

Diabec® (Alfa Intes): two studies confirm its efficacy and safety.

*Diabec® (Alfa Intes) is a nutraceutical based on **curcumin delivered in a hydrophilic carrier**, that increases its bioavailability in the blood and retina. Two recent clinical studies (a single-centre prospective observational study and a multicentre randomised study) have confirmed the **efficacy and safety of the product** in combination with standard therapy both in cases of **uveitis aggravated by macular oedema** and in patients **with diabetic macular oedema**. In the first case, treatment in combination with standard therapy, with curcumin in a hydrophilic carrier, resulted in a significant increase in corrected visual acuity (BCVA) after 6 and 12 months; in the second case, there was a greater reduction in the mean value of central retinal thickness (CRT) after 4 months, especially in patients suffering from diabetes for a period of 10 years or less.*

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Two recent clinical studies have confirmed **both the efficacy and safety** of using the curcumin-based nutraceutical (Diabec® Alfa Intes) in combination with standard therapy for the treatment of both non-infectious uveitis complicated by macular oedema and diabetic retinopathy with macular oedema.

Diabec® is a product with a patented formulation (CurcuWIN™) of curcumin in combination with a hydrophilic carrier and antioxidants of natural origin indicated for the treatment of inflammatory retinal diseases characterised by oedema.

Previous preclinical and clinical studies have shown that this formulation of curcumin in combination with a hydrophilic carrier, compared to other commercially available formulations, results in a high bioavailability of the active ingredient in the blood (46 times higher), which ensures its presence even in the retina.

The single-centre prospective observational study – Rapallo (Genoa)

The first prospective observational study, conducted **between January 2019 and May 2020** at the Centre for Infectious Eye Diseases of Rapallo Hospital (Genoa, Italy) on patients with macular oedema caused by non-infectious uveitis, showed that adjuvant curcumin-based treatment with a hydrophilic carrier can lead to a **more noticeable functional and anatomical improvement** than the use of standard steroid treatment alone.

To arrive at this result, **26 patients** with non-infectious uveitis complicated by macular oedema were **recruited**: one group of “eyes” was treated with standard therapy alone (control group); a second group was treated with standard therapy in combination with the **formulation of curcumin in a hydrophilic carrier** (Diabec®).

To establish the efficacy of the two different treatments, **Best Corrected Visual Acuity (BCVA)** values were measured as the **primary outcome**, and the reduction in Central Macular Thickness (**CMT**) was assessed at time zero, after 6 months and after 12 months for both groups.

The researchers recorded a **significant improvement in BCVA** after 6 and 12 months in the group with adjuvant treatment containing curcumin combined with the hydrophilic carrier, compared to the control patients treated with the standard treatment alone. In addition, only the group treated with Diabec® experienced a significant reduction in central macular thickness at 6 and 12 months compared with the initial value. Finally, no adverse events and side effects were recorded in either the control group or combination treatment group, demonstrating the **safety of using Diabec®**.

The multicentre, randomised controlled clinical trial

Understanding whether the combination of Diabec® with intravitreal dexamethasone injections was a promising therapeutic option in diabetic macular oedema was the aim behind a **second, multicentre study**, involving the Bietti Foundation in Rome, Humanitas in Milan and the University of Catanzaro.

To demonstrate that the combination of curcumin in a hydrophilic carrier (Diabec®) with intravitreal dexamethasone injections was able to **influence certain morphological characteristics** of the retina, 73 patients with diabetic macular oedema were recruited and divided into two groups: the control group (i.e. standard treatment with dexamethasone alone) and the group treated with **combined therapy with Diabec®** (1 capsule twice a day).

A number of parameters were assessed (at time 0 and for each month up to six months), including the mean change in **central retinal thickness (CRT)**, BCVA, the number of subsequent treatments and the time between treatments, and the safety profile of the product.

In both groups, the mean central retinal thickness decreased significantly with time compared to the initial value. However, at four months of therapy, there was a **significantly greater** anti-oedema effect (reduction in oedema) in the group treated with the oral nutraceutical in combination with the steroid administered by intravitreal injection. The effect was particularly noticeable in the group of patients with a more recent diabetic condition. Again, no adverse events were observed in this study.

Combination therapy based on oral curcumin in a hydrophilic carrier and IV injections of dexamethasone is therefore a promising therapeutic option for the treatment of diabetic macular oedema, particularly for those patients in whom the disease is at an early stage and who have an inflammatory phenotype.

Sources:

- *Allegri P, Rosa R, Masala A et al, Eur Rev Med Pharmacol Sci. 2022 Jan;26(1):46-53*
- *Parravano Mariacristina, Allegrini Davide, Carnevali Adriano et al, Frontiers in Pharmacology vol. 12, 2022*