European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

ZIMULTI

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is ZIMULTI?
ZIMULTI is a medicine containing the active substance rimonabant. It is available as white, teardrop-shaped tablets.

What is ZIMULTI used for?
ZIMULTI is used together with diet and exercise to treat adult patients:
- who are obese (very overweight) with a body mass index (BMI) greater than or equal to 30 kg/m²,
- who are overweight (with a BMI greater than or equal to 27 kg/m²) and also have other risk factors, such as type 2 diabetes or dyslipidaemia (abnormal levels of fat in their blood).

The medicine can only be obtained with a prescription.

How is ZIMULTI used?
ZIMULTI is taken as one tablet once a day before breakfast. The patients should also follow a reduced calorie diet and increase their level of physical activity. The medicine should not be used in patients who have severe problems with their liver or their kidneys.

How does ZIMULTI work?
The active substance in ZIMULTI, rimonabant, is a cannabinoid receptor antagonist. It acts by blocking a specific type of receptors, the cannabinoid type 1 (CB1) receptors. These receptors are found in the nervous system, and they are part of the system the body uses to control food intake. The receptors are also found in adipocytes (fat tissue).

How has ZIMULTI been studied?
The effects of ZIMULTI were first tested in experimental models before being studied in humans. Four studies of ZIMULTI in overweight and obese patients were carried out, involving almost 7,000 patients, whose weight at the start of the studies was on average 94 to 104 kg. One study looked more particularly at patients with abnormal levels of blood fat, and one at patients with type 2 diabetes. The studies compared the effect of ZIMULTI with that of a placebo (a dummy treatment) on weight loss over one to two years. One study also looked at how this loss could be maintained during the second year.

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Four studies of ZIMULTI as a help to stop smoking were also carried out in over 7,000 patients, comparing it with placebo, and measuring the effect of the medicine given for 10 weeks (one year in one of the studies) on smoking cessation, and on relapses in the following year.

What benefit has ZIMULTI shown during the studies?
After one year, all patients who received ZIMULTI lost more weight than those who received placebo: they lost on average 4.9 kg more than placebo, except in the study in diabetic patients, where the difference in the weight loss was 3.9 kg. The medicine also reduced the risk of regaining weight.
The studies in smoking cessation did not show consistent results, and the effect of ZIMULTI in this area was difficult to estimate. The company decided to withdraw its application for smoking cessation. Therefore, ZIMULTI is not recommended as an aid for smoking cessation

What is the risk associated with ZIMULTI?
During the studies, the most common side effects with ZIMULTI (seen in more than 1 patient in 10) were nausea (feeling sick) and infections of the upper respiratory tract. For the full list of all side effects reported with ZIMULTI, see the Package Leaflet.
ZIMULTI should not be used in patients who may be hypersensitive (allergic) to rimonabant or any of the other ingredients, or in women who are breast feeding. It must also not be used in patients with ongoing major depression or who are being treated with antidepressants, since it can increase the risk of depression, including thoughts about suicide in a small minority of patients. Patients who experience symptoms of depression should speak to their doctor and may need to stop treatment. Caution should be used when taking ZIMULTI with some medicines, such as ketoconazole or itraconazole (anti-fungal medicines), ritonavir (used in HIV infection), or telithromycin or clarithromycin (antibiotics).

Why has ZIMULTI been approved?
The Committee for Medicinal products for Human Use (CHMP) concluded that ZIMULTI had shown its effectiveness in weight reduction in obese or overweight patients with associated risk factors. The Committee decided that ZIMULTI's benefits are greater than its risks when used, in addition to diet and exercise, to treat obese patients and overweight patients with risk factors such as type 2 diabetes or dyslipidaemia. The Committee recommended that ZIMULTI be given marketing authorisation.

Which measures are being taken to ensure the safe use of ZIMULTI?
The company that makes ZIMULTI will put in place a programme to ensure that the medicine is used in patients who need it for health, rather than for cosmetic reasons, by providing educational packs for patients and doctors, and to monitor how the medicine is used. The company will use specific databases to monitor the side effects, especially those linked to the nervous system.

Other information about ZIMULTI:
The European Commission granted a marketing authorisation valid throughout the European Union for ZIMULTI to sanofi-aventis on 19 June 2006.

The full EPAR for ZIMULTI can be found here.

This summary was last updated in 10-2007.