Summary Public Assessment Report

Generics

BEOTEBAL 5 mg tablets
BEOTEBAL 10 mg tablets
biotin

SK/H/0318/001-002/DC

Date: 22.10.2025

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Generics

BEOTEBAL 5 mg tablets
BEOTEBAL 10 mg tablets

Biotin, tablets, 5 mg, 10 mg

This is a summary of the public assessment report (PAR) for BEOTEBAL 5 mg and BEOTEBAL 10 mg. It explains how BEOTEBAL 5 mg and BEOTEBAL 10 mg were assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use BEOTEBAL 5 mg and BEOTEBAL 10 mg.

For practical information about using BEOTEBAL 5 mg and BEOTEBAL 10 mg, patients should read the package leaflet or contact their doctor or pharmacist.

What is BEOTEBAL 5 mg and BEOTEBAL 10 mg and what is it used for?

BEOTEBAL 5 mg and BEOTEBAL 10 mg are 'generic medicines'. This means that BEOTEBAL 5 mg and BEOTEBAL 10 mg are similar to a 'reference medicine' already authorised in the European Union (EU) called Biotebal MAX and Biotin Polpharma.

BEOTEBAL 5 mg and BEOTEBAL 10 mg are used in the treatment of biotin deficiency in adults with symptoms such as: hair loss, hair and nail growth disorders and their excessive fragility, inflammation of the skin located around the eyes, nose, lips and ears, and prevention of its sequelae, after other causes have been ruled out by a doctor

How does BEOTEBAL work?

BEOTEBAL contains biotin in the form of d-biotin, the only biologically active isomer of biotin (d-Biotin isomer). Biotin contained in it is a water-soluble vitamin, part of the B group of vitamins.

Biotin enhances the formation of keratin - a protein that builds the structure of hair, skin and nails. In this way, biotin improves appearance and condition of hair, nails and skin. Improvement of symptoms is observed after approximately 4 weeks of use.

You must talk to a doctor if you do not feel better or if you feel worse after 4 weeks.

How is BEOTEBAL used?

The pharmaceutical form of BEOTEBAL is tablet and the route of administration is oral (through mouth).

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

Adults: 5 mg to 10 mg daily.
The usual recommended dose is 5 mg per day or, for severe symptoms, 10 mg per day.

Children and adolescents
BEOTEBAL is not recommended due to insufficient data.

The duration of treatment depends on the patient's condition and disease course. Improvement of symptoms is observed after approximately 4 weeks of use.
You must talk to a doctor if you do not feel better or if you feel worse after 4 weeks.
Do not use this product for more than 6 weeks without medical advice. If you wish to continue with the treatment, consult a doctor.

The medicine can be obtained without a prescription.

What benefits of BEOTEBAL have been shown in studies?

Because BEOTEBAL is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Biotebal Max and Biotin Polpharma. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of BEOTEBAL?

Because BEOTEBAL is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.
For the full list of restrictions, see the package leaflet.

Why is BEOTEBAL approved?

It was concluded that, in accordance with EU requirements, BEOTEBAL has been shown to have comparable quality and to be bioequivalent to reference medicine. Therefore, the SIDC decided that, as for reference medicines called Biotebal Max and Biotin Polpharma, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of BEOTEBAL?

A risk management plan has been developed to ensure that BEOTEBAL is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for BEOTEBAL, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about BEOTEBAL

The marketing authorisations for BEOTEBAL 5 mg tablets and BEOTEBAL 10 mg tablets were granted on 26.02.2025.

The full PAR for BEOTEBAL 5 mg tablets and BEOTEBAL 10 mg tablets can be found on the website. For more information about treatment with BEOTEBAL 5 mg tablets and BEOTEBAL 10 mg tablets, read the package leaflet (*link*) or contact your doctor or pharmacist.

This summary was last updated in 22-10-2025.