

Dipyron Tablets

500 mg

Antipyretic and Analgesic

Via Oral

COMPOSITION: Each uncoated tablet contains:

Dipyron (Metamizole) BP 500 mg
Excipients q.s.

INDICATIONS: Dipyron tablets are used for the treatment of pain of various origins and varying intensity: toothache, headache, arthralgia, neuralgia, mild to moderate visceral pain, and high fever unresponsive to other medications.

DOSAGE AND ADMINISTRATION: Oral Route

Usual Adult Dose: 0.5–1 gram per dose, up to a maximum of three times daily.

Children: Based on body weight, 10–20 mg/kg per dose, administered 2 or 3 times daily.

CONTRAINDICATIONS: Hypersensitivity to metamizole and other pyrazolone derivatives, acute hepatic porphyria, congenital glucose-6-phosphate dehydrogenase deficiency, various renal or hepatic diseases, blood disorders (such as aplastic anemia, leukopenia, and agranulocytosis), and pregnancy (first trimester). Parenteral administration of dipyron is contraindicated in children under 1 year of age.

WARNINGS AND SPECIAL PRECAUTIONS: Dipyron should be used with particular caution in patients with a history of hypersensitivity to foods and medications (particularly analgesic and non-steroidal anti-inflammatory drugs), as well as in patients with bronchial asthma, Quincke's edema, or chronic pulmonary infections. Dipyron should not be administered parenterally to patients with hypotension or unstable blood pressure. If the administration of dipyron is absolutely necessary, blood pressure and cardiac output must be monitored. In cases of prolonged treatment with dipyron, regular monitoring of hematocrit (including a differential white blood cell count) is required. Dipyron may adversely affect active attention; therefore, driving and operating machinery are not advised.

DRUG INTERACTIONS: Dipyron potentiates the analgesic and antipyretic actions of non-steroidal anti-inflammatory drugs. The effects of dipyron are potentiated by tricyclic antidepressants, oral contraceptives, allopurinol, and alcohol. Dipyron decreases the activity of coumarin anticoagulants and the plasma levels of cyclosporine. Enzyme inducers (barbiturates, glutethimide, phenylbutazone) attenuate the effects of dipyron. Dipyron potentiates the effects of drugs with CNS-depressant activity. Concomitant administration with chlorpromazine is associated with an increased risk of severe hypothermia.

ADVERSE REACTIONS: Following prolonged administration, agranulocytosis, leukopenia, thrombocytopenia, proteinuria, and interstitial nephritis may very rarely be observed. In sensitive patients, skin rashes, urticaria, Quincke's edema, asthmatic attacks, and—very rarely—anaphylactic shock are possible.

PHARMACOLOGICAL MECHANISMS: Dipyron is a medication belonging to the pyrazolone group that induces analgesic and antipyretic effects and possesses moderate anti-inflammatory activity. The antipyretic and analgesic activity of this drug is attributed to the blockade of the synthesis of endogenous pyrogens—prostaglandins D and E. The reduction in prostaglandin production in the periphery (and the corresponding decrease in the sensitivity of nerve endings) plays a relatively minor role. In contrast to other non-narcotic analgesics, dipyron stimulates the release of beta-endorphins, which explains its activity in cases of visceral pain. It exerts slight spasmolytic activity on the smooth muscle cells of the biliary and urinary tracts, as well as on the uterine muscle.

PRESENTATION: Blister pack of 10 tablets.

STORAGE: Store in a cool, dark, and dry place, below 30°C.

KEEP OUT OF REACH OF CHILDREN.

Manufactured by:

