DP SPECIAL STORAGE CONDITIONS
Keep away from light.
After opening: 15 days

MA 338 618.7 (1961, approved in 1997)
PRICE: 13.00 F (10ml bottle).
65% Social Security reimbursement.
License holder: Ciba Vision Ophthalmics
Distributor:

Laboratoires THÉA
12, rue Louis-Blériot, ZI du Brézet, BP 72 Saint-Jean 63016 Clermont-Ferrand Cedex 1
Pharmacovigilance:
Tel. 04 73 98 14 36 Fax: 04 73 98 14 38
Medical information:
PHARMATHÉA
12, rue Louis-Blériot, ZI du Brézet, BP 84, Saint-Jean 63016 Clermont-Ferrand Cedex 1
Tel. 04 73 98 73 00 Fax: 04 73 98 73 09

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*VITAMINS B_1-B_6 ROCHE
Thiamine, Pyridoxine

FORMS and PRESENTATIONS
(White) coated tablet: Tubs of 20 and 40.
Hospital Pack: Box of 100

COMPOSITION	per tablet	per tub of 20	per tub of 40
Thiamine (ICD) or vitamin B_1.....	250mg	5g	10g
Pyridoxine (ICD) Hydrochloride or vitamin B_6.....	35mg	700mg	1.4g

Excipients: *Core:* mannitol, povidone K90, talc, magnesium stearate. *Shell:* hypromellose 2910/6 cP, aqueous dispersion of ethylcellulose 30%, macrogol 6000, talc, titanium dioxide (E 171).

DC INDICATIONS
Adjunctive treatment of functional asthenia.

DC DOSAGE and METHOD OF ADMINISTRATION
For adults only.
1 to 4 tablets daily, spread throughout the day. The tablets should be swallowed, without chewing, with a glass of water.
The duration of treatment will be limited to 4 weeks.

DC CONTRAINDICATIONS
- Hypersensitivity to one of the constituents of the tablet.

– Levodopa (see Interactions).

DC INTERACTIONS

Contraindicated combination:

- Levodopa: inhibition of the activity of Levodopa when it is used without a peripheral dopadecarboxylase inhibitor. Avoid any intake of pyridoxine in the absence of dopadecarboxylase inhibitor.

DC PREGNANCY and BREASTFEEDING

Pregnancy:

The presence of vitamin B_1 governs the prescription of this medication in the event of pregnancy. There are no reliable data on teratogenesis in animals. To date, in clinical practice, no particular malformative of fetotoxic effect has been observed. However, the monitoring of pregnancies exposed to this medication is insufficient to exclude all risk. Consequently, as a precaution, this medication should preferably not be used during pregnancy.

Breastfeeding:

In the absence of data, to be avoided during breastfeeding.

DC UNDESIRABLE EFFECTS

Linked to vitamin B_6:

Exceptional neurological manifestations, reversible once treatment has been stopped, have been reported after high doses and/or during prolonged treatment with vitamin B_6.

PP PHARMACODYNAMICS

For antiasthenic use (A: digestive system and metabolism). Oral intake of thiamine hydrochloride (vitamin B_1) and pyridoxine hydrochloride (vitamin B_6).

PP PHARMACOKINETICS

B vitamins are absorbed through the intestine. Elimination is urinary in the form of metabolites.

MA 311 398.6 (1960, approved in 1997) 20 tablets
329 569.7 (1987, approved in 1997) 40 tablets
553 308.9 (1992, approved in 1997) 100 tablets

Indicative PRICE: 29.80 F (20 tablets)
56.20 F (40 tablets)

No Social Security reimbursement. Collect. (100 tablets).

Co-holders of MA: Produits Roche and Laboratoires Roche Nicholas SA.

PRODUITS ROCHE
52, bd du Parc, 92521 Neuilly-sur-Seine cedex
Tel. 01 46 40 50 00

***VITAMINE B_6 RICHARD ®**

See:
SUPPLEMENTARY SPECIFICATIONS

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*VITAMINE B_{12} AGUETTANT ®

FORMS and PRESENTATIONS

100 µg/ml Intramuscular injectable and oral solution: 1ml (glass) vials, box of 100.
1,000 µg/2ml Intramuscular injectable and oral solution: 2ml (glass) vials, box of 100.

COMPOSITION

Per vial:	1ml	2ml
Cyanocobalamine (ICD) or vitamin B_{12}.....	100*µg*	1,000*µg*

Excipients: sodium chloride, concentrated hydrochloric acid qs, pH 4 to 5.5, WFI

DC INDICATIONS

Intramuscular injectable route:
Proven vitamin B_{12} deficiencies due to an absorption defect: Biermer's disease, total gastrectomy, resection of the terminal ileum and Imerslund's disease.
Oral route:
Anaemia due to lack of vitamin B_{12} through food intake observed in those who have been strict vegans for more than 4 years.

