本說明書請與藥劑一同保管，
使用時請仔細閱讀。

Santen

散克巴®點眼液

Sancoba® ophthalmic solution

Cyanocobalamin 點眼液

衛署藥輸字第001973號　醫師藥師藥劑生指示藥品

發現存於肝臟之抗貧血因子；Vitamin B_{12}（Cyanocobalamin）隨近來研發之成效，其物質代謝之生化學性作用越為明瞭，因而在臨床應用上適應症遍及多元化。由於 Vitamin B_{12} 特別與神經組織有親和性。本劑係將 Vitamin B_{12}（Cyanocobalamin）製成點眼劑，藉由 Vitamin B_{12}（Cyanocobalamin）之點眼投與改善調節功能[1]，特別對調節性眼睛疲勞發揮藥效。另外，家兔研究試驗中，投與輔酵素型維生素 B_{12}（Coenzyme Vitamin B_{12}）可增加視網膜含氧量[2]。

成分／有效成分含量

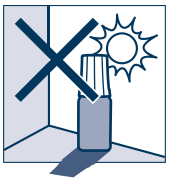
成　分	含　量	作　用
維生素B_{12}(Cyanocobalamin)	0.02%	緩解眼睛疲勞

其他成分（賦形劑）：氯化苯二甲烴銨（Benzalkonium Chloride）、硼酸（Boric Acid）、pH調節劑（Sodium Borate）、純水（Purified Water）。

用途（適應症）

眼睛疲勞。

使用上注意事項



1. 有下列情形者，請勿使用：
   曾因本藥成分引起過敏的人。
2. 有下列情形者，使用前請洽醫師診治：
   正在接受醫師治療或醫師處方眼藥的人。
3. 其他使用上注意事項：
   (1) 為防止兒童誤食請妥善保管。
   (2) 避免陽光直射。
   (3) 使用前，請洗淨雙手。
   (4) 請依照藥品標示使用。
   (5) 以下情形，請勿繼續使用：
      1.超過保存期限的眼藥水。
      2.開瓶30天後。
      3.藥液混濁、變色或出現異物時。
   (6) 為避免污染藥品，使用時勿碰觸藥瓶瓶口，並避免與他人共用，或以其他容器盛裝。
   (7) 如需同時使用兩種以上眼藥時，請依下列方式使用，以免影響藥效：
      1.使用眼藥水與眼藥膏時，請先使用藥水，間隔10分鐘以上再用藥膏。
      2.使用兩種眼藥水時，建議間隔5分鐘以上。
   (8) 配戴隱形眼鏡時，請勿使用含防腐劑及含懸浮液之眼藥水。

接背面

得意先	参天製薬
品名	サンコバ点眼液（台湾）添付文書
部品	本体　表
寸法	254×110
版式	オフ
文字	29.06.06
赤ケイ	29.06.06
訂正　大江	29.08.31
0000000 台湾	01

用法用量

一天3至4次	每次1至2滴

警 語

1.使用本藥後，若有發生以下症狀時，請立即停止使用，並接受醫師診治：
(1)連續使用三天（或72小時）症狀沒有改善。
(2)使用後產生眼睛劇痛、持續視力模糊或眼睛持續發紅、腫、熱、刺激感。
(3)若有任何不適情況產生。
(4)發生過敏反應。

〔主要文獻〕
1) 鈴村昭弘：日本眼科紀要28,340（1977）
2) 手島仁：日本眼科學會雜誌73,1711（1969）

包 裝

100毫升以下塑膠瓶裝

儲存條件

避免日光、螢光燈直射，30℃以下儲存

2016年10月

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消費者服務熱線 02-2567-8603

SK·TWN

得意先 参天製薬
品名 サンコバ点眼液(台湾)添付文書
部品 本体 ウラ
寸法 254×110 版式 オフ
文字 29.06.06
赤ケイ 29.06.06
訂正 大江 29.08.31
0000000 台湾 01

**Revised: July 2013 (5th version, change of storage condition)
*Revised: December 2007

Standard Commodity Classification No. of Japan
871319

- OPHTHALMIC PREPARATION FOR IMPROVING ACCOMMODATION FUNCTION -

Sancoba® ophthalmic solution 0.02%

< Cyanocobalamin ophthalmic solution >

****Storage :** Store at room temperature in a tight container.
Expiration date : Indicated on the package and label. (3 years)

Approval No.	21900AMX00021000
Date of listing in the NHI reimbursement price	June 2007
Date of initial marketing in Japan	June 1967
Date of latest reevaluation	February 1979

DESCRIPTION

Brand name	Sancoba ophthalmic solution 0.02%
Active ingredient	Cyanocobalamin
Content per mL	0.2mg
*Inactive ingredient	Benzalkonium chloride, boric acid and sodium borate
pH	5.5 - 6.5
Osmotic pressure ratio	About 1
Description	Clear, red sterile aqueous ophthalmic solution

INDICATIONS

Improvement of fluctuation of accommodation in accommodative asthenopia

DOSAGE AND ADMINISTRATION

Usually, apply 1-2 drops a time to the eye, 3-5 times daily. The dosage may be adjusted according to the patient's symptoms.

