Doregrippin®

Package leaflet: Information for the user

Doregrippin®

500 mg / 10 mg film-coated tablets
Active ingredients: Paracetamol / Phenylephrine hydrochloride

For children from 11 years of age and older and adults.

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 Doregrippin® is and what it is used for

Doregrippin® is a medicine for use in colds and flu-like infections. Doregrippin® contains the pain-killing and fever-lowering substance paracetamol and the nasal mucosa decongestant phenylephrine.

Indication

For the short-term treatment of symptoms of colds and flu-like infections accompanied by fever, headache, limb pain, runny or blocked nose.

For children from 11 years of age and older and adults.

2. What you need to know before you take Doregrippin®

Do not take Doregrippin®

- if you are allergic to paracetamol, phenylephrine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- during pregnancy and breast-feeding
- if you have an overactive thyroid
- if you have an adrenal medullary tumour (pheochromocytomas)
- if you have glaucoma (narrow angle glaucoma)
- if you suffer from severe liver impairment
- if you have severe organic cardiovascular changes, cardiac arrhythmias (respiratory insufficiency), high blood pressure (hypertension)
- if you suffer from bronchial asthma, chronic obstructive pulmonary disease, breathing difficulties (respiratory insufficiency) and spasm of the muscles in the airways (respiratory depression)
- if you suffer from narrowing of the upper urinary tract (e.g. with an enlargement of the prostate)
- if you suffer from impaired haemoglobin formation (porphyria)
- if you have an inherited deficiency of glucose-6-phosphate dehydrogenase (an enzyme defect)
- in children aged under 11

Warnings and precautions

Talk to your doctor or pharmacist before taking Doregrippin®.

Take special care with Doregrippin® in the following situations:

- diabetes mellitus
- tumours of the adrenal medulla
- all disorders of the heart and blood vessels (e.g. Raynaud's phenomenon)
- if you suffer from liver impairment
- if you suffer from renal impairment
- congenital elevated bilirubin level in the blood (Gilbert's syndrome or Meulengracht's disease)
- if you are a chronic alcoholic

- simultaneous administration, or administration within the preceding two weeks, of certain mood enhancing medicinal products (MAO-inhibitors, selective serotonin reuptake inhibitors or tricyclic antidepressants).

If your symptoms worsen, if there is no improvement after 3 days or if you have a high fever you must consult a doctor.

To reduce the risk of an overdose it is appropriate to ensure that other medicines which are taken simultaneously do not contain paracetamol.

The simultaneous intake of mucosal decongestants and cold remedies should also be avoided.

Painkillers which have been taken in high dosages for prolonged periods and in contravention of the intended use can cause headaches and may not be treated with increased doses of the medicine.

Generally, the habitual use of painkillers, especially those with a combination of several analgesic ingredients, can lead to permanent kidney damage with the risk of kidney failure (so called analgesic nephropathy).

Abrupt discontinuation of high doses of painkillers which have been taken for prolonged periods in contravention of the intended use can cause headaches as well as fatigue, muscular pain, nervousness and vegetative symptoms. Symptoms that occur after termination of the therapy usually recede within a few days. Until then, no more painkillers of any kind should be taken, nor should they be taken again without the advice of your doctor.

As a general rule, medicinal products containing paracetamol should only be taken for a few days and not at an increased dosage without medical or dental advice.

Other medicines and Doregrippin®

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

The simultaneous administration, or administration within the preceding two weeks, of certain mood-enhancing medicinal products (MAO-inhibitors, selective serotonin reuptake inhibitors or tricyclic antidepressants) may be accompanied by effects on the central nervous system such as agitation and confusion, high fever, disturbances of respiratory and cardiovascular function (so-called serotonin hyperfunction syndrome) as well as an increase in blood pressure.

The effect of Doregrippin® can be potentiated if taken at the same time as other medicines that depress the central nervous system or if taken concurrently with alcohol.

