Hospital Price	
CABOMETYX® 60 140 120 mg	€ 6400 (excl. VAT)

NAME OF THE MEDICINAL PRODUCT CABOMETYX 20 mg film-coated tablets CABOMETYX 40 mg film-coated tablets CABOMETYX 60 mg film-coated tablets **QUALITATIVE AND QUANTITATIVE COMPOSITION** CABOMETYX 20 mg film-coated tablets Each film-coated tablet contains cabozantinib (S)-malate equivalent to 20 mg cabozantinib. ***Excipients with known effect*** Each film-coated tablet contains 15.54 mg lactose. CABOMETYX 40 mg film-coated tablets Each film-coated tablet contains cabozantinib (S)-malate equivalent to 40 mg cabozantinib. ***Excipients with known effect*** Each film-coated tablet contains 31.07 mg lactose. CABOMETYX 60 mg film-coated tablets Each film-coated tablet contains cabozantinib (S)-malate equivalent to 60 mg cabozantinib. ***Excipients with known effect*** Each film-coated tablet contains 46.61 mg lactose. For the full list of excipients, see section List of excipients. **PHARMACEUTICAL FORM** Film-coated tablet. CABOMETYX 20 mg film-coated tablets The tablets are yellow round with no score and debossed with "XL" on one side and "20" on the other side of the tablet. CABOMETYX 40 mg film-coated tablets The tablets are yellow triangle shaped with no score and debossed with "XL" on one side and "40" on the other side of the tablet. CABOMETYX 60 mg film-coated tablets The tablets are yellow oval shaped with no score and debossed with "XL" on one side and "60" on the other side of the tablet. **CLINICAL PARTICULARS** Renal cell carcinoma (RCC) CABOMETYX is indicated as monotherapy for advanced renal cell carcinoma – as first-line treatment of adults with intermediate or poor risk (see section Pharmacodynamic properties) - in adults following prior vascular endothelial growth factor (VEGF)-targeted therapy (see section Pharmacodynamic properties). CABOMETYX, in combination with nivolumab, is indicated for the first-line treatment of advanced renal cell carcinoma in adults (see section Pharmacodynamic properties). Hepatocellular carcinoma (HCC) CABOMETYX is indicated as monotherapy for the treatment of hepatocellular carcinoma (HCC) in adults who have previously been treated with sorafenib. **Posology and method of administration** Therapy with CABOMETYX should be initiated by a physician experienced in the administration of anticancer medicinal products. Posology CABOMETYX tablets and cabozantinib capsules are not bioequivalent and should not be used interchangeably (see section Pharmacokinetic properties). CABOMETYX as monotherapy For RCC and HCC, the recommended dose of CABOMETYX is 60 mg once daily. Treatment should continue until the patient is no longer clinically benefiting from therapy or until unacceptable toxicity occurs. CABOMETYX in combination with nivolumab in first-line advanced RCC The recommended dose of CABOMETYX is 40 mg once daily in combination with nivolumab administered intravenously at either 240 mg every 2 weeks or 480 mg every 4 weeks. CABOMETYX treatment should continue until disease progression or unacceptable toxicity. Nivolumab should be continued until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression (see the Summary of Product Characteristics (SmPC) for posology of nivolumab). Treatment modification Management of suspected adverse drug reactions may require temporary treatment interruption and/or dose reduction of CABOMETYX therapy (see "Recommended CABOMETYX dose modifications for adverse reactions"). When dose reduction is necessary in monotherapy, it is recommended to reduce to 40 mg daily, and then to 20 mg daily. When CABOMETYX is administered in combination with nivolumab, it is recommended to reduce the dose to 20 mg of CABOMETYX once daily, and then to 20 mg every other day (refer to the nivolumab SmPC for recommended treatment modification for nivolumab). Dose interruptions are recommended for management of CTCAE grade 3 or greater toxicities or intolerable grade 2 toxicities. Dose reductions are recommended for events that, if persistent, could become serious or intolerable. If a patient misses a dose, the missed dose should not be taken if it is less than 12 hours before the next dose. **Recommended CABOMETYX dose modifications for adverse reactions:** Grade 1 and grade 2 adverse reactions which are tolerable and easily managed: Dose adjustment is