Package leaflet: Information for the user

Dacepton 5 mg/ml Solution for 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<, 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 Dacepton 5 mg/ml Solution for infusion, which will be referred to as Dacepton 5 mg/ml throughout this leaflet.

What is in this leaflet

1. What Dacepton 5 mg/ml is and what it is used for

Apomorphine hydrochloride hemihydrate belongs to a group of medicines known as dopamine agonists. Dacepton 5 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.

2. What you need to know before you use Dacepton 5 mg/ml

Do NOT use Dacepton 5 mg/ml
- if you are under 18 years of age
- if you have breathing difficulties or suffer from asthma
- if you have dementia or Alzheimer's disease
- if you suffer from confusion, hallucinations, or any other similar problems
- if you have liver problems
- if you have severe dyskinesia (involuntary movements) or severe dystonia (inability to move) on account of the treatment with levodopa
- if you are allergic to apomorphine or any of the other ingredients of this medicine (listed in section 6).
- if you or someone in your family are known to have an abnormality of electrocardiogram (ECG) called "long QT syndrome". Tell your doctor.

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 5 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 you have any mental disorders when Dacepton is started
- if you are elderly or frail
- when driving or operating machinery since apomorphine may cause sleepiness including sudden sleep onset episodes (you must not drive or operate machinery if Dacepton makes you sleepy)
- your doctor should check your body regularly when taking Dacepton with levopoda (another treatment for Parkinson´s disease).
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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.

If any of the above situations applies to you, please inform your doctor or nurse.

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 clarithomycin) and domperidone.

Other medicines and Dacepton 5 mg/ml
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription.

If you use Dacepton 5 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 adjust 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.

Dacepton 5 mg/ml with food and drink

Food and drink do not affect Dacepton 5 mg/ml.

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.

Dacepton 5 mg/ml should not be used during pregnancy unless clearly necessary. Check with your doctor <or nurse> before using Dacepton 5 mg/ml if you are pregnant, think you may be pregnant or you are planning to become pregnant.

It is not known whether Dacepton 5 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.

Driving and using machines
Dacepton 5 mg/ml can cause drowsiness and a strong desire to sleep. Do not drive or use any tools or machinery if Dacepton 5 mg/ml makes you sleepy.

Dacepton 5 mg/ml contains **sodium metabisulphite** which may rarely cause severe hypersensitivity reactions and bronchospasm 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 5 mg/ml contains 3.4 mg sodium per ml. To be taken into consideration by patients on a controlled sodium diet

3. How to use Dacepton 5 mg/ml

Always use this medicine 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.

Do not use Dacepton 5 mg/ml if
- The solution has turned green.
- The solution is cloudy or you can see particles in it.

Where to inject your Dacepton 5 mg/ml
Inject your Dacepton 5 mg/ml into an area under the skin (subcutaneously) as shown by your doctor <or nurse>.

Do not inject Dacepton 5 mg/ml into a vein

How much to use
Both the amount of Dacepton 5 mg/ml you should use and the total amount of time you should receive your medicine 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 administer.
The amount that will work best for you will have been determined during your visit to the specialist clinic.

- The average infusion dose per hour is between 1 mg and 4 mg apomorphine hydrochloride.
- Usually this is given to you when you are awake and generally stopped before you go to sleep.
- The amount of apomorphine hydrochloride that you receive each day should not exceed 100mg

- Your doctor <or nurse> will decide which dose is best for you

- A different site for each infusion should be used every 12 hours.

There is no need to dilute Dacepton before use. In addition, it should not be mixed with other medicines.

Dacepton has been designed for continuous infusion with a minipump or syringe driver. It is not to be used for intermittent injection. The choice of which minipump and or syringe-driver to use, and the dosage settings required will be determined by the physician in accordance with the particular needs of the patient.

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

If you use more Dacepton 5 mg/ml than you should
- Tell your doctor or contact your nearest hospital emergency department immediately.
- It is important to administer the correct dose of Dacepton and not to use more than the amount recommended by your doctor. Higher doses may cause 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 will help to treat low blood pressure.

If you forget to use Dacepton 5 mg/ml
Take it when you next require it. Do not take a double dose to make up for a forgotten dose.

If you stop using Dacepton 5 mg/ml
Contact your doctor before stopping treatment and discuss whether this appropriate or not.
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. Tell your doctor if you think your medicine is making you feel unwell or if you get any of the following:

<u>Very common side effects (may affect more than 1 in 10 users):</u>
- 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)

<u>Common side effects (may affect up to 1 in 10 users):</u>
Feeling sick or being sick, particularly when starting Dacepton 5 mg/ml. Domperidone should be started at least 2 days before Dacepton 5 mg/ml to stop you feeling or being sick.
- 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 excessive sleepy
- Confusion or hallucinations
- Yawning
- Feeling dizzy or light-headed when standing up

<u>Uncommon side effects (may affect up to 1 in 100 users):</u>
- 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 side effects (may affect up to 1 in 1000 users):
- An allergic reaction such as difficulty breathing or tightness of the chest, puffiness of eyelids, face or lips, swelling or redness of the tongue
- Eosinophilia, an abnormally high amount of white blood cells in the blood or in body tissues.

Side effects with unknown frequency (frequency cannot be estimated from the available data):
- Swelling of the legs, feet or fingers
- Fainting
- Aggression, agitation
- 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

If you get any side effects, talk to your doctor<, nurse> or pharmacist. This includes any side effects not listed in this leaflet.

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 5 mg/ml

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

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

After opening and filling the drug product in syringes attached with infusion sets: chemical and physical in-use stability has been demonstrated for 7 days at 25 °C.
From a microbiological point of view, unless the method of opening and further handling precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

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 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.

Used syringes and needles should be discarded in a 'Sharps' bin or other suitable container. 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 further information

What Dacepton 5 mg/ml contains

The active substance is apomorphine hydrochloride hemihydrate. Each millilitre of Dacepton 5 mg/ml contains 5 mg of apomorphine hydrochloride hemihydrate.

Dacepton 5 mg/ml is available in 20 ml vials containing 100 mg of apomorphine hydrochloride hemihydrate.

The other ingredients are:
- Sodium metabisulphite (E223)
- Sodium chloride
- Hydrochloric acid (for pH-adjustment)
- Water for Injections

Refer to 'Section 2: Dacepton 5 mg/ml contains metabisulphite and sodium chloride' regarding sodium metabisulphite and sodium chloride.

What Dacepton 5 mg/ml looks like and contents of the pack

Dacepton 5 mg/ml is a clear and colourless to slightly yellow solution for infusion.

Glass vials containing 20 ml solution for infusion, in packs of 1, 5 or 30 vials.

Bundle packs: 5 x 1, 10 x 1, 30 x 1, 2 x 5 and 6 x 5

Not all pack sizes may be marketed.

Marketing Authorisation Holder
EVER Neuro Pharma GmbH
Oberburgau 3
4866 Unterach
Austria

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

Dacepton
Dopaceptin

This leaflet was last revised in {MM/YYYY}
November 2016