

## BOMITIS®

**Để xá tám tay trẻ em.**  
**Đọc kỹ hướng dẫn sử dụng trước khi dùng.**  
**Thiếu này chỉ dùng theo đơn thuốc.**

### THÀNH PHẦN CÔNG THỨC THUỐC

Mỗi viên nang mềm chứa:

Thiếu phần hoạt chất:

Isotherapy

Thảo dược:

Thảo dược: dầu lecithin, dầu cọ, sáp ong trắng, gelatin, glycerin đậm đặc, D-sorbitol 70%, ethyl vanillin, oxyd sắt đỏ, oxyd sắt đen, oxyd sắt vàng, titan dioxyd, nước tinh khiết.

20 mg

### DANG BAO CHÉ

Bệnh nhân:

Trẻ em:

Thảo dược:

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**Keep out of reach of children.**  
**Read insert paper carefully before use.**  
**This drug is only used under physician's prescription.**

◆ **COMPOSITION**

Each soft capsule contains:

**Active ingredient:** Isotretinoin 20 mg

**Inactive ingredients:**

Corn oil, lecithin oil, palmitic, white beeswax, gelatin, concentrated glycerin, D-sorbitol 70%, ethyl vanillin, red ferric oxide, black ferric oxide, yellow ferric oxide, titanium dioxide, purified water.

◆ **PACKAGING FORM**

Yellow substance in oral soft capsule with one side of cap is brown and other side is white.

◆ **INDICATIONS**

Isotretinoin is indicated for the treatment of severe forms of acne (such as nodular or conglobate acne or acne at risk of permanent scarring), resistant to adequate courses of standard therapy with systemic antibiotics and topical therapy.

◆ **DOSAGE AND ADMINISTRATION**

Isotretinoin should be taken orally, under the supervision of physicians with expertise in the use of systemic retinoids for the treatment of severe acne and a full understanding of the risks of isotretinoin therapy and monitoring requirements.

The capsules should be taken without food or twice daily.

**Additional information adolescents and the elderly:**

Isotretinoin therapy should be started at a dose of 0.5 mg/kg daily. The therapeutic response to isotretinoin and some of the adverse effects are dose-related and vary between patients. This necessitates individual dosage adjustment during therapy. For most patients, the dose ranges from 0.5 to 1.0 mg/kg per day.

Length of remission and relapse rates are more closely related to the total dose administered than to either duration of treatment or daily dose. It has been shown that no substantial additional benefit is to be expected from a cumulative treatment dose of 120-150 mg/kg. The duration of treatment will depend on the individual daily dose. A treatment course of 16-24 weeks is normally sufficient to achieve remission.

In the majority of patients, complete clearing of the acne is obtained with a single treatment course. In those of a defined relative risk of developing acne, isotretinoin therapy may be considered using the same daily dose as the maintenance dose. As further improvement of the acne can be expected up to 8 weeks after discontinuation of treatment, a further course of treatment should not be considered until at least this period has elapsed.

**Patients with renal insufficiency:**

In patients with severe renal insufficiency treatment should be started at a lower dose (e.g. 0.10 mg/day). The dose should then be increased up to 1 mg/kg/day or until the patient is receiving the maximum tolerated dose.

**Children:**

Isotretinoin is not indicated for the treatment of prepubertal acne and is not recommended in patients less than 12 years of age.

**Patients with intolerance:**

In patients who show severe intolerance to the recommended dose, treatment may be continued at a lower dose with the consequences of a longer therapy duration and a higher risk of relapse. In order to achieve the maximum possible efficacy in these patients the dose should normally be continued at the highest tolerated dose.

◆ **CONTRAINDICATIONS**

Isotretinoin is contraindicated in women who are pregnant or breastfeeding.

Isotretinoin is also contraindicated in patients with hypersensitivity to isotretinoin or to any component of the drug.

Isotretinoin is also contraindicated in patients:

- With hepatic insufficiency.

- With excessively elevated blood lipid values.

- With hypervitaminosis A.

- During concurrent treatment with tetracyclines.

◆ **WARNINGS AND PRECAUTIONS FOR USE**

**Pregnancy:**

Teratogenicity of isotretinoin is very high. Therefore, isotretinoin must not be taken by females who are pregnant or who may become pregnant while undergoing treatment. Although isotretinoin is female sexed to isotretinoin is not recommended in women of childbearing potential.

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