Good afternoon, Mr. Chairman, ladies and gentlemen, it’s nice for me to be back in Lisbon again.

The last time I was here, I was doing my favourite hobby.
As Dr. Valovirta said in his previous presentation, the prevalence of allergy has been increasing in recent years.

For example, in this European Academy of Allergy campaign, it is stated that 1 in every 4 children is allergic, and children is the future! Therefore, the first thing we have to do to meet the patients needs is to perform allergy tests to diagnose them.
Once our patients have been diagnosed, they can be treated according to current therapeutic guidelines. For example, regarding allergic rhinitis, ARIA guidelines remind us pharmacotherapy should not only be safe and effective, but should also be easy to administer.
Patient-centred management in allergic rhinitis

- Guidelines provide the template for patient management

- Significant issues about how we meet patient needs
  - Adherence to treatment *
    - pharmaceutical formulation

- Patients are increasingly demanding in what they want and expect from their treatments
  - Efficacy
  - Tolerability
  - Convenience

In summary, guidelines provide the template for patient management, and this management should be patient-centred.

Despite the presence of these guidelines, there are still significant issues about how we meet patient needs.

For example, non-adherence, or non-compliance to treatment is an ongoing problem.

One area where adherence might be improved is pharmaceutical formulation.

Patients are increasingly demanding in what they want and expect from their treatments.

This is why treatments must meet patient needs.

For the management of allergic rhinitis efficacy is expected; good tolerability is expected.

New formulations provide the potential to offer the convenience that patients also want from their treatments.

This presentation will focus on the large studies that have assessed whether new Ebastine FDT meets those patient needs.


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As I have mentioned in the previous slide, I am going to speak to you about the new FDT formulation of ebastine.

But, first of all, it must be pointed out that the efficacy and safety of the new FDT formulation is the same as that of the traditional ebastine tablet.

To demonstrate the bioequivalence of the 2 formulations, this graph shows the results of 2 phase I, single dose, randomized, crossover bioequivalence studies of Ebastine 10 and 20 mg regular tablets versus 10 and 20 mg of fast-dissolving tablets performed in healthy volunteers.

You can see that the mean plasma concentrations of carebastine, the active metabolite of ebastine, did not significantly differ in the 2 formulations administered, independently of the dose (10 or 20 mg)
Going back to fulfilling patient needs, what we first need to know is what these needs are and which are the most important to the patient.

In a recent IMR study carried out in several European countries, patients and physicians were asked about what they considered to be the most relevant attributes required for an anti-H1.

It was found that the main characteristics demanded were:
- Efficacy, including a fast onset of action and a long term effect
- A safe side effects profile
- Once daily administration
- And easy to use

What can the new FDT improve with respect to other anti-H1 or formulations? I will focus on 2 of these attributes: fast onset of action and ease (is) of use, which are the characteristics which most differentiate the new FDT from the conventional ones.
To comment this characteristics, I will focus on 4 recent studies in which I have participated.

In this slide the first 2 references.
**Ebastine FDT studies**

**EMPRAE study**

**EUROPEAN PREFERENCE SURVEY**

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And in this slide, the other 2.  
Let’s have a look at them.
The first study was called Ebaflas (from Ebastel Flas).
The aim of the study was to evaluate the convenience of the new FDT formulation.
Convenience is defined as the quality of being suitable to one's comfort, purposes, or needs
Almost 3 thousand Spanish doctors assessed satisfaction with the new FDT formulation in more than 7600 adult patients
These patients had been diagnosed previously with rhinitis or urticaria or dermatitis. Rhinitis accounted for 71% of these diagnoses
The methodology used to evaluate patient convenience was a questionnaire
The degree of patient satisfaction with the FDT formulation, assessed by the physicians, was very high in general. For example, 95% of patients were quite or very satisfied with the disgregation time, 90% with the initial taste and 82% with the size of the tablet.
Likewise, the patients considered it to be quiet or very important that Ebastine FDT can be taken anytime and anywhere in 93% of the cases, that it leaves no residue in 93% of the cases, that the disgregation is fast in 91% and finally that it can be taken without water in 87% of the patients.
Here I present you the second study, an international market research.
The aim of the study was to evaluate formulation preferences.
This was a randomised, multicenter, crossover study carried out in Germany, Italy and Mexico
A total of 420 adult patients with AR were included, 70% having IAR and the remaining 30% PAR
These patients were given either placebo regular tablets or placebo FDT
The methodologies used to evaluate patient preference were:
- Multiple choice scoring system
- Visual analogue scores
- And spontaneous likes/dislikes
Professional interviewers made these assessments.
When patients were asked to rate specific attributes, they only had to choose which of the 2 formulations best fulfilled their needs, and FDT was clearly preferred.

-52% of the patients considered the size of the FDT tablet to be more suitable than the traditional formulation.

-84% of the patients found the taste of FDT to be much more pleasant.

-Almost 90% of the patients considered the FDT formulation suitable for taking without water.

-Along the same line, 87% stated that the new FDT was suitable for taking anywhere/anytime.

-Almost ¾ of the patients indicated that they preferred the FDT to carry about in the bag.

-Keeping in mind the different lifestyles of the patients, it’s important to underline that 3 out of 4 patients said that FDT suited their lifestyle.