usually not required. Add supportive care as indicated. Grade 2 adverse reactions which are intolerable and cannot be managed with a dose reduction or supportive care: Interrupt treatment until the adverse reaction resolves to grade ≤1. Add supportive care as indicated. Consider re-initiating at a reduced dose. Grade 3 adverse reactions (except clinically nonrelevant laboratory abnormalities): Interrupt treatment until the adverse reaction resolves to grade ≤1. Add supportive care as indicated. Re-initiate at a reduced dose. Grade 4 adverse reactions (except clinically nonrelevant laboratory abnormalities): Interrupt treatment. Institute appropriate medical care. If adverse reaction resolves to grade ≤1, re-initiate at a reduced dose. If adverse reaction does not resolve, permanently discontinue CABOMETYX. Liver enzymes elevations for RCC patients treated with CABOMETYX in combination with nivolumab. ALT or AST > 3 times ULN but ≤10 times ULN without concurrent total bilirubin ≥ 2 times ULN: Interrupt CABOMETYX and nivolumab until these adverse reactions resolves to grades≤1. Corticosteroid therapy may be considered if immune-mediated reaction is suspected (refer to nivolumab SmPC). Re-initiate with a single medicine or sequential re-initiating with both medicines after recovery may be considered. If re-initiating with nivolumab, refer to nivolumab SmPC. ALT or AST > 10 times ULN or > 3 times ULN with concurrent total bilirubin ≥ 2 times ULN: Permanently discontinue CABOMETYX and nivolumab. Corticosteroid therapy may be considered if immune-mediated reaction is suspected (refer to nivolumab SmPC). Note: Toxicity grades are in accordance with National Cancer Institute Common Terminology Criteria for Adverse Events version 4.0 (NCI-CTCAE v4) ***Concomitant medicinal products*** Concomitant medicinal products that are strong inhibitors of CYP3A4 should be used with caution, and chronic use of concomitant medicinal products that are strong inducers of CYP3A4 should be avoided (see sections Special warnings and precautions for use and Interaction with other medicinal products and other forms of interaction). Selection of an alternative concomitant medicinal product with no or minimal potential to induce or inhibit CYP3A4 should be considered. Special populations. ***Elderly*** No specific dose adjustment for the use of cabozantinib in elderly patients (≥ 65 years) is recommended. ***Race*** No dose adjustment is necessary based on ethnicity (see section Pharmacokinetic properties). ***Renal impairment*** Cabozantinib should be used with caution in patients with mild or moderate renal impairment. Cabozantinib is not recommended for use in patients with severe renal impairment as safety and efficacy have not been established in this population. ***Hepatic impairment*** In patients with mild hepatic impairment no dose adjustment is required. Since only limited data are available for patients with moderate hepatic impairment (Child Pugh B), no dosing recommendation can be provided. Close monitoring of overall safety is recommended in these patients (see sections Special warnings and precautions for use and Pharmacokinetic properties). There is no clinical experience in patients with severe hepatic impairment (Child Pugh C), so cabozantinib is not recommended for use in these patients (see section Pharmacokinetic properties).***Cardiac impairment*** There are limited data in patients with cardiac impairment. No specific dosing recommendations can be made. ***Paediatric population*** The safety and efficacy of cabozantinib in children and adolescents aged <18 years have not yet been established. No data are available. Method of administration CABOMETYX is for oral use. The tablets should be swallowed whole and not crushed. Patients should be instructed to not eat anything for at least 2 hours before through 1 hour after taking CABOMETYX. **CONTRAINDICATIONS** Hypersensitivity to the active substance or to any of the excipients listed in section List of excipients. **UNDESIRABLE EFFECTS** Cabozantinib as monotherapy Summary of safety profile The most common serious adverse drug reactions in the RCC population (≥1% incidence) are abdominal pain, diarrhoea, nausea, hypertension, embolism, hyponatraemia, pulmonary embolism, vomiting, dehydration, fatigue, asthenia, decreased