

Colchicum-Dispert®

Coated Tablets

50 Coated Tablets

Formula:

1 Coated tablet

Active Substance : 15.6 mg Colchici seed dry extract contains 0.5 mg Colchicine

Excipient : Ponceau 4 R, titanium dioxide, sugar.

Pharmacological Properties:

Colchici seed colchicine has been successfully used in gout (drop) disease for a long time. In spite of developments of analgesics and antiphlogistics, colchicines therapy still maintains its value in the treatment of acute gout cases. Its mechanism of action is not completely defined.

By oral administration, colchicine is immediately absorbed. It is found in kidneys, liver and spleen with elevated concentrations. It is excreted through kidneys and bile.

Indications:

Acute and chronic gout disease, supportive treatment for treatment of Familial Mediterranean Fever and Behçet's syndrome.

Contraindications:

It is contraindicated for individuals who are sensitive to any substance of the preparation composition.

Special Warnings and Precautions for Use:

It is recommended to consult to a physician in cases of severe diarrhea. Colchicum-Dispert coated tablets should be administrated cautiously in elderly and weak patients, particularly patients with renal, gastrointestinal and heart disease.

It may lead to fetal damages when using in pregnancy, in cases of need, it should be administered by considering benefit/damage ratio.

Side Effects/Advers Effects:

At elevated doses, gastrointestinal symptoms such as nausea, vomiting, watery and hemorrhagic diarrhea, abdominal pain may occur. Also at elevated doses, it may lead to hypovolemia, shock, hematuria, and as a result of "shut down", oliguria in kidneys. Dermatitis may occur. Hypersensitivity reactions may occur. Agranulocytosis, thrombocytopenia and aplastic anemia with bone marrow depression may occur in prolonged treatments.

CONSULT YOUR DOCTOR IF AN UNEXPECTED EFFECT ENSUES

Drug Interactions and Other Forms of Interaction:

Colchicine leads reversible malabsorption of the vitamin B 12. Effect of colchicine is inhibited with acidic substances while it is potentiated with alkaline substances. Colchicine may increase the sensitivity to CNS depressants; response to sympatomimetic agents may also be increased. Colchicine treatment may cause increased alkalinephosphatase levels.

Administration Route and Dosage:

If it is not recommended in different form, it is administered as 6-7 coated tablets a day with one hour intervals in acute cases. Dose may be increased since the mild diarrhea occurs. In order to prevent acute gout crisis, 1-3 coated tablets a day or on alternate days is administrated. 4 mg limit should not be exceeded within 24 hours.

Colchicum-Dispert coated tablets can be used concomitant with Allopurinol and uricosuric preparations.

Overdose Symptoms:

Overdose symptoms are recognized after 1-2 hours.

First signs are vomiting, abdominal pain and diarrhea. Diarrhea may aggravate; hemorrhage may occur and also lead metabolic acidosis, dehydration, hypotension and shock occur. Burn feelings in pharyngeal, stomach and skin may occur.

It may cause convulsions, delirium, muscle jerks, CNS stroke. Death may occur caused by respiratory system depression, cardiovascular collapse or bone marrow depression.

Precautions in Case of Overdose:

It is recommended that consulting to a physician in cases of severe diarrhea. Diarrhea may be prevented by discontinuation of the drug or with teinture opium. Hemorrhagic diarrhea due to hemorrhagic gastro enteritis and broad vascular damages due to shock may occur. Gastric lavage and measurements should be done in order to prevent shock. Hemodialysis and peritoneal dialysis may also be recommended. Analgesics are administrated to control diarrhea and cramps.

Storage Conditions:

Keep this and all drugs out of reach of children and store in its packaging. It should be stored at room temperatures less than 25 °C.

Do not use without consulting your doctor.

Type of Supply and Container Content:

Blisters containing 50 coated tablets.

Registration Holder: Dr. F. Frik İlaç San. Ve Tic. A.Ş. Küçükyalı / İSTANBUL

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Place of Manufacture: Yeni İlaç ve Hammaddeleri San. Tic. A.Ş. Esenyurt / İSTANBUL

Sold with prescription only.