The concurrent administration of tricyclic antidepressants, narcotics (anaesthetics), cardiac glycosides (e.g. digoxin), so-called COMT inhibitors for the treatment of Parkinson's disease, mucosal decongestants, appetite suppressants and other sympathomimetic (adrenaline-like) medicines can potentiate the cardiovascular effects of these medicines (e.g. rise in blood pressure, irregular heartbeat, increased risk of a heart attack). The effect of atropine sulphate and medicines that depress the central nervous system can also be potentiated.

The concurrent administration of beta-blockers (e.g. propranolol) or other antihypertensive preparations (e.g. guanethidine or reserpine) with phenylephrine can lead to an increase in blood pressure. The effect of antidiabetic preparations may be weakened.

Other interactions are possible with:

- medicines for treating gout, e.g. probenecid: The dose of Doregrippin® should be reduced during concurrent administration with probenecid as the latter can slow down the decomposition of Doregrippin®
- medicines for lowering elevated blood lipid levels, e.g. cholestyramine: These can reduce the absorption of paracetamol and thus the effectiveness of Doregrippin®.
- medicines for epilepsy, e.g. phenytoin, carbamazepine or phenobarbital, certain hypnotics and doses of the active ingredient paracetamol. The same also applies in the case of alcohol abuse.
- broad-spectrum antibiotics such as chloramphenicol: The elimination of chloramphenicol can be slowed markedly, with a risk of increased toxicity, during the concurrent administration of paracetamol and chloramphenicol.

Since the clinical significance of interactions between paracetamol and coumarin derivatives (drugs for reducing the clotting ability of the blood) cannot be assessed at the present time, Doregrippin® should be used in the long term in patients treated with blood-clotting inhibitors (oral anticoagulants) only under medical supervision.

Since the concurrent administration of paracetamol and zidovudine increases the tendency towards a reduction in the white cell count (neutropenia), Doregrippin® should be used concurrently with zidovudine only on medical advice.

The concurrent administration of substances that slow down gastric emptying, e.g. propantheline, can delay the absorption and onset of effect of paracetamol.

The concurrent administration of substances that accelerate gastric emptying, e.g. metoclopramide, can accelerate the absorption and onset of effect of paracetamol.

Effects of the administration of Doregrippin® on laboratory tests:

Tests for determining uric acid or blood sugar levels may be influenced.

Doregrippin® with food, drink and alcohol

Alcohol should be avoided if possible during the administration of Doregrippin®.

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.

Doregrippin® should not be taken during pregnancy or while breast-feeding.

Driving and using machines

No adverse effects on the ability to drive or use machines have been observed to date in connection with the administration of Doregrippin®.

During these activities the possibility of adverse effects such as dizziness, confusion or impaired vision should be taken into account.

3. How to take Doregrippin®

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 juveniles over 14 years take 1-2 film-coated tablets as needed, up to a maximum of 3 times a day. Children aged 11 to 14 receive 1 film-coated tablet up to 3 times a day.

Method of administration

Swallow Doregrippin® whole with some fluid. Taking the tablets after meals can lead to a delayed onset of action.

Duration of administration

Do not take Doregrippin® for longer than 3 days without medical advice.

Particular patient groups

Liver function disorders and slightly impaired renal function

For patients with liver or renal disorders and those suffering from Gilbert's syndrome, the dosage must be reduced or the interval between each dose extended.

Elderly patients

Special dosage adjustments are not necessary.

Children under 11 years of age

Doregrippin® should not be taken by children under 11 years of age.

If you take more Doregrippin® than you should

If overdosage with Doregrippin® is suspected, a doctor must be informed immediately, inrer alia because of the risk of liver failure.

In the event of a deliberate or accidental overdose with Doregrippin®, headache, nausea, vomiting, elevated blood pressure with palpitations, visual disturbances, dizziness and general malaise can occur initially.

