

PACKAGE LEAFLET: INFORMATION FOR THE USER

Dacepton (Dopaceptin) 10 mg/ml solution for injection/infusion 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 or pharmacist.
- This medicine has been prescribed for you. 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Dacepton (Dopaceptin) 10 mg/ml solution for injection/infusion, which will be referred to as Dacepton (Dopaceptin) 10 mg/ml throughout this leaflet.

What is in this leaflet:

1. What Dacepton (Dopaceptin) 10 mg/ml is and what it is used for
2. What you need to know before you use Dacepton (Dopaceptin) 10 mg/ml
3. How to use Dacepton (Dopaceptin) 10 mg/ml
4. Possible side effects
5. How to store Dacepton (Dopaceptin) 10 mg/ml
6. Contents of the pack and other information

1. WHAT Dacepton (Dopaceptin) 10 mg/ml IS AND WHAT IT IS USED FOR

Dacepton (Dopaceptin) 10 mg/ml contains apomorphine solution for injection. It is injected into the area under the skin (subcutaneously). The active ingredient in Dacepton (Dopaceptin) 10 mg/ml is apomorphine hydrochloride hemihydrate. There is 10 mg of apomorphine hydrochloride hemihydrate in each millilitre of solution.

Apomorphine hydrochloride belongs to a group of medicines known as dopamine agonists. Dacepton (Dopaceptin) 10 mg/ml 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 Dacepton (Dopaceptin) 10 mg/ml

Do NOT use Dacepton (Dopaceptin) 10 mg/ml

- 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 anti-sickness medicine ondansetron

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 Dacepton (Dopaceptin) 10 mg/ml

- 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 Dacepton (Dopaceptin) 10 mg/ml and other medicines used to treat Parkinson's disease.

Check with your doctor or pharmacist before using 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 Dacepton (Dopaceptin) 10 mg/ml

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

If you use Dacepton (Dopaceptin) 10 mg/ml 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 Dacepton (Dopaceptin) 10 mg/ml or any of your other medicines.

If you are taking levodopa (another medicine for Parkinson's disease) as well as Dacepton (Dopaceptin) 10 mg/ml your doctor should check your blood regularly.

Using Dacepton (Dopaceptin) 10 mg/ml with food and drink

Food and drink do not affect the way Dacepton (Dopaceptin) 10 mg/ml will work.

Pregnancy and breast-feeding

Dacepton (Dopaceptin) 10 mg/ml should not be used during pregnancy unless clearly necessary.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is not known whether Dacepton (Dopaceptin) 10 mg/ml 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.

Ask your doctor or pharmacist for advice before using any medicine.

Driving and using machines

Dacepton (Dopaceptin) 10 mg/ml can cause drowsiness and a strong desire to sleep. Do not drive or use any tools or machinery if Dacepton (Dopaceptin) 10 mg/ml affects you in this way.

Dacepton (Dopaceptin) 10 mg/ml contains sodium metabisulphite

Dacepton (Dopaceptin) 10 mg/ml contains sodium metabisulphite which rarely can 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.

Dacepton (Dopaceptin) 10 mg/ml contains less than 1 mmol (23mg) of sodium per 10 ml, i.e. essentially sodium-free.

3. HOW TO USE DACEPTON (DOPACEPTIN) 10 MG/ML

Always use Dacepton (Dopaceptin) 10 mg/ml exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Before you use Dacepton (Dopaceptin), your doctor will ensure that you tolerate the medicine and an anti-sickness medicine that you need to use simultaneously.

Domperidone should be taken at least 2 days before Dacepton (Dopaceptin) 10 mg/ml is started to stop you feeling or being sick.

Do not use Dacepton (Dopaceptin) 10 mg/ml if

- the solution has turned green.
- the solution is cloudy or you can see particles in it.

Where to inject your Dacepton (Dopaceptin) 10 mg/ml

Inject your Dacepton (Dopaceptin) 10 mg/ml into an area under the skin (subcutaneously) as shown by your doctor or nurse.

Do not inject Dacepton (Dopaceptin) 10 mg/ml into a vein.

How much to use

The amount of Dacepton (Dopaceptin) 10 mg/ml 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 injection should not be more than 10 mg per hour.

If your symptoms are not controlled well enough with separate injections or if you find you are requiring more than 10 injections per day, you may require a continuous infusion of apomorphine. Your doctor will decide if you need this.

For a continuous infusion:

- The usual dose is between 1 mg and 4 mg per hour.
- Usually this is given to you when you are awake and stopped before you go to sleep.
- A different site for each infusion should be used every 12 hours.

The choice of which minipump and/or syringe driver to use will be decided by your doctor.

You should check with your doctor, nurse or pharmacist if you are not sure.