PRECAUTIONS

1. Adverse Reactions

The incidence of adverse reactions of this drug has not been investigated in surveys such as drug use investigation.

If the following adverse reaction is observed, appropriate measures such as discontinuing administration should be taken.

	Incidence unknown
Hypersensitivity	Hypersensitivity symptom

2. Precautions concerning Use

1) Route of administration: Ophthalmic only
2) At the time of administration: Instruct the patient to be careful not to touch the tip of the bottle to the eye directly in order to avoid the contamination of the drug.

PHARMACOKINETICS[1)]

Intraocular distribution

(rabbits)

Labeled cyanocobalamin was instilled into the eyes of rabbits 15 times every 2 minutes to the total amount of 0.3mL. The penetration rates of cyanocobalamin into ocular tissues immediately after and 1 hour after the last instillation were as follows.

	Immediately after (%)	1 hour after (%)
Conjunctiva	1.286	0.132
Cornea	0.156	0.115
Sclera (ciliary region)	0.097	0.033
Posterior sclera	0.212	0.027
Anterior aqueous humor	0.008	0.015
Crystalline lens	0.007	0.008
Iris	0.015	0.022
Ciliary body	0.045	0.036
Vitreous body	0.007	0.013
Retinochoroid	0.013	0.011

CLINICAL STUDIES

The effectiveness rates of this drug were evaluated in 972 patients with asthenopia. In 608 patients with accommodative asthenopia, the effectiveness rate in the group under the monotherapy of this drug was 66.1% (162/245), and that under the combination therapy (mainly with oral vitamin B_1 or ATP preparations) was 62.5% (227/363) [2)].

The efficacy of this product on accommodative asthenopia was evaluated in a placebo-controlled double-blind study. The results demonstrated statistically significant difference in efficacy between this product and placebo, especially in fine fluctuations of accommodation, and significant superiority of this product to placebo in usefulness evaluation [3)].

PHARMACOLOGY

1. Improvement in accommodation function[4)]

The effect of this drug on accommodation function in patients with accommodative asthenopia was investigated in a double blind study.

The group with this drug administered showed a tendency of improvement in the accommodation time and accommodation movements, and significant improvement in fine fluctuations of accommodation compared with that of the placebo group.

2. Promotion of tissue respiration

(albino rabbits <in vitro>, rats <in vitro/ in vivo>)

When cobamamide (coenzyme vitamin B_{12}) at concentrations of 0.0025, 0.025, 0.1, 0.5, 5.0, 10.0, 50.0 and 100.0 μg/mL was added to the retinal suspension of albino rabbits, the retinal oxygen consumption increased in a concentration-dependent manner[5].

Cyanocobalamin increased the oxygen consumption in the skeletal muscle of rats both in vitro and in vivo, and restored the lowered tissue respiration in the denervated atrophy muscle of rats. Combination of cyanocobalamin and AMP resulted in more production of ATP in the muscle and the eyeball than single administration of AMP [6].

3. **Effect on nerve conduction [7), 8)]**

(frogs･albino rabbits<in vitro>)

The effect of coenzyme vitamin B_{12} (or methylcobalamin) on nerve conduction was investigated using the sciatic nerve of frogs and rabbits in vitro. At low concentrations, hyperpolarized cell membrane and increased amplitude of action potentials were observed, while at high concentrations membrane depolarization and deareased amplitude of action potentials were found. At much higher concentrations the depolarization resulted in interruption of nerve conduction. However, it was suggested that nerve excitability was increased and the refractory period was shortened when the membrane depolarization remained below the threshold for generating action potential.

PHYSICOCHEMISTRY

Nonproprietary name:

Cyanocobalamin

Chemical name:

Co α -[α -(5,6-Dimethylbenzimidazolyl)]-Co β -cyanocobamide

Structural formula:

Molecular formula:

$C_{63}H_{88}CoN_{14}O_{14}P$

Molecular weight:

1355.37

Description:

Cyanocobalamin occurs as dark red crystals or powder. It is sparingly soluble in water, slightly soluble in ethanol, and practically insoluble in ether. It is hygroscopic.

PACKAGING

5mL : Boxes of 10 and 50 plastic bottles

REFERENCES

1) Tsutsui, J., et al.: Folia Ophthalmol. Jpn., **18**, 1156 (1967)
2) Suzumura, A.: Jpn. Rev. Clin. Ophthalmol., **70**, 36 (1976)
3) Yamaji, R., et al.: Jpn. J. Clin. Ophthalmol., **32**, 1013 (1978)
4) Suzumura, A.: Folia Ophthalmol. Jpn., **28**, 340 (1977)
5) Tejima, H.: J. Jpn. Ophthalmol. Soc., **73**, 1711 (1969)
6) Chiba, T., et al.: Effect of an AMP/cyanocobalamin preparation on oxygen consumption in rat muscle. (Santen Internal Report)
7) Takeshige, C., et al.: Vitamins, **44**, 272 (1971)
8) Takeshige, C., et al.: Vitamins, **50**, 251 (1976)

REQUEST FOR LITERATURE SHOULD BE MADE TO:

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