-And lastly, and perhaps the most important from the physicians point of view, 77% of the patients considered that the FDT facilitated treatment compliance.
After asking the patients about these different specific attributes, the patients were also asked to give a global evaluation of the 2 formulations. The mean score for the FDT was 8.2 and for tablets was 7.
The third study, the EMPRAE study (Estudio de mercado retrospectivo sobre percepción rapidez de acción ebastina liofilizado oral) was designed to evaluate the perception of fast onset of action and satisfaction with the FDT. 100 adult patients with allergic rhinitis: 41% intermittent and 57% persistent were included in this multicenter Spanish study. Patients were recruited when they went to the pharmacy with a FDT prescription. Later a professional interviewer telephoned them. Patients were asked to evaluate the product characteristics compared to the previous experience with other antihistamines or formulations.
As you can see here, 10% of patients considered that FDT had a very fast onset of action and another 75% stated that the action was fast. Therefore we can say that 85% of patients felt that the new Ebastine FDT was a quick acting anti-H1.
If we focus the perception of the rapid onset of action on the most worrisome or predominant symptom, which may vary from patient to patient, 48% of the patients (the first 2 left bars) noticed alleviation within just 30 min, while another 33% of patients (the second 2 left bars) recognised improvement within 60 min.

In total 81% of patients felt better within the first hour.
On a scale from 1 to 10 rating overall satisfaction, 7 was considered the minimum level expressed by the patient to indicate satisfaction with the treatment.

Taking into account this rating, 96% of the patients felt satisfaction.

The mean score of the 100 patients included was 8.5

It is therefore not surprising that when patients were specifically asked, 98% were quite or totally interested in continuing to take Ebastine FDT.
Last, the fourth study, an European Market Research, was designed to know the strengths of the new FDT formulation.

This was a multicentre, questionnaire based study carried out in France, Germany, Belgium, Italy and Finland

A total of 60 adult allergic patients who regularly take anti-histamines (30 men and 30 women) and 82 physicians who were used to prescribing antihistamines (a mixture of specialists and GPs) were included in the study

All the subjects were given Placebo FDT
What does the new Ebastine FDT offer?

• **Strengths**
  – Fast Dissolving
  – Easy to use
  – No need for water
  – Pleasant taste
  – Easy to take around
    (good for acute allergies / active people)

• **Controversial Aspects**
  – Handling of the blister (not easy to open)
    Disappeared once subjects were instructed

The greatest strengths reported by both, patients and physicians, were:
- Fast dissolving
- Easy to use
- No need for water
- Pleasant taste
- And easy to take around, in special good for acute allergies and active people

On the other hand, the most commented controversial aspect was the handling of the blister (not easy to open), but this aspect disappeared once subjects were instructed how to do it.
FDT was preferred by the majority of both patients and physicians …

… Patients views on FDT were very similar to those of physicians interviewed.

75% of patients stated that the new formulation will improve their compliance

It is of mention that FDT was preferred by the majority of both patients and physicians and….

…. that patients views on FDT were very similar to those of physicians interviewed.

I will give you 3 specific data as examples of these remarks

Most patients (45 out of 60, 75%) considered that the new formulation can improve their compliance
Most of the patients preferred FDT: they will ask the doctor for FDT
The majority of physicians would be very likely to prescribe FDT

In this graph, it is shown, in white bars, the likelihood of patients for taking Ebastine FDT, and in orange bars, the likelihood of physicians for prescribing Ebastine FDT.

Although there was a high level of satisfaction with current antihistamine formulations, 78% (47 out of 60) of patients preferred the new FDT formulation, thus these patients indicated that they would definitely ask their doctor for FDT.

Similarly, the majority of physicians reported that it would be very likely that they would prescribe Ebastine FDT. You can see that on a scale from 0 to 10, the mean average for prescribing FDT in the different countries rates between 7.4 and 8.1.
The effect of formulation:  
FDT advantages


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Up to now, I have given you the Ebastine FDT studies that I wanted to present to you.

Now, 2 small reflexions to discuss the results presented.

First of all: Are the results you have listened in my speech in accordance with the medical literature?

These FDT formulation advantages should not surprise us, because prior to ebastine, other drugs have been developed in the same way.

The importance of not having to swallow and not needing water has been reported in several studies such as those cited here.
Second, I want to highlight this study comparing 5 new anti-histamines. It concluded that for the newer non-sedating anti-histamines, there appears to be no clinically relevant differences in activities (but let me say that it seems different after listening Dr. Valovirta presentation).

But, what’s more important to underline, the conclusions of this study end with the following phrase: preference of the patient may be one the most important factors in making a choice between these drugs.
Ebastine FDT meets patients needs

- Same efficacy and safety profile as Ebastine regular tablets
- Improved formulation preferred by patients and physicians:
  - Ease of use and easy to take around
  - No need for water
  - Perception of rapid onset of action
  - Desire to continue or start with Ebastine FDT

Improved treatment compliance, and thus improve management

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To conclude, we can state that Ebastine FDT meets patients needs. Ebastine FDT possesses the same efficacy and safety profile as traditional Ebastine regular tablets. This improved formulation is preferred by both, patients and physicians. Pan European studies have consistently shown that Ebastine FDT’s key attributes include:
- Ease of use and easy to take around
- No need for water
- Perception of rapid onset of action
- And desire to continue or start with Ebastine FDT
So, by meeting patient’s needs, Ebastine FDT offers the opportunity to improve treatment compliance, and thus improve management.
Remember …..

The main objective of medical practice is to ensure that the quality of life of our patients is not affected by the disease itself or the treatments we prescribe.

We need to offer patients treatments that they prefer and that can help to improve their quality of life.

..... meeting patient´s needs

Dr Roger
Marzo 2006

And last, but not least, remember that the main objective of medical practice is to ensure that the quality of life of our patients is not affected by the disease itself or the treatments we prescribe.

So, we need to offer patients treatments that they prefer and that can help to improve their quality of life.

Doctors, you can make such things happen ….... just by thinking about meeting patient´s needs.

Thank you for your kind attention.

Moito obrigao per la sua atencio