

PACKAGE LEAFLET: INFORMATION FOR THE USER

CINET® 1 mg/ml oral suspension Domperidone

Read all of this leaflet carefully before you start taking this medicine because it has 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 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What CINET is and what it is used for
2. What you need to know before you take CINET
3. How to take CINET
4. Possible side effects
5. How to store CINET
6. Contents of the pack and other information

1. What CINET is and what it is used for

CINET is a medicinal product that contains domperidone as active substance (Pharmacotherapeutic group: Modifiers of gastric motility and prokinetic agents).

This medicinal product is indicated in adults and adolescents (aged 12 years and older and weighing 35 kg or more) to treat nausea (feeling sick) and vomiting (being sick).

After the administration of CINET, domperidone is absorbed quickly and completely.

2. What you need to know before you take CINET

Do not take CINET:

- if you are allergic (hypersensitive) to domperidone or any of the other ingredients of this medicine (listed in section 6);
- if you have a disease or a prolactin-releasing tumour of the pituitary gland (prolactinoma)
- if you have gastrointestinal bleedings, mechanical obstruction or gastrointestinal perforation
- if you have a moderate or severe liver disease
- if your ECG (electrocardiogram) shows a heart problem called “prolonged QT corrected interval”
- if you have or had a problem where your heart cannot pump the blood round your body as well as it should (condition called heart failure)
- if you have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood

- if you are taking certain medicines (see “Other medicines and CINET”).

Warnings and precautions

Talk to your doctor before taking this medicine if you:

- suffer from liver problems (liver function impairment or failure) (see “Do not take CINET”)
- suffer from kidney problems (kidney function impairment or failure). It is advisable to ask your doctor for advice in case of prolonged treatment as you may need to take a lower dose or take this medicine less often, and your doctor may want to examine you regularly.

Domperidone may be associated with an increased risk of heart rhythm disorders and cardiac arrest. This risk may be more likely in those over 60 years old or taking doses higher than 30 mg per day. The risk also increases when domperidone is given together with some medicines. Tell your doctor or pharmacist if you are taking medicines to treat infection (fungal infections or bacterial infection) and/or if you have heart problems or AIDS/HIV (see the section “Other medicines and CINET”).

Domperidone should be used at the lowest effective dose in adults and adolescents aged 12 years and older and weighing 35 kg or more.

While taking domperidone, contact your doctor if you experience heart rhythm disorders such as palpitations, trouble breathing, and loss of consciousness. In this case, treatment with domperidone should be stopped.

Children

Since the blood-brain barrier and metabolic functions are not fully developed, the risk of adverse neurological effects, rare in adults, is higher in small children.

Other medicines and CINET

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take CINET if you are taking medicines to treat:

- fungal infections such as azole antifungals, specifically oral ketoconazole, fluconazole or voriconazole
- bacterial infections, specifically erythromycin, clarithromycin, telithromycin, moxifloxacin, pentamidine (these are antibiotics)
- heart problems or high blood pressure (e.g., amiodarone, dronedarone, quinidine, disopyramide, dofetilide, sotalol, diltiazem, and verapamil)
- psychoses (e.g., haloperidol, pimozone and sertindole)
- depression (e.g., citalopram and escitalopram);
- gastrointestinal disorders (e.g., cisapride, dolasetron and prucalopride);
- allergy (e.g., mequitazine and mizolastine);
- malaria (in particular halofantrine);
- AIDS/HIV (protease inhibitors);

- cancer (e.g., toremifene, vandetanib and vincamine).

Tell your doctor or pharmacist if you are taking medicines to treat infections, heart problems or AIDS/HIV.

CINET and apomorphine

Before you use CINET and apomorphine, your doctor will ensure that you tolerate both medicines when used simultaneously. Ask your doctor or specialist for a personalised advice. Please refer to the apomorphine leaflet.

It is important to ask your doctor or pharmacist if CINET is safe for you when you are taking any other medicines, including medicines obtained without prescription.

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 or pharmacist for advice before taking this medicine.

Pregnancy

Post-marketing data on the use of domperidone in pregnant women is limited. Therefore, CINET should only be used during pregnancy when justified by the anticipated therapeutic benefit. If you are pregnant, do not use CINET unless it is prescribed by your doctor.

Breast-feeding

Small amounts of domperidone have been detected in breast milk. Domperidone may cause unwanted side effects affecting the heart in a breast-fed baby. Domperidone should be used during breast-feeding only if your physician considers this clearly necessary. Ask your doctor for advice before taking this medicine.

Driving and using machines

CINET does not affect or has a negligible influence on the ability to drive and use machines.

CINET contains sorbitol and methyl parahydroxybenzoate

The oral suspension contains:

- sorbitol solution (E420) at 70%. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216), which may cause allergic reactions (possibly delayed).

3. How to take CINET

Follow these instructions closely unless your doctor has advised you otherwise.

Duration of treatment:

Symptoms usually disappear within 3 to 4 days of taking this medicine. Do not take CINET for longer than 7 days without consulting your doctor.

CINET oral suspension must be administered before meals. If the medication is taken after meals, the absorption of the active substance can take longer.

