This package insert is continually updated: please read carefully before using a new pack!

Novalgin®

Active ingredient: Metamizole sodium

Composition

Each film-coated tablet contains 500 mg metamizole sodium 1 H_2O as active ingredient.

Excipients: Macrogol 4000, magnesium stearate, methylhydroxypropylcellulose, saccharin sodium, macrogol 8000, titanium dioxide (E171), talc.

Properties

Novalgin has analgesic, antipyretic, antispasmodic, and anti-inflammatory effects.

Indications

Severe pain, acute or chronic, e.g. in association with rheumatic diseases, headache, toothache, or tumours, and after injuries or operations.

Severe pain associated with smooth muscle spasms, acute or chronic, e.g. muscular spasm or colic affecting the gastrointestinal tract, the biliary passages, kidneys, or lower urinary tract.

To lower fever, when refractory to other treatment (e.g. cold wet compresses).

Novalgin is not to be used in trivial complaints.

Contraindications

Novalgin must not be administered to patients with pyrazolone allergy (hypersensitivity to medicines containing metamizole, isopropylaminophenazone, propyphenazone, phenazone, or phenylbutazone) or metabolic diseases (hepatic porphyria, congenital glucose-6-phosphate dehydrogenase deficiency).

Pregnancy and lactation

During the first three months of pregnancy use of Novalgin should be avoided. Between the fourth and sixth months, use should only be considered where compelling medical reasons are present. Novalgin must not be used during the last three months of pregnancy.

Breast-feeding must be avoided for 48 hours after use of Novalgin.

Special warnings and precautions

Patients who suffer from pre-existing defective blood formation (e.g. from cytostatic therapy) should take Novalgin only under medical supervision.

Patients suffering from bronchial asthma or chronic respiratory tract infections (especially when combined with hay-fever-like manifestations), and patients with hypersensitivity to pain-relieving and antirheumatic drugs of every kind are at risk of attacks of asthma or shock (analgesic asthma/analgesic intolerance) from the administration of Novalgin. Prior to its use, they should consult their doctor. The same applies to patients who react to alcoholic beverages, even to small amounts, with sneezing, lacrimation, and pronounced reddening of the face, as well as to patients who are allergic (cutaneous reactions, itching, urticaria) to other substances (e.g. foodstuffs, furs, hair dyes, and preservative agents).

Novalgin film-coated tablets are not suitable for the treatment of children under 15 years of age.

Adverse effects

The principal adverse effects of Novalgin are due to hypersensitivity reactions. The most important are blood dyscrasias (agranulocytosis, leucopenia, thrombocytopenia) and shock. Both reactions are rare, but life-threatening, and they may occur even after Novalgin has previously been taken on many occasions without complications.

The manifestations of agranulocytosis include high fever, chills, sore throat, difficulty in swallowing, inflammatory lesions in the mouth, nose, and throat, as well as in the genital or anal regions. Immediate discontinuation is decisive for recovery. For this reason, in the event of any unexpected deterioration in the general condition, if fever fails to subside or begins anew, or if painful mucosal lesions appear, especially in the mouth, nose, or throat, Novalgin must be stopped **immediately** and the doctor consulted.

Thrombocytopenia causes an increased tendency to bleeding with or without minute haemorrhagic spots in the skin and mucous membranes.

The other major form of hypersensitivity reactions is shock. The warning signs of imminent shock are cold sweat, giddiness, stupor, nausea, change of skin colour, and shortness of breath. In addition, there may be swelling of the face, itching, a feeling of constriction in the heart region, rapid pulse, and a sensation of coldness in the arms and legs. These symptoms may occur at once or up to one hour after administration. If one or more of these signs is recognized, medical aid must be sought immediately. Until the doctor arrives, ensure that the patient remains lying with legs raised and airways patent.

In occasional instances, mainly in patients with a history of pre-existing renal disease or in cases of overdose, there have been transient renal disorders with reduction or cessation of urine production (oliguria, anuria), accompanied by excretion of protein in the urine (proteinuria) and inflammation of the kidney tissue (interstitial nephritis).

Further unwanted effects which may be encountered include hypersensitivity reactions. These may affect the skin, the conjunctivae, and the nasopharyngeal mucosa (e.g. urticarial eruptions or fixed drug eruption, the latter being characterised by roundish, coin- to palm-sized, violet- to deep-red-coloured bullous skin reactions), and, in very rare cases, even include severe, sometimes life-threatening bullous skin reactions, usually with mucosal involvement (Stevens-Johnson syndrome or Lyell's syndrome). In the event of such skin reactions, the drug should be discontinued at once and a doctor consulted.
Attacks of asthma in patients predisposed to this condition may also be observed.
Please consult a physician if you notice any of the adverse effects listed in this package insert or any other undesired effects or unexpected changes.

Interactions
In case of concomitant treatment with cyclosporin, a fall in the cyclosporin level may occur. Regular controls are therefore necessary.
Novalgin and alcohol may have a reciprocal influence on each other's effects.

Dosage and administration
Adults and adolescents aged 15 years or over receive 1 to 2 film-coated tablets as single dose. Unless otherwise prescribed, the single dose can, if necessary, be given up to 4 times daily.
Novalgin film-coated tablets should not be chewed, but swallowed whole with a little fluid.

Special notes
In the event of an overdose, a doctor must be consulted.
Excretion of a harmless metabolite (rubazonic acid) may cause a red colouration of the urine, which disappears on discontinuation of treatment.
Pain-relieving drugs must not be used over prolonged periods of time or in high doses without the doctor's or dentist's advice.

Expiry date
Do not use later than the date of expiry.

Keep medicines out of the reach of children.

Presentation
20 film-coated tablets of 0.5 g each

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