Symptoms of a paracetamol overdose generally appear within 24 hours and include nausea, vomiting, loss of appetite, pallor and abdominal pain. Despite an improvement in subjective well-being, progressive liver damage can still occur, possibly developing into a hepatic coma.

Independently of these hepatic effects, kidney damage and a reduction in urine output can also occur.

Depending on how much time has elapsed since the drug was taken, the following measures are recommended:

- Removal of the toxins by induced vomiting or a stomach wash-out can be useful within the first six hours.
- Antidotes such as cysteamine or n-acetylcysteine should be administered intravenously within the first eight hours after poisoning in order to neutralise the cell-damaging metabolic products of paracetamol.
- Dialysis can lower the level of paracetamol in the blood.

The administration of alpha-receptor blockers may be useful if blood pressure is dangerously elevated.

The other options for treating Doregrippin® intoxication will depend on the extent, progress and signs of illness.

If you forget to take Doregrippin®

Do not take a double dose to make up for a forgotten dose. Continue administration as described in the dosage directions.

If you stop taking Doregrippin®

No special aspects are observed if Doregrippin® is administered correctly.

The abrupt termination of administration (discontinuation) after prolonged, incorrect use of high doses of analgesics can lead to headaches, tiredness, muscle pains, nervousness and vegetative symptoms. These withdrawal symptoms subside within a few days. Until then, no further painkillers should be taken, nor should they be taken again thereafter without medical advice.

Consult your doctor or pharmacist if you have any further questions on the use of this medicine.

4. Possible side effects

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

The figures for the frequencies of side effects are categorized as follows:

- Very common: more than 1 in 10 patients
- Common: 1 to 10 patients in 100
- Uncommon: 1 to 10 patients in 1,000
- Rare: 1 to 10 patients in 10,000
- Very rare: less than 1 patient in 10,000
- Not known: Frequency cannot be estimated on the basis of the available data.

Possible side effects

Cardiac disorders

Very rare: palpitations, cardiac arrhythmias and a sensation of chest tightness (angina pectoris)

Vascular disorders

Rare: rise in blood pressure, severe headache

Hepatobiliary disorders

Rare: slight rise in certain liver enzymes (serum transaminases)

Blood and lymphatic system disorders

Very rare: changes in blood count, including reductions in white blood cells (leukopenia, agranulocytosis), platelets (thrombocytopenia) or all blood cells (pancytopenia)

Immune system disorders

Very rare: hypersensitivity reactions concerning the respiratory system. Spasm of the muscles in the airways (bronchial spasms) can be triggered in sensitive individuals (analgesic asthma)

Very rare: hypersensitivity reactions, including skin rashes, edema, breathing difficulties, sweating, nausea, reduction in blood pressure extending to shock

Disorders of skin and subcutis

Very rare: Very rare cases of serious skin reactions have been reported.

What countermeasures should be taken in the event of side effects?

Doregrippin® should be discontinued at the first signs of a hypersensitivity reaction. Please inform your doctor so that he can then decide on their severity and any required further measures.

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 Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger Allee 3, 53175 Bonn, www.bfarm.de.

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

5. How to store Doregrippin®

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 blister and carton after „Verwendbar bis:“. 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 Doregrippin® contains

The active substances are:
1 film-coated tablet contains 500 mg paracetamol and 10 mg phenylephrine hydrochloride.

The other ingredients are:
Povidone 25, povidone 30, microcrystalline cellulose, pregelatinized maize starch, maize starch, stearic acid, talc, simethicone, colloidal anhydrous silica, magnesium stearate, Macrogol 6000, croscarmellose sodium, crospovidone, poly[butylmethacrylate-co-(2-dimenthylaminoethyl)- methacrylate-co-methyl methacrylate] (1:2:1).

What Doregrippin® looks like and contents of the pack

White, round tablet, marked “21” on the underside

Original pack with 20 film-coated tablets

Marketing Authorisation Holder and Manufacturer

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Unofficial translation of the German package leaflet.

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