

Package leaflet: Information for the user

Neo Emedyl coated tablets

Active substances: dimenhydrinate, caffeine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Keep this leaflet. You may need to read it again.

- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

1. What *Neo Emedyl coated tablets* are and what they are used for
2. What you need to know before you take *Neo Emedyl coated tablets*
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1. What *Neo Emedyl coated tablets* are and what they are used for

Therapeutic indications

Neo Emedyl coated tablets are used to prevent and treat motion sickness in *adults and adolescents aged 12 years and older*.

How they work

Neo Emedyl coated tablets contain the active substance dimenhydrinate, a tried-and-tested agent for dizziness, nausea and vomiting. It acts directly on the balance centre and vomiting centre in the brain and is therefore suitable for the prevention and treatment of symptoms in motion sickness (dizziness, nausea and vomiting caused by sea, air, rail, bus and car travel).

Caffeine counteracts the sedative effect of dimenhydrinate. It stimulates the cerebral cortex, the respiratory and circulatory centres and promotes cardiac output. 1 coated tablet contains about as much caffeine as ½ cup of filter coffee or 1 cup of black tea. Caffeine reduces fatigue.

2. What you need to know before you take *Neo Emedyl coated tablets*

Do not take/use *Neo Emedyl coated tablets*

- if you are allergic to dimenhydrinate and caffeine or any of the other ingredients of this medicine (listed in section 6)
- in children under 12 years of age
- in the last 3 months of pregnancy
- if you are breast-feeding
- if you are having an acute asthma attack
- if you suffer from increased inner eye pressure (glaucoma),

- if you suffer from convulsive seizures, such as epilepsy
- if you suffer from porphyria (problems in haemoglobin formation)
- if you have been diagnosed with phaeochromocytoma (adrenal medulla tumour)
- if you have a narrowing of the gastrointestinal tract or bladder neck
- if you have intestinal paralysis (paralytic ileus) or a bowel obstruction
- if you are currently taking medicines known as MAO inhibitors (used to treat depression) or have done so within the last week.

Warnings and precautions

Talk to your doctor or pharmacist before taking *Neo Emedyl coated tablets*.

Take special care with *Neo Emedyl coated tablets* if you

- suffer from chronic respiratory problems, asthma or emphysema
- have an enlarged prostate with residual urine formation
- have increased pressure on the brain or poor blood flow to the brain
- if you have a potassium or magnesium deficiency
- have a weak heart
- suffer from heart rhythm disorders or bradycardia (slowed heart activity),
- have gastrointestinal ulcers and bleeding
- suffer from an overactive thyroid
- have severe liver and kidney dysfunction.

You are strongly advised not to consume alcohol while taking this medicine.

The effects of both dimenhydrinate and caffeine can lead to addiction. *Neo Emedyl coated tablets* should therefore be used for as short a time as possible.

If symptoms persist or if you do not respond to treatment as expected, you should consult a doctor as soon as possible.

Before treatment with *Neo Emedyl coated tablets*, you must tell your doctor if you are pregnant.

Other medicines and *Neo Emedyl coated tablets*

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

The effect of this and other medicines may be mutually enhanced:

- Sedatives, sleeping pills, painkillers containing morphine or morphine-like substances and alcohol may reduce responsiveness
- The effect of medicines for high blood pressure may be enhanced
- Certain medicines for Parkinson's disease and depression (known as tricyclic antidepressants and MAO inhibitors) may enhance and prolong the effects of *Neo Emedyl coated tablets*. As a result, intestinal paralysis (paralytic ileus), urinary retention or an acute increase in inner eye pressure may occur
- Co-administration of disulfiram, bupropion and medicines that cause muscle twitches can lead to seizures.
- Do not take *Neo Emedyl coated tablets* together with alcohol.

Neo Emedyl coated tablets should not be taken at the same time as other medicines containing dimenhydrinate, diphenhydramine, 8-chlorotheophylline or caffeine.

You should avoid using *Neo Emedyl coated tablets* at the same time as other medicines that further prolong the QT time (contraction of the heart's ventricular muscles), such as class Ia and III antiarrhythmics (medicines used to treat heart rhythm disorders), antibiotics, antimalarial agents, neuroleptics (used for mental illnesses) and antihistamines, as this can lead to heart rhythm disorders, fits of dizziness and fainting or potassium deficiency.

The harmful effect of certain antibiotics (aminoglycoside antibiotics) and certain anti-cancer medications (cisplatin) on the inner ear is masked.

Stop taking *Neo Emedyl coated tablets* at least 3 days before having an allergy test, as they can cause false results.

Neo Emedyl coated tablets with food and drink

Do not take *Neo Emedyl coated tablets* together with alcohol.

Caution is advised if taken in combination with caffeine-containing foods and drinks.

Pregnancy and breastfeeding

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.

In the first 6 months of pregnancy, medical advice is recommended before using *Neo Emedyl coated tablets*, whereby the caffeine content of this product is to be taken into account.

Do not take *Neo Emedyl coated tablets* in the last 3 months of pregnancy, as labour may be triggered at this stage.

Do not use *Neo Emedyl coated tablets* if you are breast-feeding.

Driving and using machines

Do not drive or use any tools or machines, as this medicine may affect your responsiveness. This applies particularly in combination with alcohol or other medicines that depress brain function.

Neo Emedyl coated tablets contain sucrose (sugar)

This medicine contains sucrose. If you have been told that you have an intolerance to some sugars, please contact your doctor before taking *Neo Emedyl coated tablets*.

3. How to take *Neo Emedyl coated tablets*

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults and adolescents aged 12 years and older: Take 1 coated tablet 30 minutes before starting the journey, then 1 coated tablet every 4-6 hours thereafter.

