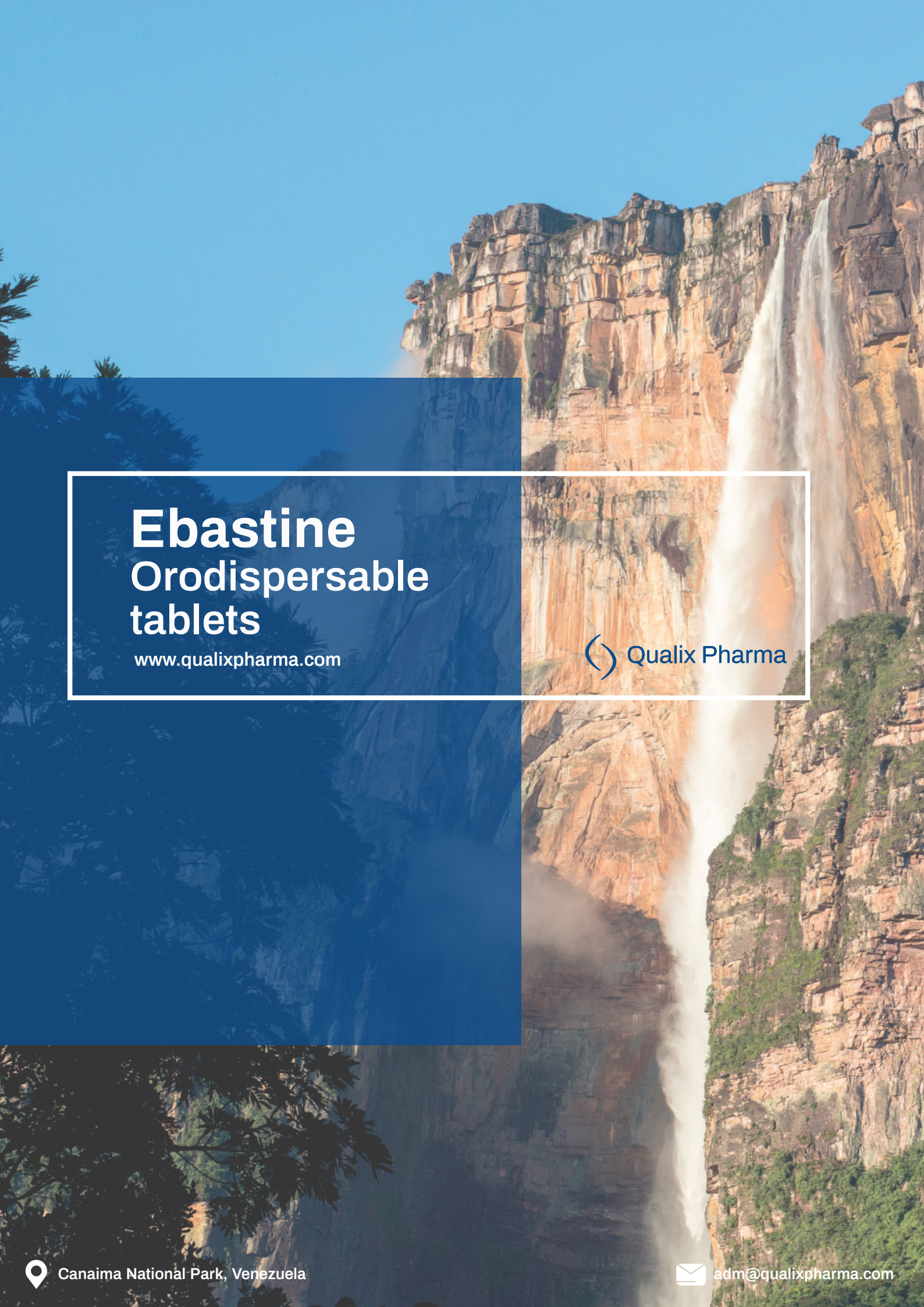


Ebastine
Orodispersable tablets

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Qualix Pharma

EBASTINE 10MG/20MG ORODISPERSABLE TABLETS

ANTIHISTAMINIC

LICENSE AND COMMERCIAL TERMS

PRODUCT: EBASTINE 10MG/20MG ORODISPERSABLE TABLETS

PACK SIZE: 20 TABLETS

MANUFACTURER: EUROPEAN (GMPS-EU)

API

EUROPEAN (CEP)

SHELF-LIFE: 4 YEARS

NO SPECIAL STORAGE CONDITION

BE

BE STUDY: YES

TYPE OF AGREEMENT: LICENSE AND SUPPLY AGREEMENT

TERRITORIAL SCOPE: TO BE AGREED

TM

TRADEMARKER: TO BE AGREED

LICENSE FEE: TO BE AGREED

DOSSIER FORMAT: EU-CTD

DOSSIER STATUS: AVAILABLE

STABILITY: CLIMATIC ZONE II AND IVa

CERTIFICATE OF PHARMACEUTICAL PRODUCT (CPP): AVAILABLE

TECHNICAL INFORMATION

Ebastine in comparison with other antihistamines

The traditional antihistamines that are used for allergy treatment such as Difenhydramine, Chlorphenamine, Promethazine and Ketotifen– also known as first-generation antihistamines – present discomforting side effects: they depress the central nervous system; they cross the blood-brain barrier; and they have sedative and anticholinergic effects.