appetite, deep vein thrombosis, dizziness, hypomagnesaemia and palmar-plantar erythrodysaesthesia syndrome (PPES). The most frequent adverse reactions of any grade (experienced by at least 25% of patients) in the RCC population included diarrhoea, fatigue, nausea, decreased appetite, PPES, hypertension, weight decreased, vomiting, dysgeusia, constipation, and AST increased. Hypertension was observed more frequently in the treatment naïve RCC population (67%) compared to RCC patients following prior VEGF-targeted therapy (37%). The most common serious adverse drug reactions in the HCC population (≥1% incidence) are hepatic encephalopathy, asthenia, fatigue, PPES, diarrhoea, hyponatraemia, vomiting, abdominal pain and thrombocytopenia. The most frequent adverse reactions of any grade (experienced by at least 25% of patients) in the HCC population included diarrhoea, decreased appetite, PPES, fatigue, nausea, hypertension and vomiting. Adverse reactions identified in clinical trials of cabozantinib as monotherapy or reported after post-marketing use of cabozantinib are listed, according to MedDRA system organ class and frequency categories. Frequencies are based on all grades and defined as: very common (≥1/10), common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); not known (cannot be estimated from the available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness. **Adverse drug reactions (ADRs) reported in clinical trials or after post-marketing use in patients treated with cabozantinib in monotherapy:** Infections and infestations: Common, abscess. Blood and lymphatic disorders: Very common, anaemia, thrombocytopenia. Common, neutropenia, lymphopenia. Endocrine disorders: Very common, hypothyroidism. Metabolism and nutrition disorders: Very common, decreased appetite, hypomagnesaemia, hypokalaemia, hypoalbuminaemia. Common, dehydration, hypophosphataemia, hyponatraemia, hypocalcaemia, hyperkalaemia, hyperbilirubinemia, hyperglycaemia, hypoglycaemia. Nervous system disorders: Very common, dysgeusia, headache, dizziness. Common, peripheral neuropathy (including sensory). Uncommon, convulsion. Not known, cerebrovascular accident. Ear and labyrinth disorders: Common, tinnitus. Cardiac disorders: Not known, myocardial infarction. Vascular disorders: Very common, hypertension, haemorrhage*. Common, deep vein thrombosis, venous thrombosis, arterial thrombosis. Not known, aneurysms and artery dissections. Respiratory, thoracic, and mediastinal disorders: Very common, dysphonia, dyspnoea, cough. Common, pulmonary embolism. Gastrointestinal disorders: Very common, diarrhoea*, nausea, vomiting, stomatitis, constipation, abdominal pain, dyspepsia, upper abdominal pain. Common, gastrointestinal perforation*, fistula*, gastroesophageal reflux disease, haemorrhoids, oral pain, dry mouth, dysphagia, glossodynia. Uncommon, pancreatitis. Hepatobiliary disorders: Common, hepatic encephalopathy*. Uncommon, hepatitis cholestatic. Skin and subcutaneous tissue disorders: Very common, palmar-plantar erythrodysaesthesia syndrome, rash. Common, pruritus, alopecia, dry skin, dermatitis acneiform, hair colour change, hyperkeratosis, erythema. Musculoskeletal and connective tissue disorders: Very common, pain in extremity. Common, muscle spasms, arthralgia. Uncommon, osteonecrosis of the jaw. Renal and urinary disorders: Common, proteinuria. General disorders and administration site conditions: Very common, fatigue, mucosal inflammation, asthenia, peripheral oedema. Investigations[a]: Very common, weight decreased, serum ALT increased, AST increased. Common, blood ALP increased, GGT increased, blood creatinine increased, amylase increased, lipase increased, blood cholesterol increased, blood triglycerides increased. Injury, poisoning and procedural complications: Uncommon, wound complications[b]. *See section Undesirable effects, Description of selected adverse reactions for further characterisation. aBased on reported adverse reactions. [b]Impaired healing and incision site complication. ***Cabozantinib in combination with nivolumab in first-line advanced RCC*** Summary of safety profile When cabozantinib is administered in combination with nivolumab, refer to the SmPC for nivolumab prior to initiation of treatment. For additional information on the safety profile of