

Betula verrucosa for treating moderate to severe allergic rhinitis or conjunctivitis caused by tree pollen

Technology appraisal guidance

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www.nice.org.uk/guidance/ta1087

Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should [assess and reduce the environmental impact of implementing NICE recommendations](#) wherever possible.

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1 Recommendation

- 1.1 Betula verrucosa can be used as an option to treat moderate to severe allergic rhinitis or conjunctivitis caused by pollen from the birch homologous group of trees in adults with:
- symptoms despite using symptom-relieving medicines
 - a positive sensitisation test (skin prick test or specific immunoglobulin E) to a member of the birch homologous group.

What this means in practice

Betula verrucosa must be funded in the NHS in England for the condition and population in the recommendation, if it is considered the most suitable treatment option. Betula verrucosa must be funded in England within 90 days of final publication of this guidance.

There is enough evidence to show that betula verrucosa provides benefits and value for money, so it can be used routinely across the NHS in this population.

NICE has produced [tools and resources to support the implementation of this guidance](#).

Why the committee made these recommendations

For this evaluation, betula verrucosa was considered only for use in adults. This does not include everyone who it is licensed for.

Usual treatment for moderate to severe allergic rhinitis and conjunctivitis caused by pollen from the birch homologous group of trees includes symptom-relieving medicines such as antihistamine tablets and corticosteroid nasal sprays.

Clinical trial evidence shows that betula verrucosa reduces the severity of allergic rhinitis and conjunctivitis symptoms compared with placebo (both when given with symptom-

relieving medicines).

There is uncertainty in the economic model about how many healthcare appointments would be saved by using betula verrucosa. But even when taking this into account, the likely cost-effectiveness estimates are all within the range that NICE considers an acceptable use of NHS resources. So, betula verrucosa can be used.

For all the evidence, see the [committee papers](#). For more information on streamlined evaluations, see [NICE's manual on health technology evaluations](#).

2 Information about betula verrucosa

Marketing authorisation indication

- 2.1 Betula verrucosa (Itulazax 12 SQ-Bet, Alk-Abelló) is indicated 'in adults and children (5 years or older) for the treatment of moderate-to-severe allergic rhinitis and/or conjunctivitis induced by pollen from the birch homologous group. Itulazax is indicated in patients with a clinical history of symptoms despite use of symptom-relieving medication and a positive test of sensitisation to a member of the birch homologous group (skin prick test and/or specific IgE)'.

Dosage in the marketing authorisation

- 2.2 The dosage schedule is available in the [summary of product characteristics for betula verrucosa](#).

Price

- 2.3 The list price of betula verrucosa is £80.12 per pack of 30 tablets (excluding VAT; company submission).
- 2.4 Costs may vary in different settings because of negotiated procurement discounts.

Carbon Reduction Plan

- 2.5 For information, Alk-Abelló did not disclose its Carbon Reduction Plan for UK carbon emissions.

3 Implementation

- 3.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 90 days of its date of publication.
- 3.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 60 days of the first publication of the final draft guidance.
- 3.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has moderate to severe allergic rhinitis, conjunctivitis, or both, caused by birch tree pollen and the healthcare professional responsible for their care thinks that betula verrucosa is the right treatment, it should be available for use, in line with NICE's recommendations.

4 Evaluation committee members and NICE project team

Evaluation committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered as a streamlined evaluation by the lead team of committee B, which includes the chair.

Committee members are asked to declare any interests in the technology being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

Chair

Dr Charles Crawley

Chair, technology appraisal committee B

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

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