Do not exceed the maximum daily dose of 6 coated tablets.

Neo Emedyl coated tablets should be swallowed with a sufficient amount of non-alcoholic liquid (e.g. 1 glass of water).

The duration of treatment should be as short as possible.

In prolonged use, treatment must be reviewed by a doctor.

In old or debilitated patients and patients with severe liver damage, the dose should be reduced. Before taking this medicine, your dose should therefore be carefully adjusted to the clinical picture by your doctor.

In patients with kidney damage, the interval between taking tablets should be prolonged to 6-12 hours (moderate damage) or 12-18 hours (severe kidney damage) depending on the degree of impairment.

Use in children

Neo Emedyl coated tablets are not suitable for *children under 12 years of age*.

If you take more *Neo Emedyl coated tablets* than you should

Please contact your doctor immediately.

Signs of overdose (intoxication) may be altered states of consciousness (such as drowsiness, hallucinations), states of anxiety, agitation, seizures and tremors as well as dizziness, a drop in blood pressure, dry mouth, flushing, fever, dilated pupils, impaired hearing and vision, heart rhythm disorders, faster or slower pulse.

Information for the physician:

Therapeutic measures:

Measures to reduce absorption: gastric emptying (lavage), gastric lavage may also provide benefits hours after the overdose, treatment with activated charcoal, acceleration of intestinal transit (sodium sulphate). Treatment of intoxication with dimenhydrinate is symptomatic, with supportive measures such as artificial respiration, intravenous fluid administration and external cooling for hyperthermia.

Convulsions may be controlled with intravenous diazepam. Do not give any stimulants!

As an antidote for central anticholinergic effects, repeat doses of physostigmine can be given (0.02 - 0.06 mg/kg body weight intravenously). In the event of physostigmine overdose, atropine is recommended.

For hypotension, vasopressors such as norepinephrine or phenylephrine can be used, but adrenaline must not be given, as there may be a further paradoxical decrease in blood pressure.

If you forget to take *Neo Emedyl coated tablets*

Do not take a double dose to make up for a forgotten dose.

If you stop taking *Neo Emedyl coated tablets*

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.

The following frequency statements are used for evaluating side effects:

- *Very common* ($\geq 1/10$)
- *Common* ($\geq 1/100$ to $< 1/10$)
- *Uncommon* ($\geq 1/1,000$ to $< 1/100$)
- *Rare* ($\geq 1/10,000$ to $< 1/1,000$)
- *Very rare* ($< 1/10,000$)
- *Not known* (cannot be estimated from the available data)

Possible side effects:

Blood and lymphatic system disorders

Very rare: Abnormal blood counts

Psychiatric disorders

Common: Mood swings

Nervous system disorders

Uncommon: Dimenhydrinate makes you tired, caffeine acts as a stimulant. Even so, tiredness and decreased alertness may still occur after taking *Neo Emedyl coated tablets*, depending on individual sensitivity and at higher dosages. This particularly applies in elderly patients and when taken together with alcohol.

Common: *Caffeine*, especially at higher dosages, often causes problems in falling asleep and restlessness.

Very rare: Excitation, restlessness, irritability, insomnia, tremors, seizures

Eye disorders

Rare: Visual disturbances (at higher dosages)
Very rare: Increased inner eye pressure

Cardiac and vascular disorders

Rare: Drop in blood pressure, rapid pulse
Very rare: Heart rhythm disorders (at higher dosages)

Gastrointestinal disorders

Uncommon: Gastrointestinal discomfort, constipation

Hepatobiliary disorders

Not known: Liver dysfunction (cholestatic jaundice: jaundice due to bile congestion)

Skin and subcutaneous tissue disorders

Uncommon: Dry mouth, nose and throat
Very rare: Allergic skin reactions, itching
Not known: Skin photosensitivity (avoid direct sunlight)

Musculoskeletal and connective tissue disorders

Uncommon: Muscle weakness

Renal and urinary disorders

Uncommon: Bladder voiding dysfunction
Common: *Caffeine:* increased urinary urge

General disorders and administration site conditions

Uncommon: Headache
Very rare: Hypersensitivity reactions including anaphylactic shock.

As with other hypnotics, dependence is possible after long-term, improper use.

Skin photosensitivity has been observed in isolated cases during treatment with dimenhydrinate.

With prolonged use of dimenhydrinate, the development of drug dependence cannot be excluded in conjunction with its depressant effect.

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. You can also report side effects directly via the national reporting system:

Bundesamt für Sicherheit im Gesundheitswesen
(Federal Office for Safety in Health Care)
Traisengasse 5
1200 VIENNA
AUSTRIA
fax: + 43 (0)50 555 36207
website: <http://www.basg.gv.at/>

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Neo Emedyl coated tablets

Do not store above 30°C.

Store in the original package in order to protect from light and moisture.

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 container 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 *Neo Emedyl coated tablets* contain

- The active substances are: dimenhydrinate and caffeine.
1 coated tablet contains 50 mg dimenhydrinate and 50 mg caffeine.
- The other ingredients are: magnesium stearate, crospovidone, maltodextrin, hydroxypropyl cellulose, gum arabic, sucrose, methyl cellulose, talc, calcium carbonate, povidone, titanium dioxide, glycerol 85%, silica, sunset yellow FCF (E110), cochineal red A (E124), montan glycol wax.

What *Neo Emedyl coated tablets* look like and contents of the pack

Blister with 12 orange-red coated tablets

12 tablets in a carton (1 blister in a carton) or

36 tablets in a carton (3 blisters in a carton)

Marketing Authorisation Holder and Manufacturer

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