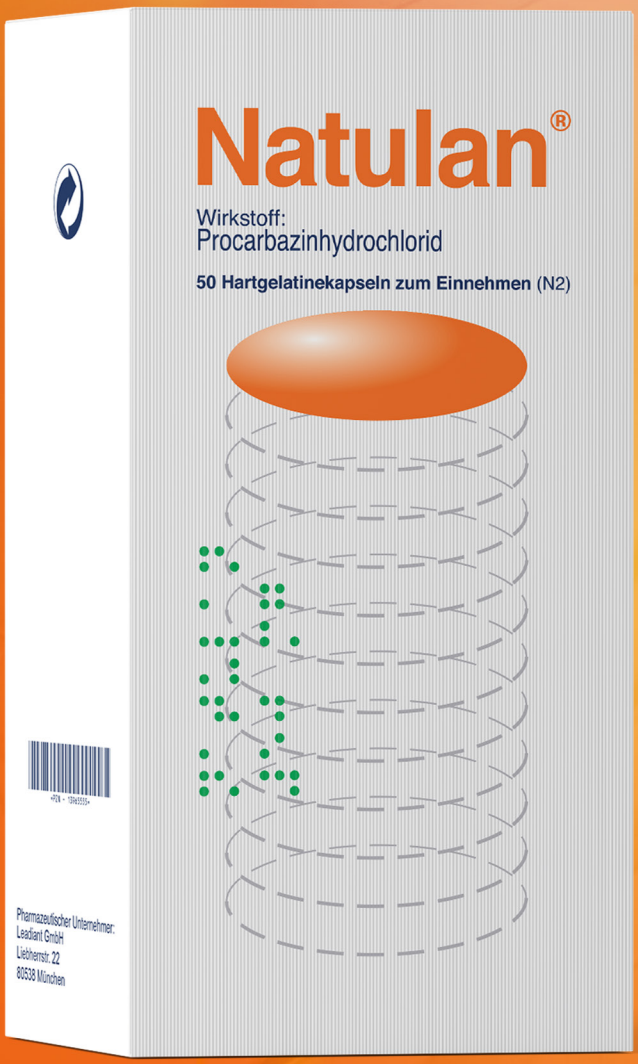
Natulan®

Procarbazinhydrochlorid



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Procarbazinhydrochlorid

NATULAN (Procarbazine hydrochloride) - Brief summary of product characteristics.
NATULAN 50 mg, capsule. Procarbazine hydrochloride 58.3 mg for one capsule. **Therapeutic indications:** Treatment of Hodgkin's lymphoma within the scope of combination chemotherapy Natulan is used to treat Hodgkin's lymphoma in adults as well as in children and adolescents aged 2 to 18 years together with other cytostatics, following a suitable protocol. In combination with lomustine and vincristine, Natulan is indicated for the treatment of adult patients with anaplastic oligodendroglial tumours in addition to radiation therapy within the scope of primary therapy. In monochemotherapy, the dosage is progressive: 50 mg the first day, then increase by 50 mg/day to achieve a daily dose of 150 to 200 mg/m2/day. In current use in association, the dose is 100 to 150 mg/m2/day for 5 to 14 days. The dose per m2 used in most tests published was generally similar to the dose used in adults (100 mg/m2 for up to 14 days). Dosages treatment and maintenance of procarbazine should be determined only by a physician experienced in the use of major antineoplastic drugs in children. **This medicine is contraindicated in the following situations:** Hypersensitivity to procarbazine, its metabolites or any of the other ingredients, Myelosuppression with granulocytopenia and thrombocytopenia which does not result from bone marrow infiltration due to the underlying malignancy, severe kidney and/or liver damage. **Special warnings and precautions employment:** Before starting treatment, the patient should be warned of the risk of sterility by sometimes permanent azoospermia linked to the number of polychemotherapy cycles. **Breastfeeding:** in the absence of data on the passage of procarbazine into breast milk, this medication is contraindicated during of breastfeeding. Before any administration of procarbazine, it is essential to check the blood count. blood count as well as the existence of possible kidney damage and/or liver failure. A Hematological monitoring is necessary 2 times a week. In patients with renal insufficiency or hepatic problems, treatment with procarbazine should be initiated in hospital. Kidney and liver functions must be checked at least once a week. **Side effects:** Gastrointestinal effects (common): gastrointestinal disorders such as anorexia, nausea, vomiting, constipation, diarrhea and stomatitis. Hematological changes (common): like any product cytostatic, NATULAN inhibits hematopoiesis. We mainly observe leukopenia and thrombocytopenia reversible when treatment is stopped. Hypersensitivity reactions (15 to 18%): have been reported skin manifestations such as urticarial, maculopapular rash, accompanied by pruritus and sometimes arthralgia occurring shortly after starting or resuming treatment. These demonstrations require the cessation of treatment. Effects on fertility: azoospermia (very common) sometimes permanent. In women: disorders of cycle, amenorrhea (very common). Neurological disorders: Central effects: drowsiness (common), confusion (common), agitation, depressive state (rare), headache, ataxia, hallucination (rare), psychosis (rare), sleep disorder. These effects are generally moderate and reversible upon stopping treatment. Achievements pulmonary: Interstitial lung disease (common) reported only during the first or second second cycle of treatment combining in particular mechlorethamine, vincristine, procarbazine and prednisone (MOPP type chemotherapy). Reporting suspected adverse reactions after authorization from the medication is important. It allows continuous monitoring of the benefit/risk ratio of the drug. **Healthcare professionals report any suspected adverse reactions via the national reporting system:** National Agency for the Safety of Medicines and Health Products (ANSM) and network of Regional Centers for Pharmacovigilance - Website: www.signalement-sante.gouv.fr. **Pharmacotherapeutic group:** Anticancer immunosuppressant, **ATC code:** L01XB01 Cytostatic derived from methylhydrazine. **Properties pharmacokinetics:** Procarbazine administered orally is completely absorbed from the tube digestive. **Elimination is via the urine mainly in inactive form:** 55% of the dose at the 6th hour and 70% at the 24th hour, and only 5% in unchanged form. 10 to 20% are eliminated by lungs. **List of excipients:** Mannitol, corn starch, talc, magnesium stearate. **Composition of the capsule shell:** gelatin, iron oxide yellow (E172), titanium dioxide (E171). **Precautions special conservation:** Brown glass bottles: Store at a temperature not exceeding 25 °C. LEADIANT GmbH. LIEBHERRSTRASSE 22. 80538 MUNICH. GERMANY.

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