Atmos Tablets*& Syrup*

ایٹموس ٹیبلٹس اور سیرپ

COMPOSITION:

Each tablet contains: Ebastine BP.....10 & 20 mg, respectively

Each 5 ml contains: Ebastine BP.....5 mg/5 ml

DESCRIPTION: Ebastine is chemically described as 1-[4-(1,1-Dimethylethyl)-phenyl]-4-[4-(diphenylmethoxy)-1-piperidinyl]-1-butanone; 4'-tert -butyl-4-[4-(diphenylmethoxy)piperidino]butyrophenone; 4-diphenylmethoxy-1-[3-(4- tert-butylbenzoyl)propyl]piperidine. The empirical formula is $C_{32}H_{39}NO_2$. The molecular weight of ebastine is 469.66.

PHARMACOLOGY: ***Pharmacodynamics:*** Ebastine is a long-acting and selective H_1-histamine receptor antagonist. After repeated administration, inhibition of peripheral receptors remain at a constant level. The duration of action of ebastine allows to be administered once daily. Since it has no access to central H_1 receptors for histamine, it doesn't show sedative effects. ***Pharmacokinetics:*** Ebastine is rapidly absorbed and undergoes extensive first pass metabolism following oral administration. Ebastine is almost totally converted to the pharmacologically active acid metabolite, carebastine. After a single 10 mg oral dose, peak plasma levels of carebastine occur at 2.6 to 4 hours and achieve levels of 80 to 100 ng/mL. The half-life of carebastine is between 15 and 19 hours with 66% of the medicine being excreted in the urine mainly as conjugated metabolites. Following repeated administration of 10 mg once daily, steady state is achieved in 3 to 5 days with peak plasma levels ranging from 130 to 160 ng/mL. *In vitro* studies with human liver microsomes show that ebastine is metabolised to carebastine predominantly via the CYP3A4 pathway. Concurrent administration of ebastine with ketoconazole or erythromycin (both CYP3A4 inhibitors) to healthy volunteers was associated with significantly increased plasma concentration and elimination half-life of ebastine and carebastine. With ketoconazole the C_{max} and AUC were 15 times and 40 times respectively increased, with erythromycin the values were doubled. Both ebastine and carebastine are highly protein bound, >95%. In patients with renal insufficiency the elimination half-life of carebastine was increased to 23-26 hours. Similarly, in patients with hepatic insufficiency, the half-life increased to 27 hours.

INDICATIONS: Symptomatic treatment of allergic conditions, such as allergic rhinitis or conjunctivitis, both seasonal and perennial (nasal discharge, nasal itching, sneezing, itching in the eyes, etc.) chronic urticaria and allergic dermatitis.

CONTRAINDICATIONS: Known hypersensitivity to the ingredient.

POSSIBLE ADVERSE EFFECTS: The most common side-effects are headache, dry mouth

and drowsiness. Other less commonly reported side effects include pharyngitis, abdominal pain, dyspepsia, asthenia, epistaxis, rhinitis, sinusitis, nausea and insomnia.

DRUG INTERACTIONS: No significant drug interactions have been reported so far.

WARNINGS: ***Dermal Allergic Tests:*** Ebastine can interfere with the results of dermal allergic tests and therefore it is recommended not to perform these tests until 5 to 7 days after treatment discontinuation. It could strengthen the effects of other anti-histaminic agents. ***Pregnancy:*** Since there are no well controlled and adequate studies in pregnant women, therefore ebastine should be used during pregnancy only if clearly indicated. ***Lactation:*** It is not known whether ebastine is excreted in human milk. Therefore ebastine should not be used during lactation. ***Pediatric Use:*** Safety and effectiveness in children under 2 years of age have not been established.

DOSAGE & ADMINISTRATION: Adults & Children 12 Years & Older: 1 tablet (10 mg) or 2 teaspoonful (10 ml) of syrup once daily. In severe symptoms, 1 tablet (20 mg) or 4 teaspoonful (20 ml) of syrup once daily. **Children (6 to 11 Years):** 1 teaspoonful (5 ml) of syrup once daily. **Children (2 to 5 Years):** 1/2 teaspoonful (2.5 ml) of syrup once daily. There is no need for dosage adjustment in patients with mild to moderate liver function disorders.

SPECIAL INSTRUCTIONS TO THE PHYSICIAN: ***Overdosage:*** If there is any sign of intoxication, perform gastric lavage with appropriate symptomatic treatment.

STORAGE/PRECAUTIONS: Store in a cool, dry and dark place between 15-30 °C for ATMOS 10 & 20 mg tablets & below 25 °C for ATMOS syrup. Keep all medicines out of the children's reach.

PRESENTATION: ATMOS 10 mg Tablets & ATMOS 20 mg Tablets are available in packing containing 10 tablets, respectively while ATMOS Syrup is available in packing containing 30 ml.

*Scotmann Specs.

عمومی خوراک: ڈاکٹر کی ہدایت کے مطابق۔

احتیاط: دوا صرف مستند ڈاکٹر کے زیر ہدایت استعمال کریں۔ روشنی، نمی اور گرمی سے بچائیں۔ ایٹوس 10 اور 20 ملی گرام ٹیبلٹس 15 سے 30 ڈگری سینٹی گریڈ کے درمیان جبکہ ایٹوس سیرپ 25 ڈگری سینٹی گریڈ سے کم درجہ حرارت پر محفوظ کریں۔ تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

Complete Medical Information available only for doctors on request.

Manufactured by:

scotmann

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