Novalgin®

Active ingredient: Metamizol sodium

Composition
Each ml of injection solution contains 500 mg metamizol sodium 1 H_2O as active ingredient.

Properties
Novalgin has analgesic, antipyretic, antispasmodic, and anti-inflammatory effects.
As Novalgin can be injected intravenously, it is possible to obtain extremely potent analgesia in a variety of conditions and thus to control pain which would otherwise respond only to products containing opiates. Even in high doses, Novalgin, unlike opiates, causes neither addiction nor respiratory depression. It does not interfere with intestinal peristalsis, labour contractions, or the expulsion of calculi.

Indications
Novalgin injection solution must be used only when oral or rectal administration is inappropriate in the following 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 metamizol, isopropylaminophenazone, propyphenazone, phenazone, or phenylbutazone) or metabolic diseases (hepatic porphyria, congenital glucose-6-phosphate dehydrogenase deficiency).

Precautions
Especially careful consideration of the necessity for Novalgin is essential in patients whose blood pressure is below 100 mm Hg, or who are in a state of circulatory instability (e.g. incipient circulatory failure associated with myocardial infarction, multiple injuries, early shock), and in patients with pre-existing defective blood formation (e.g. from cytostatic therapy).
Patients suffering from bronchial asthma or chronic respiratory tract infections (especially when combined with hay-fever-like manifestations such as chronic urticaria, frequent episodes of conjunctivitis, and rhinosinusitis polyposa), and patients with hypersensitivity to pain relieving and antirheumatic drugs (analgesic asthma / analgesic intolerance) are at risk of attacks of asthma or shock from the administration of Novalgin. 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 to foodstuffs, furs, hair dyes, and preservative agents.
Although analgesic intolerance is indeed an extremely rare manifestation, the danger of shock is relatively greater after parenteral than after enteral administration. The patient should be thoroughly questioned to exclude any such condition before injecting Novalgin.
Because of the possibility of interference with renal function, Novalgin should not be given to infants under 3 months of age or under 5 kg body weight, unless there is a compelling indication.
During pregnancy, especially in the first three months or the last six weeks, Novalgin should be used only if strictly indicated.

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

The warning signs of imminent shock – often already during the injection – 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 sensations of coldness in the arms and legs (critical fall in blood pressure). These symptoms may even occur up to one hour after the injection.

In patients with exceptionally high fever (hyperpyrexia) and/or after too rapid injection, there may be a dose-dependent critical fall in blood pressure without further signs of hypersensitivity.

At the first signs of shock, initiate standard emergency measures for the treatment of anaphylactic shock immediately (see below).

The manifestations of agranulocytosis, the other important adverse reaction, include high fever, chills, sore throat, difficulty in swallowing, inflammatory lesions in the mouth, nose, throat, as well as in the genital or anal regions. Swelling of the lymph nodes or spleen is slight or absent. The erythrocyte sedimentation rate is greatly increased, and the granulocytes are considerably reduced in number or completely absent, although haemoglobin and erythrocyte count remain normal in most cases. Immediate discontinuation is decisive for recovery. For this reason, in the event of any unexpected deterioration in 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** without waiting for the results of laboratory tests.
Thrombocytopenia causes an increased tendency to bleeding with or without minute haemorrhagic spots in the skin and mucous membranes.
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 oliguria or anuria, proteinuria, and interstitial nephritis.

Further unwanted effects, which may be encountered, include hypersensitivity reactions affecting

the skin (e.g. urticarial eruptions), the conjunctivae, and the nasopharyngeal mucosa, in very rare cases progressing to 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 that condition may also be observed.
Pain and/or local reactions at the injection site are possible.

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

Dosage
Unless otherwise prescribed, the following dosages are recommended:
Adults and adolescents aged 15 years or over: As a single dose, 2–5 ml (i.v. or i.m.); as a daily dose, up to 10 ml of injection solution.
Children and infants:
In children under 1 year of age, Novalgin should be injected by the intramuscular route only.
For a child of approximately 30 kg body weight, the single dose is 0.4 to 1 ml of injection solution. Lighter or heavier children should receive correspondingly smaller or larger doses. The following dosage scheme should be used as a guide.

Weight range	Injection solution i.v.	i.m.
Babies 5–8 kg	–	0.1–0.2 ml
Children 9–15 kg	0.2–0.5 ml	0.2–0.5 ml
Children 16–23 kg	0.3–0.8 ml	0.3–0.8 ml
Children 24–30 kg	0.4–1 ml	0.4–1 ml
Children 31–45 kg	0.5–1.5 ml	0.5–1.5 ml
Children 46–53 kg	0.8–1.8 ml	0.8–1.8 ml

The single dose can be given up to 4 times daily.

Mode of administration
The requirements for the treatment of shock should be met. The solution should be warmed to body temperature prior to injection.
The commonest cause of a critical drop in blood pressure and shock is an unduly rapid rate of injection. Therefore, intravenous injections must be given slowly (not more than 1 ml per minute) with the patient lying down. The blood pressure, heart rate, and respiration must be monitored.
In view of the suspicion that the non-allergic drop in blood pressure is dose-dependent, the indication for the administration of doses higher than 1 g should be particularly carefully considered.

Special notes
Because of the possibility of incompatibilities, Novalgin must not be mixed with other drugs in the syringe.
An occasional red coloration of the urine is harmless; it is due to the excretion of rubazonic acid, an innocuous metabolite.

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

Keep medicines out of the reach of children.

Presentation
5, 10, and 100 ampoules of 2 ml each
5, 25, and 100 ampoules of 5 ml each
Also available: tablets, drops, syrup, suppositories, and suppositories for children.

Emergency measures to be taken in the event of anaphylactic shock
Generally, the following emergency procedure is recommended: At the first signs (sweating, nausea, cyanosis) interrupt the injection immediately, but leave the venous cannula in place or perform venous cannulation. In addition to the usual emergency measures, ensure that the patient remains lying, with the legs raised and airways patent.

Emergency drug therapy
Immediately epinephrine (adrenaline) i.v.: Dilute 1 ml of commercially available epinephrine solution 1:1000 to 10 ml. In the first instance, slowly inject 1 ml of this dilution (equivalent to 0.1 mg epinephrine) while monitoring pulse and blood pressure (watch for disturbances of cardiac rhythm). Repeat as required.
Then glucocorticoids i.v., e.g. 250–1000 mg methylprednisolone. Repeat as required.
The dosage recommendations refer to adults of normal weight. In children, the reduction of dose should be in relation to body weight.
Subsequently volume substitution i.v., e.g. plasma expanders, human albumin, balanced electrolyte solution.
Other therapeutic measures, e.g. artificial respiration, oxygen inhalation, antihistaminics.

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إن هذا دواء

- الدواء مستحضر يؤثر على صحتك واستعلاكه خلافا للتعليمات يعرضك للخطر
- إتبع بدقة وصفة الطبيب وطريقة الإستعمال المنصوص عليها وتعليمات الصيدلاني الذي صرفها لك
- فالطبيب والصيدلاني هما الخبيران بالدواء وبنفعه وضرره
- لا تقطع مدة العلاج المحددة لك من تلقاء نفسك
- لا تكرر صرف الدواء بدون وصفة طبية

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