Gradually, over time, new kinds of antihistamines known as second-generation antihistamines were produced. All of these share the feature of not having a sedative effect, opposed to the first kind. Some examples are Loratadinem Terfenadine, Cetirizine and Ebastine. These drugs do not cross the blood-brain barrier in an appreciable manner, they do not include drowsiness side effect; and, they do not have anticholinergic effects such as blurry vision.

Amongst the second-generation drugs, the ones that were initially investigated like Loretadine and Cetirizine, showed a less-favourable profile. In order to improve said profile they replace them with their active enantiomer (Levocetirizine) or their metabolites (Desloratadine). Their goal was to improve the effectiveness on the allergy symptoms and at the same time reduce the side effects, so as to approximate them to the more recent antihistamines such as Ebastine. Nevertheless, there is no evidence that the active enantiomers will lessen their side effects, which is why Ebastine continues to be amongst the latest generation and the best-balanced drugs.

Even though, second-generation antihistamines' have proved to be very effective, they still present side effects. In the case of Ebastine, since its therapeutic effect has a medium-prolonged duration, one take a day is enough to treat allergy with high effectiveness and thereby side effects could are lesser or less probable.

Ebastine has shown a profile of tolerability and total safety. The most common side effects were comparable to the ones that the patients of the placebo groups presented during the clinic development phase, which confirms the safety of the drug.

Ebastine is a powerful antihistamine that allows in a fast, safe and effective way to get rid of the allergy symptoms for a long time. Opposed to the first-generation antihistamine agents and some their second-generation drugs, Ebastine has significant advantages that include:

- Fast and long-term anti-allergic effect.
- Safe and with a tolerability profile.
- Low toxicity and minimal side-effect risk.
- No significant anticholinergic action, no sedative effect.
- Low risk of interaction with other drugs.



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1. WHAT EBASTINE IS AND WHAT IT IS USED FOR

Ebastine belongs to a group of medicines called antihistaminics.
Ebastine is indicated for the treatment of allergic process such as seasonal or perennial allergic rhinitis associated or not with allergic conjunctivitis (nasal discharges, nose itching eyes itching, watery eyes, sneezing), chronic urticaria and allergic dermatitis.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE EBASTINE

Do not take Ebastine

- If you are allergic (hypersensitive) to ebastine or any of the other excipients of this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ebastine.
Take special care with Ebastine:

- If your ECG data are altered.
- If you have low blood levels of potassium.
- If you suffered from severe hepatic insufficiency.
- If you are taking medicines for the treatment of fungus infections such as azole antifungals and macrolide antibiotics.
- If you are taking rifampicine, a medicine used to treat tuberculosis.

If you suffer an emergency case of acute allergic manifestations since Ebastine takes from 1 to 3 hours in developing effect.

Children

Ebastine should not be administered to children less than 12 years. It is recommended the use of Ebastine 1mg/ml oral solution.

Other medicines and Ebastine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

This is because Ebastine can affect the way some medicines work and some medicines can have an effect on Ebastine:

- Ebastine may enhance the effects of other antihistaminic drugs.
- Ebastine should be used with caution in patients when ebastine is co- administered with ketoconozole and itraconazole, or erythromycin.
- The effect of Ebastine could be affected by rifampicin, a medicine for the treatment of tuberculosis.

There is no interaction described between ebastine and theophylline, warfarin, cimetidine, diazepam and alcohol.

Interference with diagnostic tests

Ebastine may interfere in the results of cutaneous allergic tests, so it is advised not to carry them out until elapsed 5-7 days since the interruption of the treatment.

Ebastine with food and drink

You can take the orodispersable tablets with food or on an empty stomach.

Pregnancy, breast-feeding and fertility

Do not take this medicine if you are pregnant, think that you may be pregnant or intend to become pregnant whilst taking these tablets or are breast-feeding or planning to breast-feed.

Driving and using machines

No effects have been observed on the psychomotor function in human, or in the ability to drive or use machinery, at the recommended therapeutic doses. Since somnolence and dizziness are found between the adverse effects, you should observe the response to the treatment before driving or using machinery.



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3. HOW TO TAKE EBASTINE

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
Your doctor will tell you how long to take them for.

POSOLOGY

Adults and children above 12 years:
The usual dose for adults and children above 12 years is 1 orodispersible tablet (10 mg) once a day, but some patients could need 1 orodispersible tablet of 20 mg once a day.

Severe hepatic insufficiency:
It is not recommended to exceed the dose of 10 mg once a day.

Method of administration:
Oral use.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following adverse effects were reported in clinical trials or from post marketing experience:

Very common (may affect more than 1 in 10):
- Headache.

Common (may affect up to 1 in 10 people):
- Somnolence.
- Dry mouth.

Rare (may affect up to 1 in 1,000 people):
- Hypersensitivity reactions (anaphylaxis and angioedema).
- Nervousness, Insomnia.
- Dizziness, decreased sensitivity, headache.
- Palpitations, tachycardia.
- Vomiting, abdominal pain, nausea, gastrointestinal disorders.
- Abnormal liver function test.
- Urticaria, rash, dermatitis.
- Menstrual disorders.
- Oedema, asthenia.

Not known (frequency cannot be estimated from the available data):
- Weight increase.
- Increased appetite.

5. HOW TO STORE EBASTINE

Keep this medicine out of the sight and reach of children.
This medicinal product does not require any special storage conditions.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ebastine looks like and contents of the pack
Ebastine 10 mg orodispersible tablets: white and round orodispersible tablets packed in Al/Al blisters.
Ebastine 20 mg orodispersible tablets: white and round orodispersible tablets packed in Al/Al blisters.
Pack size: 20 orodispersable tablets.