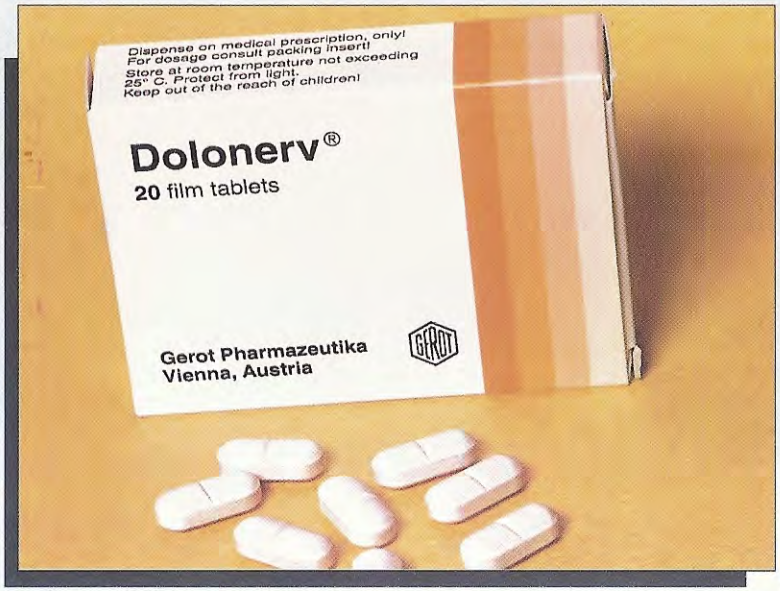

Dolonerv® film tablets

analgesic

Composition:
1 film tablet contains:

paracetamol	500 mg
thiamin nitrate (vitamin B1)	50 mg
pyridoxine hydrochloride (vitamin B6)	100 mg
cyanocobalamin (vitamin B12)	0.5 mg

Characteristics
Dolonerv is a combination of the analgesic paracetamol and neurotropic B-vitamins-complex.
Paracetamol exerts an analgesic as well as an antipyretic effect due to an inhibition of the prostaglandin synthesis.
The primary pharmacological action takes place in the CNS and to a lesser degree in the periphery which results in a low antiphlogistic effect and therefore a good gastric tolerance.
Paracetamol is quickly and completely absorbed. Maximum plasma concentration is reached 30-120 minutes after oral administration, plasma half-life is 1-4 hours (age independent). Paracetamol is metabolised in the liver and excreted as glucuronide and in children and adolescents as sulfate, respectively, with the urine. An intermediate n-hydroxy-derivative metabolite is responsible for the toxicity of paracetamol in case of overdosage or long-term treatment.
Dolonerv contains also a combination of important B-vitamins, which being coenzymes of numerous interacting processes are responsible for maintaining the normal nervous function. The combined use of B-vitamins at high doses for fast compensation of deficiency syndromes is considered superior to the efficacy of the individual factors as the single vitamin-B components. Vitamin B12 at a pharmacodynamically effective dosage also exerts an analgesic effect.

Indications
For the short-term treatment of acute intense pain:
neuritis, lumbar syndrome, complaints after invertebral disc surgery and herpes zoster infection.

Administration
The film tablets are to be taken unchewed with some liquid.

Dosage
Adults and adolescents of more than 50 kg body weight: 1 film tablet up to 4 times daily.
Single dose: 500 mg; maximum daily dose: 2000 mg.
Dosage based on body weight: approx. 10-15 mg paracetamol per kg body weight up to 4 times daily.

Contraindications
- hypersensitivity to paracetamol or other components,
- serious impairment of liver and renal function,
- hereditary, congenital deficiency of glucose-6-phosphate-dehydrogenase (hemolytic anemia),
- excessive and chronic consumption of alcohol.

