ABBREVIATED PRESCRIBING INFORMATION. The abbreviated prescribing information hereunder may vary in different countries. Before prescribing Rupafin 10 mg Tablets please consult the full local approved Summary of Product Characteristics (SmPC).

RUPAFIN 10 mg Tablets.

Name of the medicinal product: Rupafin 10 mg Tablets. **Qualitative and quantitative composition:** Each tablet contains:10 mg of rupatadine (as fumarate). Excipient with known effect:
Lactose 57.57 mg as lactose monohydrate. **Pharmaceutical form:** Tablet. Round, light salmon coloured tablets. **Therapeutic indications:** Symptomatic treatment of allergic rhinitis and urticaria in adults and adolescents (over 12 years of age). **Posology and method of administration:** Adults and adolescents (over 12 years of age): The recommended dose is 10 mg (one tablet) once a day, with or without food. Elderly: Rupatadine should be used with caution in elderly people. Paediatric patients: Rupatadine 10 mg Tablets is not recommended for use in children below age 12. In children aged 2 to 11 years, the administration of rupatadine 1 mg/ml oral solution is recommended. Patients with renal or hepatic insufficiency: As there is no clinical experience in patients with impaired kidney or liver functions, the use of rupatadine 10 mg Tablets is at present not recommended in these patients. **Special warnings and precautions for use:** The administration of rupatadine with grapefruit juice is not recommended. The combination of rupatadine with potent CYP3A4 inhibitors should be avoided and with moderate CYP3A4 inhibitors should be administered with caution. Dose adjustment of sensitive CYP3A4 substrates (e.g. simvastatin, lovastatin) and CYP3A4 substrates with a narrow therapeutic index (e.g. ciclosporin, tacrolimus, sirolimus, everolimus, cisapride) could be required as rupatadine may increase plasma concentrations of these drugs. Cardiac safety of rupatadine was assessed in a Thorough QT/QTc study. Rupatadine up to 10 times therapeutic dose did not produce any effect on the ECG and hence raises no cardiac safety concerns. However, rupatadine should be used with caution in patients with known prolongation of the QT interval, patients with uncorrected hypokalemia, patients with ongoing proarrhythmic conditions, such as clinically significant bradycardia, acute myocardial ischemia. Rupatadine 10 mg Tablets should be used with caution in elderly patients (65 years and older). Although no overall differences in effectiveness or safety were observed in clinical trials, higher sensitivity of some older individuals cannot be excluded due to the low number of elderly patients enrolled. Due to the presence of lactose monohydrate in rupatadine 10 mg tablets, patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine. **Interaction with other medicinal products and other forms of interaction:** Interaction studies have only been performed in adults and adolescents (over 12 years of age) with rupatadine 10 mg tablets. *Effects of other drugs on rupatadine:* Co-administration with potent CYP3A4 inhibitors (e.g. itraconazole, ketoconazole, voriconazole, posaconazole, HIV protease inhibitors, clarithromycin, nefazodone) should be avoided and co-medication with moderate CYP3A4 inhibitors (erythromycin, fluconazole, diltiazem) should be used with caution. The concomitant administration of rupatadine 20 mg and ketoconazole or erythromycin increases the systemic exposure to rupatadine 10 times and 2-3 times respectively. These modifications were not associated with an effect on the QT interval or with an increase of the adverse reactions in comparison with the drugs when administered separately. Interaction with grapefruit: The concomitant administration of grapefruit juice increased 3.5 times the systemic exposure of rupatadine. Grapefruit juice should not be taken simultaneously. *Effects of rupatadine on other drugs:* Caution should be taken when rupatadine is co-administered with other metabolised drugs with narrow therapeutic windows since knowledge of the effect of rupatadine on other drugs is limited. Interaction with alcohol: After administration of alcohol, a dose of 10 mg of rupatadine

