.



Optional:
Place the outer pen needle shield in the appropriate left notch of your carrying case. The opening of the needle shield should be pointing up. Carefully insert the needle (attached to your pen) into the opening of the shield. Without holding onto the shield, push down firmly and turn counter-clockwise to twist off the pen needle.

Attach the pen cap securely after each use.



- Leave the cartridge in your pen.
- A new cartridge can be used for up to 15 days (for more information please refer to 5. "How to store [Nationally approved name]")
- If there is not enough solution left for your next dose, remove and discard the cartridge.
- Dispose of the needle safely, as described in the Instructions for Use of your pen.

If you use more [Nationally approved name] than you should
- Tell your doctor or contact your nearest hospital emergency department immediately.
- You may experience a slow heart rate, excessive sickness, excessive sleepiness and/or difficulty breathing. You may also feel faint or dizzy particularly when you stand up, due to low blood pressure. Lying down and raising your feet may help you to treat low blood pressure.

If you forget to use [Nationally approved name]

Use it when you next require it. Do not use a double dose to make up for a forgotten dose.

If you stop using [Nationally approved name]
Do not stop using [Nationally approved name] without first talking with your doctor.

If you have any further questions on the use of this medicine, ask your doctor<, nurse or> pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience an allergic reaction **stop** taking [Nationally approved name] 10 mg/ml and contact a doctor or your nearest hospital emergency department **immediately**.
The signs of an allergic reaction may include:
- rash
- breathing difficulties or
- tightness of the chest,
- puffiness of eyelids, face or lips,
- swelling or redness of the throat or tongue.

[Nationally approved name] may sometimes cause the following side effects:

Very common (may affect more than 1 in 10 people):
- Lumps under the skin at the site of injection which are sore, troublesome and may be red and itchy. In order to avoid getting these lumps, it is advisable to change the site of injection every time you insert the needle.
- Hallucinations (seeing, hearing or feeling things that are not there)
-

Common (may affect up to 1 in 10 people):
- Feeling sick or being sick, particularly when starting [Nationally approved name]. lf you are taking domperidone and still feel sick, or if you are not taking domperidone and you have sickness, tell your doctor <or nurse >as soon as possible
- Feeling tired or extremely sleepy
- Confusion or hallucinations
- Yawning
- Feeling dizzy or light-headed when standing up

Uncommon (may affect up to 1 in 100 people):
- Increased involuntary movements or increased shakiness during ‘on‘ periods
- Haemolytic anaemia, an abnormal breakdown of red blood cells in the blood vessels or elsewhere in the body. This is an uncommon side effect that can occur in patients also taking levodopa.
- Suddenly falling asleep
- Rashes
- Breathing difficulties
- Injection site ulceration
- Reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness
- Reduction in blood platelets, which increases the risk of bleeding or bruising

Rare (may affect up to 1 in 1,000 people):
- An allergic reaction
- Eosinophilia, an abnormally high amount of white blood cells in the blood or in body tissues.

Not known (frequency cannot be estimated from the available data):
- Swelling of the legs, feet or fingers

- Fainting
- Aggression, agitation
- Headache
- Inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:
    - Strong impulse to gamble excessively despite serious personal or family consequences.
    - Altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive.
    - Uncontrollable excessive shopping or spending
    - Binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger)

Tell your doctor if you experience any of these behaviors; she or he will discuss ways of managing or reducing the symptoms

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist< or nurse>. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Nationally approved name]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C.
Do not refrigerate or freeze.
Keep the cartridge in the outer carton in order to protect from light.
Store at the same conditions after opening and between withdrawals.
When you start using a new cartridge, it can be used for up to 15 days. Do not re-use the cartridge after this time. Use a new cartridge.

Do not use this medicine if you notice that the solution has turned green. It should only be used if the solution is clear, colourless to slightly yellow and free of particles.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and further information

What [Nationally approved name] contains

The active substance is apomorphine hydrochloride hemihydrate. Each millilitre of [Nationally approved name] contains 10 mg of apomorphine hydrochloride hemihydrate.

[Nationally approved name] is available in 3 ml cartridges containing 30 mg of apomorphine hydrochloride.

The other ingredients are:
- Sodium metabisulphite (E223)

- Hydrochloric acid (for pH-adjustment)
- Sodium hydroxide (for pH-adjustment)
- Water for Injections

Refer to section 2, "[Nationally approved name] contains sodium metabisulphite", regarding sodium metabisulphite.

What [Nationally approved name] looks like and contents of the pack

[Nationally approved name] is a clear, colourless to slightly yellow solution for injection, free of particles, in a clear glass cartridge with a bromobutyl rubber stopper and an aluminium cap with bromobutyl/synthetic polyisoprene rubber seal.

Each cartridge contains 3 ml solution for injection. Packs contain 5, 10 or 30 cartridges.
Bundle packs: 2 x 5, 6 x 5 and 3 x 10 of 3 ml cartridges in a moulded plastic tray in an outer cardboard carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

{Name of the Member State} {Name of the medicinal product}

This leaflet was last revised in {MM/YYYY}