

BAYER ARTWORK PANEL

Bayer Ref No: **BAY594134**
 Trident Reference No: TR3072613
 Brand: Claritin
 Range: N/A
 Product: Syrup
 Pack Type: Leaflet
 Pack Size: 100 ml
 Action: **A**
 Date: 16/12/2023
 Country: Ethiopia, Ghana, Kenya, Tanzania, Uganda

Finished Goods Code: **84542555**
 Synaps Request Code: **TL031420**
 Component Code: **6000234500**
 2nd Component Code: **N/A**

CAD Ref No: IN16GV [180 x 300 Folding Size 180x37] SK03 V2
 Printer: Multi Packaging Solutions (Bornem, Belgium)
 Packaging Site: Organon International Services GmbH (BE)
 Substrate: White Paper

Barcode 1 Type: Code 2 Of 5 Interleaved
 Barcode 1 Mag: 21.1082%
 Barcode 2 Type: N/A
 Barcode 2 Mag: N/A
 Barcode 3 Type: N/A
 Barcode 3 Mag: N/A
 Pharmacode No/NE: N/A

Technical & Non Printing Items
 ■ Dieline ■ Guides

Colours
 Process black
 1
 1TH



Connaught House, Connaught Road,
 Kingswood Business Park, Hull, HU7 3AP, England.
 T: +44 (0) 1482 828100

Please note that any low resolution paper Canon colour copies associated with this job should be referred to for content, layout and colour separation only.

UNDER NO CIRCUMSTANCES SHOULD THIS ARTWORK BE ALTERED WITHOUT PRIOR PERMISSION FROM TRIDENT.

FONT SIZE PANEL

Main Text (body copy): 8.0pt
 Height (based on lower case x): 1.4mm



180
160
108

10 16 10 10 10 16 10

10

Y = 35

2

2

10

Y = 65

Y = 72

Text should start below ITFcode in case of little amount of text (y = 65).

6 0 0 0 2 3 4 5 0 0

6000234500
1/1

6 0 0 0 2 3 4 5 0 0

6 0 0 0 2 3 4 5 0 0

CLARITYNE™ Tablets and Syrup
Brand of Loratadine
Long-Acting, Non-Sedating Antihistamine

DESCRIPTIONS: Each Clarityne tablet contains 10mg micronized loratadine and the inactive ingredients corn starch, lactose and magnesium stearate. Each 5ml of Clarityne Syrup contains 5mg of micronized loratadine and the inactive ingredients propylene glycol, glycerin, citric acid monohydrate, sodium benzoate, sugar, peach flavor and purified water.

ACTIONS: Loratadine is a long-acting, non-sedating, tricyclic antihistamine with histamine H1 receptor antagonist peripheral selective activity.

INDICATIONS: Clarityne is indicated for the relief of symptoms associated with perennial and / or seasonal allergic rhinitis, such as sneezing, itching and itching of the nose or throat, nasal discharge (rhinorrhea) and tearing, urticaria and some dermatological disorders. It is also indicated for the relief of symptoms and signs of chronic urticaria and other allergic dermatological conditions.

DOSAGE AND ADMINISTRATION

CLARITYNE TABLET: Adults and Children 12 years of age and over, or over 30 kg: 1 Tablet (10 mg) once daily (each 24 hours).

CLARITYNE SYRUP: Adults and children 6 years or older with body weight over 30 kg: 10 mg (2 teaspoonful) once daily. Children 2 – 5 years of age with Body Weight less than 30 kg: 5 mL (2 teaspoonful) once daily. Do not take more than the recommended dosage.

DRUG INTERACTIONS: An increase in plasma concentrations of loratadine following concomitant administration of ketoconazole, erythromycin or cimetidine in controlled studies, but without clinically significant changes (including electrocardiographic). Other drugs known to inhibit hepatic metabolism should be co-administered with caution until definitive interaction studies can be completed.

CLARITYNE products should be discontinued approximately 48 hours prior to skin testing procedures since antihistamines may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

ADVERSE REACTIONS: CLARITYNE products have no clinically significant sedative properties at the daily recommended dose. Loratadine can cause somnolence (at doses greater than the recommended one). Most commonly reported side effects include fatigue, headache, somnolence, dry mouth, gastrointestinal disorders such as nausea, gastritis, and also allergic symptoms like rash. In rare occasions during the commercialization of CLARITYNE products, alopecia, anaphylaxis, abnormal hepatic function, tachycardia, palpitations, dizziness, seizure and angioedema have been reported.

CONTRAINDICATIONS: Clarityne products are contraindicated in patients who have shown hypersensitivity to this medicament or to the components of this formula, or to medicaments with similar chemical structure.

WARNINGS AND PRECAUTIONS: Taking more than the recommended dose can produce somnolence. Do not administer along with products with the same active ingredient, other sedative products or alcohol. Do not use for a long time. Patients with severe hepatic impairment should initially be given a lower dose, as these patients may have a slower clearance of the drug, an initial dose of 5mg or 5ml once daily, or 10mg or 10ml every other day is recommended. The safety and efficacy of Clarityne products in children under 2 years of age have not yet been established. Clarityne Syrup contains sugar. Patients with hereditary fructose intolerance, glucose or galactose malabsorption, or sucrase-isomaltase deficiency should not take this medicine. This medicinal product contains 6 grams of sugar per 10 mL, which should be taken into account in the treatment of patients with glucose or galactose malabsorption and in patients with diabetes mellitus. Clarityne Tablets contains lactose. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose or galactose malabsorption should not take this medicine.

USE DURING PREGNANCY AND LACTATION: It has not been established whether the administration of Clarityne may represent some alteration during pregnancy. Therefore, the drug should only be used if the potential benefit to the mother justifies the potential risk to the fetus or newborn. It has been established that loratadine is excreted in human milk, because of the potential risk of administering antihistamines to infants, particularly newborns and preterm infants a decision should be made whether to discontinue breast-feeding or discontinue the drug. Loratadine and its active metabolite are excreted in the breast milk of lactating women. Forty-eight hours after dosing, only 0.029% of the dose of loratadine is detected in milk as unchanged loratadine and its active metabolite.

OVERDOSAGE: Somnolence, tachycardia and headache have been reported with overdoses. In the event of overdosage, treatment, which should be started immediately, is symptomatic and supportive. There is no information to indicate dependence or abuse with loratadine.

TREATMENT: Loratadine is not cleared by hemodialysis in any appreciable degree. It is not known whether loratadine can be removed by peritoneal dialysis. After emergency treatment, the patient should be kept under medical supervision.

HOW SUPPLIED:
 CLARITYNE tablets are available in packages of 30 tablets

 CLARITYNE Syrup 1mg/ml in bottles of 100ml

STORAGE: Store between 2° and 30° C.
 Blister pack tablets should be protected from excessive moisture.

Manufactured by Organon International Services GmbH, at Industriepark 30
 Zone A, B-2220Heist-op-den Berg,
 Belgium
 NAFDAC NO: 04-2471 (For Tablets)

Bayer

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10

10

10

300

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