produced marginal effects in some psychomotor performance tests although they were not significantly different from those induced by intake of alcohol only. A dose of 20 mg increased the impairment caused by the intake of alcohol. Interaction with CNS depressants: As with other antihistamines, interactions with CNS depressants cannot be excluded. Interaction with statins: Asymptomatic CPK increases have been uncommonly reported in rupatadine clinical trials. The risk of interactions with statins, some of which are also metabolised by the cytochrome P450 CYP3A4 isoenzyme, is unknown. For these reasons, rupatadine should be used with caution when it is co-administered with statins.Interaction with midazolam: After the administration of 10 mg rupatadine in combination with 7.5 mg midazolam, an increase of exposure (Cmax and AUC) of midazolam was mildly higher observed. For this reason, rupatadine acts as a mild inhibitor of CYP3A4. **Fertility, pregnancy and lactation:** Pregnancy: There are limited amount of data from the use of rupatadine in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. As a precautionary measure, it is preferable to avoid the use of rupatadine during pregnancy. Breastfeeding: Rupatadine is excreted in animal milk. It is unknown whether rupatadine is excreted into breast milk. A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from rupatadine therapy taking into account the benefit of breastfeeding for the child and the benefit of therapy for the woman. Fertility: There are no clinical data on fertility. Studies in animals have shown a significant reduction of fertility at exposure levels higher than those observed in humans at the maximum therapeutic dose. **Effects on the ability to drive and use machines:** Rupatadine 10 mg had no influence on the ability to drive and use machines. Nevertheless, care should be taken before driving or using machinery until the patient's individual reaction on rupatadine has been established. **Undesirable effects:** Rupatadine 10 mg tablets has been administered to over 2,043 adult and adolescents patients in clinical studies, 120 of whom received rupatadine for at least 1 year. The most common adverse reactions in controlled clinical studies were somnolence (9.4%), headache (6.9%), fatigue (3.1%), asthenia (1.5%), dry mouth (1.2%) and dizziness (1.03%). The majority of the adverse reactions observed in clinical trials were mild to moderate in severity and they usually did not require cessation of therapy. The frequencies of adverse reactions reported in patients treated with rupatadine 10 mg tablets during clinical trials and spontaneous reporting were as follows:

System Organ Class (Body System)	**Common (≥ 1/100 to < 1/10)**	**Uncommon (≥ 1/1,000 to < 1/100)**
Infections and infestations		Pharyngitis rhinitis
Metabolism and nutrition disorders		Increase appetite
Nervous system disorders	Dizziness Headache Somnolence	Disturbance in Attention
Respiratory, Thoracic and Mediastinal Disorders		Cough Dry Throat Epistaxis Nasal Dryness Oropharyngeal Pain
Gastrointestinal disorders	Dry Mouth	Abdominal Pain Abdominal Pain Upper Diarrhoea Dyspepsia Nausea Vomiting Constipation

Skin and subcutaneous tissue disorders		Rash
Musculoskeletal, connective tissues, and bone disorders		Arthralgia Back Pain Myalgia
General Disorders and administration site condition	Asthenia Fatigue	Malaise Pyrexia Thirst Irritability
Investigations		Alanine aminotransferase Increased Aspartate aminotransferase Increased Blood Creatine Phosphokinase Increased Liver Function Test Abnormal Weight increase

Additionally, three rare adverse reactions were reported in the post-authorisation period: Tachycardia, palpitations and hypersensitivity reactions (including anaphylactic reactions, angioedema and urticarial) have been reported in post-marketing experience with rupatadine 10 mg tablets. **Overdose:** No case of overdose has been reported. In a clinical safety study rupatadine at daily dose of 100 mg during 6 days was well tolerated. The most common adverse reaction was somnolence. If accidental ingestion of very high doses occurs symptomatic treatment together with the required supportive measures should be given. **Marketing authorisation holder:** Noucor Health, S.A., Av. Camí Reial, 51-57, 08184 Palau-solità i Plegamans (Spain).

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