



FLUMIX[®] BENTA

Cold and Flu

FORMS AND PRESENTATION

Flumix[®] Benta: Film coated tablets: Box of 20.

Flumix[®] Benta: Film coated tablets: Box of 10.

COMPOSITION

Flumix[®] Benta: Each film coated tablet contains:

Chlorpheniramine Maleate.....	2mg
Phenylephrine Hydrochloride.....	5mg
Guaifenesin.....	200mg
Ibuprofen.....	200mg
Excipients: croscarmellose sodium, pregelatinized starch, colloidal silicone dioxide, crospovidone, microcrystalline cellulose, sodium lauryl sulfate, magnesium stearate, polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, yellow iron oxide, FD&C yellow.	

MODE OF ACTION

Therapeutic class: Anti-inflammatory and anti-rheumatic products.

ATC code: M01AE51.

Chlorpheniramine is a potent Histamine H1 – receptor antagonist with mild central nervous system depressant properties which may cause mild sedation. This mild sedation and the potent anti-Histamine effect provides symptomatic relief in conditions believed to depend wholly or partly upon the triggered release of histamine.

Phenylephrine has direct and indirect sympathomimetic activity and is an effective upper respiratory tract decongestant.

Guaifenesin is used here both for productive cough as a well known expectorant and for dry cough associated with flu and allergic conditions by activity on the peripheral receptor of cough at the pharyngeal mucosa level.

Ibuprofen is the prototype of non-steroidal anti-inflammatory drugs (NSAID) and has analgesic, anti-inflammatory and anti-pyretic activity, which relieves sore throat, headache, low back and muscle pain and reduces fever.

INDICATIONS

Flumix[®] Benta is used for temporally relief of symptoms associated with common Cold and Flu, hay fever and the other upper respiratory allergies:

- Runny nose
- Sneezing
- Headache
- Itching of nose and throat
- Sinus pressure
- Minor aches and pains
- Itchy, watery eyes
- Nasal congestion
- Fever

DOSAGE AND ADMINISTRATION

- 12 years of age and older: 1 tablet every 4 to 6 hours while symptoms persist. Do not use more than 6 tablets in any 24 hours unless directed by a doctor.

- Under 12 years of age: do not take.

CONTRA-INDICATIONS

- Known hypersensitivity to Phenylephrine, Ibuprofen or any of the other active or non-active ingredients.
- Phenylephrine is contraindicated in severe coronary disease, severe hypertension, cardiovascular disease, hyperthyroidism and in patients who are taking or have taken, within the last 2 weeks, monoamino oxidase inhibitors (MAOI)

- Gastric bleeding and/or gastric ulcers.

SIDE EFFECTS

Phenylephrine may produce tachycardia, palpitations, nausea, headache and changes in blood pressure.

Ibuprofen may produce gastric pain and/or gastric bleeding in ulcer disease and may produce heartburn.

Chlorpheniramine may produce sedation, drowsiness and impaired performance.

PRECAUTIONS

Flumix[®] Benta may cause mild sedation and drowsiness and may impair performance. Patients should not drive or operate machinery until they have determined their own response. The concomitant use of alcohol is prohibited.

Although phenylephrine has virtually no pressor effects in normotensive patients, Flumix[®] Benta should be used with caution in patients taking hypertensive agents. The minimum dose of this drug is recommended in this situation and the effect of a single dose on the blood pressure of these patients should be assessed before recommending repeated or unsupervised treatment.

Caution should be exercised in the presence of severe renal or hepatic impairment and the use in elderly.

Caution should be exercised in thyroid disease, glaucoma, enlarged prostate or other urinary out flow disease.

DRUG INTERACTIONS

Monoamine oxidase inhibitors (MAOI) can exacerbate the systemic effect of phenylephrine.

Phenylephrine may interfere with the action of anti-hypertensive agents.

OVERDOSAGE

Immediate medical attention (in hospital if possible) is required in the event of overdosage even if there are no significant early symptoms.

STORAGE CONDITIONS

Store below 30°C

Do not refrigerate and protect from light.

Keep in original pack in intact conditions.

DATE OF LEAFLET REVISION

April 2019.

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor
- Medicament: keep out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

Benta S.A.L.
Dbayeh - Lebanon

