PRODUCT INFORMATION

NATULAN®

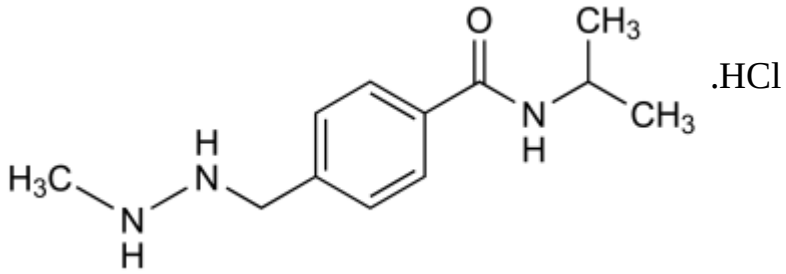
50 mg procarbazine (as hydrochloride)

Name of medicine:

The name of the medicine is procarbazine. Each capsule contains 50 mg procarbazine (as the hydrochloride)

Description:

Natulan contains the active component procarbazine (as the hydrochloride). Each capsule also contains purified talc, mannitol, titanium dioxide, iron oxide yellow, maize starch, magnesium stearate and gelatin.



Chemical Name:
N-1(1-Methylethyl)-4-[(2-methylhydrazino)methyl]benzamide monohydrochloride

Procarbazine hydrochloride is a white to pale yellow crystalline powder with a slight odor. It is sensitive to oxidation. It is very soluble in water and methanol and freely soluble in chloroform and diethyl ether.

Cas No. 366-70-1

Emperical Formulae: $C_{12}H_{19}N_3O.HCl$

MW: 257.59

Actions:

Natulan is a derivative of methylhydrazine with cytostatic properties.

Indications:

Treatment of Hodgkin's disease (multiple lymphadenoma); treatment of other malignant lymphomas including lymphosarcoma, reticulosarcoma, Brill-Symmers disease. Natulan is dissimilar to other cytostatic agents and may be effective in cases resistant to other drugs and X-rays.

Contra-indications:

Pre-existing leucopenia or thrombocytopenia; severe hepatic or renal damage; If allergic skin reactions occur, treatment must be stopped.

Use in Pregnancy:

Category D. Contra-indicated.
Australian categorisation definition of:
Category D:
Drugs which have caused, are suspected to have caused or may be expected to cause, an increased incidence of human foetal malformations or irreversible damage. These drugs may also have adverse pharmacological effects. Accompanying text above should be consulted for further details.

Precautions:

Bone marrow depression may occur and frequent blood counts are advisable. If allergic skin reactions occur, treatment should be interrupted. Intolerance to alcohol may develop and abstinence may be advisable during therapy.

Adverse Reactions:

Gastrointestinal upsets and bone marrow depression are most prominent. Anorexia and nausea occur in most cases, sometimes with vomiting; these symptoms are usually confined to the first few weeks of treatment. Leucopenia and thrombocytopenia are almost always reversible and seldom require complete cessation of therapy. Alopecia may occur, this is reversible in the majority of cases. There have also been reports of neurological disorders (headache, paresthesias, neuropathy and ataxia), disturbances of liver function (cholestatic jaundice) and allergic skin reactions (rash, urticaria, pruritus) and azoospermia.

Interactions:

Natulan is a weak MAOI; it may thus potentiate barbiturates, and sympathomimetic and psychotropic agents.

Patients should be advised to avoid cheese and other foods high in sympathomimetic amines during treatment. Patients may become intolerant to alcohol, and abstinence is advised during the course of therapy.

Dosage and Administration:

Initial dosage: Natulan is given by mouth, initially in small doses which are increased gradually to a maximum of 250 to 300 mg daily. Dosage is 50 mg on the first day, increasing by 50 mg daily up to 250 to 300 mg daily after 5 or 6 days. Dosage is maintained at this level until the greatest possible remission has occurred.

If during this time, leucopenia of about 3, 000/mm^3 or thrombocytopenia of about 80, 000/mm^3 occurs, treatment should be suspended until leucocyte and platelet levels recover and then recommenced.

Maintenance dosage: 50 to 150 mg daily until a total dose of 6 g has been given. Otherwise a negative result is not significant.

Presentation and Storage:

Each capsule contains 50 mg procarbazine (as the hydrochloride) Store below 30°C in a dry place
Shelf life 3 years.
Capsules, 50 mg, (pale yellow): Bottle of 50 capsules.

Natulan also contains: mannitol, maize starch, purified talc, magnesium stearate, iron oxide yellow, titanium dioxide and gelatin.

Name and Address of the Sponsor:

Link Medical Products Pty. Ltd.
5 Apollo Street,
Warriewood,
NSW 2102,
Australia

Poisons Schedule of the Medicine:

Schedule 4

AUST R 13752

Date of First Inclusion in the Australian Register of Therapeutic Goods:

October 1995

Date of Most Recent Amendment:

26 September 2012