Pregnancy and Lactation
There is no evidence of teratogenic effects for the use of Doloner, however, when Doloner is used during pregnancy and lactation, accurate diagnosis and a clear cut risk-benefit evaluation are imperative, and the dosage must be kept as low as possible and limited to single doses.
The tolerance of high doses of vitamin B6 during pregnancy is not fully established. Paracetamol is excreted with the breast milk. Data on the potential accumulation of vitamins in breast milk above physiologic levels are not available.

Side-Effects
At the recommended dosage side effects are rarely observed.

Rarely:
allergic cutaneous reaction - erythema, urticaria - occasionally associated with drug fever and irritations of the mucosa.
With the active ingredient paracetamol single cases of hypersensitivity reactions (Quincke's disease, dyspnea, profuse sweating, vomiting, decrease in blood pressure and even shock) were reported.

Very rarely:
allergic reactions of the bone marrow, e.g. pancytopenia, leucocytopenia, thrombocytopenia.

Extremely rarely:
methaemoglobinemia, asthma, hey fever, swelling of the nasal mucosa.
Intake of higher dosses of paracetamol, prolonged and chronic use of several grams per day may lead to renal function disorders and severely impaired liver function.
With chronic intake of extremely high doses of vitamin B6 single cases of nervous lesions, such as sensory neuropathy including absence of reflexes, ataxia, impaired superficial and deep perception disorders.

Interactions
Concomitant administration of Dolonerv with.
- hepatic enzymes inducing drugs (e.g.barbiturates, antiepileptics and rifampicin) causes increased formation of toxic metabolites;
- chloramphenicol leads to a 5 times prolongation of its elimination half life;
- salicylamide prolongs the elimination half-life of paracetamol, to a certain extent causes a cumulative affect and as a result formation of hepatotoxic metabolites;
- oral anticoagulants with chronic administration of paracetamol may potentiate the effect of anticoagulants; with short-term administration only minor interaction may occur;
- metoclopramide increases the absorption of paracetamol;
- insuline may reduce (at high doses of paracetamol) the hypoglycemic effect of insuline;
- L-dopa can reduce the dopaminergic effect due to vitamin B6;
- colchicine, PAS, neomycine, antidiabetics of the biguanid type inhibits the absorption of vitamin B12.
Concomitant consumption of alcohol increases the hepatotoxicity of paracetamol.

Drug Dependence
A single case was reported in 1964 with abrupt discontinuation of the drug after long-term use of 200 mg vitamin B6 per day. However, this was not established by a large patient population as published in 1985. Drug dependence is therefore unlikely.

Instructions for Safe Use
Caution has to be exercised in impaired liver and renal function. Vitamin B12 containing drugs may mask the clinical signs and the laboratory finding of a funicular myelosis and/or pernicious anemia. This should be considered before starting treatment.

Information for the Patient
Prior to the start of treatment the physician has to be informed of previous allergic reactions related to vitamin and/or paracetamol-containing preparations.
The physician is to be consulted on the occurrence of symptoms of side-effects.
During treatment the consumption of alcohol should be avoided.
In case of simultaneous treatment with drugs mentioned under "interaction"
the physician has to be informed.
The physician has to be informed of pregnancy immediately.
During pregnancy and lactation Dolonerv may be taken only on explicit medical advice.

Attention:
Dolonerv film tablets contain vitamins of the B-complex in an amount which in part exceeds by up to 50 times the amount of the usual daily vitamin requirement in otherwise healthy adults.
Therefore the drug is on no account recommended for self-treatment of other complaints.
In case of overdosage or intoxications the physician is to be consulted immediately.

Overdosage
After intake of overdoses: Antidote N-acetyl-cysteine within 10 hours (oral: initial dose 140 mg/kg body weight, after 8 hours maintenance doses of 70 mg/kg body weight every 4 hours).

Pack Size
20 film tablets
50 film tablets

Storage Advice
Store at room temperature not exceeding 25° C. Protect from light.
Keep out of the reach of children!

Sole Agent in Lebanon and Syria:
LIBA PHARM

Gerot Pharmazeutika Vienna, Austria