DC DOSAGE and METHOD OF ADMINISTRATION

Dosage:
Vitamin B_{12} deficiencies due to an absorption defect (intramuscular injectable route).

- Initial treatment: 1mg (one 1,000µg vial) per day or three times per week by intramuscular injection, i.e. 10mg (10 x 1,000µg vials) in total.
- Maintenance treatment: one 100µg vial by intramuscular injection per month.

Anaemia due to lack of vitamin B_{12} through food intake observed in strict vegans (oral route).

- Initial treatment: 1 x 1,000µg vial or 2 x 100µg vials per day for 15 days to 1 month.
- Maintenance treatment: 1 x 1,000µg vial or 2 x 100µg vials every 10 days.

Method of administration:
Pour the contents of the vial into a glass of water.

DC CONTRAINDICATIONS

- History of allergy to cobalamins (vitamin B_{12} and related substances)
- Malignant tumor: due to the action of vitamin B_{12} on the growth of tissues with a high rate of cellular multiplication, the risk of exacerbation must be taken into account.

DC UNDESIRABLE EFFECTS

- Allergic reactions: pruritus, urticaria, eczema, erythema and oedema that may be severe: anaphylactic shock, cutaneous necrosis or Quincke's oedema
- Risk of acne
- Possibility of pain at the injection site
- Red coloration of urine (corresponding to the urinary elimination of vitamin B_{12}).

DC OVERDOSE

There is no B_{12} hypervitaminosis

PP PHARMACODYNAMICS

Antianemic, vitamin B_{12} (B: blood and hematopoietic organs).
Cyanocobalamine: hematopoietic factor

PP PHARMACOKINETICS

Vitamin B_{12} is absorbed through the terminal ileum, after an enterohepatic cycle, by two mechanisms: a passive mechanism when the quantities are large and an active mechanism that allows the absorption of physiological doses and for which the presence of the intrinsic factor is essential.
It is carried through the bloodstream by transcobalamins.
The serum peak is reached one hour after intramuscular injection.
Excretion is urinary at high doses and mainly biliary at low doses.

DP INCOMPATIBILITIES

The pH stability of vitamin B_{12} is 3.8 to 5.5.

DP SPECIAL STORAGE CONDITIONS

To be kept away from light.

MA 553 755.5 (1963, approved in 1996, rev. 1997) 100 X 1ml vials
553 756.1 (1963, approved in 1996, rev. 1997) 100 X 2ml vials
Only available from hospital pharmacies. Collect.

Laboratoire AGUETTANT
1, rue Alexander-Fleming
69007 Lyon Tel: 04 78 61 51 41

***VITAMINE B_{12} ALLERGAN ®**
cyanocobalamine

FORMS and PRESENTATIONS

0.5% collyrium: 5ml (PE) bottle

COMPOSITION

	per 100ml	*per bottle*
Cyanocobalamine (ICD).....	50mg	2.5mg

Excipients: sodium chloride, benzododecinium bromide, sodium edetate, sodium hydroxide or hydrochloric acid, purified water.

DC INDICATIONS
Adjunctive treatment for corneal scarring disorders.

DC DOSAGE and METHOD OF ADMINISTRATION
[illegible]

DC CONTRAINDICATIONS
Hypersensitivity to one of the ingredients of the product.

DC WARNINGS and PRECAUTIONS FOR USE
Due to the coloration of the Vitamine B_{12} Allergan collyrium and the presence of preservative, do not wear contact lenses throughout the duration of the treatment.
In the event of concomitant treatment with another collyrium, wait 15 minutes between the two instillations.
Do not touch the eye with the nozzle of the bottle.
Replace the cap on the bottle after use.

DC UNDESIRABLE EFFECTS
Possibility of allergic reactions.

PP PHARMACODYNAMICS
Medication for ophthalmic use and curative therapy.
(S: sense organs).

DP SPECIAL STORAGE CONDITIONS
After opening: use within 30 days

MA 311 343.7 (1961, approved in 1997)
PRICE: 14.00 F (5ml bottle).
65% Social Security reimbursement.

Laboratoires ALLERGAN FRANCE SA
PO Box 442, Sophia Antipolis, 06251 Mougins Cedex
Tel. 04 92 92 44 00

VITAMINE B_{12} DELAGRANGE ®
cyanocobalamine

FORMS and PRESENTATIONS
1000 µg [illegible] oral solution and by intramuscular injection [illegible]
2ml vials, box of 6.

COMPOSITION

DOCKET ALARM

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