Oral suspension must be shaken before each use.

Posology:**Adults and adolescents aged 12 years or older, and weighing 35 kg or more**

The usual dose is 10 mg (which corresponds to 10 ml of oral suspension, i.e. one 10 ml measuring spoon) taken up to three times per day, if possible before meals. Do not take more than 30 mg per day.

Instructions for use:

To open the bottle press the lid and turn it anticlockwise.

Use the 10 ml measuring spoon included with the medicinal product to take the dose indicated by your doctor.

When using the dosing pipette for oral use, slide the ring to the mark corresponding to the weight in kilograms and give the measured amount. If necessary, to obtain the dose that corresponds to the body weight, repeat the measuring procedure and administer again.

For correct use of the pipette provided in the pack, proceed as follows:

1. Shake the bottle of suspension before use.
2. Put the end of the pipette into the oral suspension.
3. To measure the correct dose, hold the lower ring still and gently slide the upper ring up to the mark corresponding to the weight in kilograms (unless the doctor recommends otherwise). Figure 1.
4. Tipping the head back slightly, put the end of the pipette directly into the mouth and give the measured amount.
5. Rinse the pipette with running water, particularly the outside (which has been in contact with the mouth), dry it and put it back in the pack.

Figure 1

**If you take more CINET than you should**

If you have used or taken too much CINET, contact your doctor, pharmacist or the poison centre immediately, in particular if a child has taken an excessive dose. In the event of an overdose, symptomatic treatment could be implemented. An ECG monitoring could be undertaken, because of the possibility of a heart problem called prolonged QT interval.

With an excessive dose of the medicine there can be agitation, consciousness disorders, convulsions, drowsiness, disorientation and extrapyramidal reactions, especially in nursing infants and children.

The patient must be taken to a hospital to receive adequate treatment, such as gastric lavage, administration of activated charcoal and symptomatic treatment (extrapyramidal reactions can be suppressed with the administration of an antiparkinsonian or anticholinergic agent).

If you forget to take CINET

Take your medicine as soon as you remember. If it is almost time for your next dose, wait until that is due and then continue as normal. Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

Rare (occur in 1 or more for every 10 000 patients and in less than 1 for every 1 000 patients):

- gastrointestinal disorders: gastrointestinal disturbances, including very transient intestinal cramps
- endocrine disorders: increase of the prolactin levels
- reproductive system and breast disorders: galactorrhoea (appearance of milk), amenorrhoea (irregular or absent menstruation) or gynaecomastia (increased volume of the breasts)

Domperidone can cause an increase in the levels of prolactin in blood, which, in rare cases, can cause other effects (neuroendocrinological effects), such as gynaecomastia, galactorrhoea, and amenorrhoea.

Very rare (occur in less than 1 in every 10 000 patients):

- immune system disorders: allergic reactions, such as: rash, itching, shortness of breath, wheezing and/or swelling of the face; discontinue treatment immediately if you experience any of these symptoms
- nervous system disorders: extrapyramidal effects (abnormal muscle movements or tremor), convulsions, drowsiness, headaches; the risk of abnormal muscle movements is higher in neonates, infants, and children;
- skin and subcutaneous tissue disorders: urticaria, pruritus (itching) or rash;
- gastrointestinal disorders: diarrhoea
- psychiatric disorders: agitation, nervousness
- investigations: abnormal liver function tests.

Neurological side effects (extrapyramidal effects) are very rare in children and nursing infants, and exceptional in adults. In general, they disappear spontaneously and completely after treatment is stopped.

Other central nervous system-related effects, such as convulsion, agitation and drowsiness, are also very rare and reported mostly in nursing infants and children.

Not known (frequency cannot be estimated from available data):

- disorders of the cardiovascular system: prolongation of the QTc interval.

Heart rhythm disorders (rapid or irregular heartbeat) have been reported; if this happens, you should stop the treatment immediately. Domperidone may be associated with an increased risk of heart rhythm disorders and cardiac arrest. This risk may be more likely in those over 60 years old or taking doses higher than 30 mg per day. Domperidone should be used at the lowest effective dose in adults and adolescents aged 12 years and older.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CINET

Do not store above 30°C.

Keep the bottle with the suspension tightly closed.

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, after EXP. The expiry date refers to the last day of that month.

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 protect the environment.

6. Contents of the pack and other information

What CINET contains

- The active substance is domperidone. The oral suspension 1 mg of domperidone per milliliter (ml) of suspension.
- The other ingredients (excipients) are: polysorbate 20, microcrystalline cellulose and carboxymethylcellulose sodium, sorbitol solution (E420) at 70%, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), saccharin sodium (E954), and purified water.

What CINET looks like and contents of the pack

The medicinal product is presented as an oral suspension for oral use.

The oral suspension is white with a sweet taste.

CINET is supplied in type III amber glass bottles of 100 ml or 200 ml containing the oral suspension (with child-resistant cap). The pack with the oral suspension contains a 10 ml measuring spoon and a dosing pipette for oral use.

Not all presentations may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

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Manufacturer

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