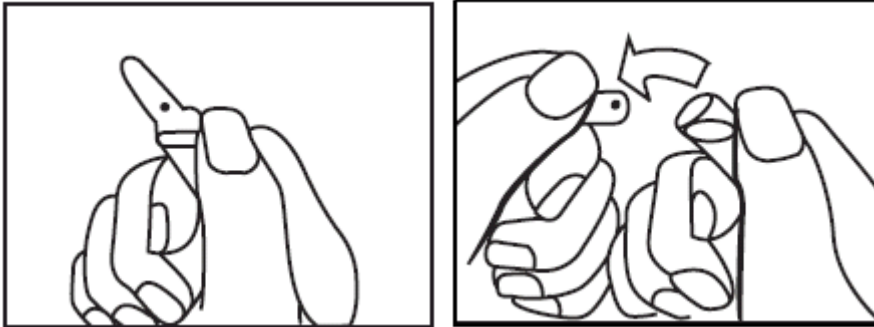
What you need to inject Dacepton (Dopaceptin) 10 mg/ml

For an injection, you will need:

- One syringe and needle
- A bin called a 'Sharps' bin to dispose safely of the used needles and glass containers. These are available from your doctor or pharmacist. Alternatively, use another suitable container such as an empty coffee jar.

How to open Dacepton (Dopaceptin) 10 mg/ml

Ampoules with a single spot (blue break point):



- Locate the **spot** positioned directly above the short score mark on the thin part of the neck. This score is the breaking point of the ampoule.
- Hold the bottom of the ampoule in one hand.
- **Cover the spot with your thumb** and use your forefinger to grasp the neck of the ampoule as shown in the diagram.
- Apply pressure with your thumb covering the spot in a **backward** direction.
- Carefully dispose of the top of the ampoule in a 'Sharps' bin.

Once opened Dacepton (Dopaceptin) 10 mg/ml should be used immediately.

Injecting Dacepton (Dopaceptin) 10 mg/ml

- Place the needle firmly on the end of the syringe.
- Withdraw the volume you require for your dose as advised by your doctor or nurse.
- You may need to dilute Dacepton (Dopaceptin) 10 mg/ml before use. Your doctor or nurse will have told you if you need to do this and how to do it.
- Inject your medicine as shown by your doctor or nurse into an area under the skin (subcutaneously).
- Discard used syringes, needles and ampoules in a "Sharps" bin (available from your doctor or pharmacist) or other suitable container, such as an empty coffee jar.
- Take care not to splash any of the solution onto yourself or the carpet as it may stain green.

If you have any further questions about the use of this medicine, ask your doctor or nurse.

If you use more Dacepton (Dopaceptin) 10 mg/ml 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 feel better.

If you forget to use Dacepton (Dopaceptin) 10 mg/ml

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

If you stop using Dacepton (Dopaceptin) 10 mg/ml

Do not stop using Dacepton (Dopaceptin) 10 mg/ml 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, Dacepton (Dopaceptin) 10 mg/ml can cause side effects, although not everybody gets them.

If you experience an allergic reaction **stop** taking Dacepton (Dopaceptin) 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.

Dacepton (Dopaceptin) 10 mg/ml 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 Dacepton (Dopaceptin) 10 mg/ml. If you are taking domperidone and still feel sick, or if you are not taking domperidone and you feel sick, 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:
 - o Strong impulse to gamble excessively despite serious personal or family consequences.
 - o Altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive.
 - o Uncontrollable excessive shopping or spending
 - o 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 DACEPTON (DOPACEPTIN) 10 MG/ML

Keep out of the sight and reach of children.

Do not use Dacepton (Dopaceptin) 10 mg/ml 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.

Keep the ampoules in the outer carton in order to protect from light.
Do not refrigerate or freeze.

Chemical and physical in-use stability has been demonstrated for up to 24 hours at 15°C - 25°C when the product is diluted with sodium chloride 9 mg/ml (0.9%).
From a microbiological point of view the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the

responsibility of the user and would normally not be longer than 24 hours at 15°C to 25°C, unless opening and dilution has taken place in controlled and validated aseptic conditions.

Once you have opened the ampoule, use it immediately.

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

Used syringes, needles and ampoules should be discarded in a 'Sharps' bin or other suitable container, such as an empty coffee jar. When your 'Sharps' bin or container is full, please give it to your doctor or pharmacist for safe disposal.

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 OTHER INFORMATION

What Dacepton (Dopaceptin) 10 mg/ml contains

The active substance is apomorphine hydrochloride hemihydrate. Each millilitre of Dacepton (Dopaceptin) 10 mg/ml contains 10 mg of apomorphine hydrochloride hemihydrate.

Dacepton (Dopaceptin) 10 mg/ml is available in 5 ml ampoules containing 50 mg of apomorphine hydrochloride hemihydrate.

Dacepton (Dopaceptin) 10 mg/ml also contains:

- Sodium metabisulphite (E223)
- Hydrochloric acid or sodium hydroxide for pH-adjustment
- Water for Injections

Refer to section 2 for information about the ingredients of Dacepton (Dopaceptin) 10 mg/ml regarding sodium metabisulphite.

What Dacepton (Dopaceptin) 10 mg/ml looks like and contents of the pack

Dacepton (Dopaceptin) 10 mg/ml is a clear and colourless to slightly yellow solution for injection/infusion.

Glass ampoules containing 5ml solution for injection/infusion, in packs of 1, 5 or 10 ampoules.

Bundle packs: 5 x 1, 10 x 1, 2 x 5, 5 x 5, 10 x 5, 3 x 10 and 10 x 10

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[to be completed nationally] EVER Neuro Pharma GmbH

AT_H_0364_001_PIL_ev8.0

Manufacturer

EVER Neuro Pharma GmbH

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

Dacepton
Dopaceptin

This leaflet was last revised in July 2020