nivolumab monotherapy, please refer to the nivolumab SmPC. In a dataset of cabozantinib 40 mg once daily in combination with nivolumab 240 mg every two weeks in RCC (n =320), with a minimum follow-up of 16 months, the most common serious adverse drug reactions (≥1% incidence) are diarrhoea, pneumonitis, pulmonary embolism, pneumonia, hyponatremia, pyrexia, adrenal insufficiency, vomiting, dehydration. The most frequent adverse reactions (≥25%) were diarrhoea, fatigue, palmar-plantar erythrodysaesthesia syndrome, stomatitis, musculoskeletal pain, hypertension, rash, hypothyroidism, decrease appetite, nausea, abdominal pain. The majority of adverse reactions were mild to moderate (Grade 1 or 2). Tabulated list of adverse reactions Adverse reactions identified in the clinical study of cabozantinib in combination with nivolumab are listed in Table 3, according to MedDRA System Organ Class and frequency categories. Frequencies are based on all grades and defined as: very common (≥1/10), common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); not known (cannot be estimated from the available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness. **Adverse reactions with cabozantinib in combination with nivolumab:** Infections and infestations: Very common, upper respiratory tract infection. Common, pneumonia. Blood and lymphatic disorders: Common, eosinophilia. Immune system disorders: Common, hypersensitivity (including anaphylactic reaction). Uncommon, infusion related hypersensitivity reaction. Endocrine disorders: Very common, hypothyroidism, hyperthyroidism. Common, adrenal insufficiency. Uncommon, hypophysitis, thyroiditis. Metabolism and nutrition disorders: Very common, decreased appetite. Common, dehydration. Nervous system disorders: Very common, dysgeusia, headache, dizziness. Common, peripheral neuropathy. Uncommon, encephalitis autoimmune, Guillain-Barré syndrome, myasthenic syndrome. Ear and labyrinth disorders: Common, tinnitus. Eye disorders: Common, dry eye, blurred vision. Uncommon, uveitis. Cardiac disorders: Common, atrial fibrillation, tachycardia. Uncommon, myocardiitis. Vascular disorders: Very common, hypertension. Common, thrombosisa. Respiratory, thoracic, and mediastinal disorders: Very common, dysphonia, dyspnoea, cough. Common, pneumonitis pulmonary embolism, epistaxis, pleural effusion. Gastrointestinal disorders: Very common, diarrhoea, nausea, vomiting, stomatitis, constipation, abdominal pain, dyspepsia. Common, colitis, gastritis, oral pain, dry mouth, haemorrhoids. Uncommon, pancreatitis, small intestine perforationb, glossodynia. Hepatobiliary disorders: Common, hepatitis. Skin and subcutaneous tissue disorders: Very common, palmar-plantar erythrodysaesthesia syndrome, rashc, pruritus. Common, alopecia, dry skin, erythema, hair colour change. Uncommon, psoriasis, urticaria. Musculoskeletal and connective tissue disorders: Very common, musculoskeletal paind, arthralgia, muscle spasm. Common, arthritis. Uncommon, myopathy, osteonecrosis of the jaw, fistula. Renal and urinary disorders: Very common, proteinuria. Common, renal failure, acute kidney injury. Uncommon, nephritis. General disorders and administration site conditions: Very common, fatigue, pyrexia, oedema. Common, pain, chest pain. Investigations[e]: Very common, increased ALT, increased AST, hypophosphataemia, hypocalcaemia, hypomagnesaemia, hyponatraemia, hyperglycaemia, lymphopaenia, increased alkaline phosphatase, increased lipase, increased amylase, thrombocytopaenia, increased creatinine, anaemia, leucopoenia, hyperkalaemia, neutropaenia, hypercalcaemia, hypoglycaemia, hypokalaemia, increased total bilirubin, hypermagnesaemia, hypernatraemia, weight decreased. Common, blood cholesterol increased, hypertriglyceridaemia. The abovementioned adverse reaction frequencies may not be fully attributable to cabozantinib alone but may contain contributions from the underlying disease or from nivolumab used in a combination. [a]Thrombosis is a composite term which includes portal vein thrombosis, pulmonary vein thrombosis, pulmonary thrombosis, aortic thrombosis, arterial thrombosis, deep vein thrombosis, pelvic vein thrombosis, vena cava thrombosis, venous thrombosis, venous thrombosis limb. [b]Fatal cases have been reported. [c]Rash is a composite term which includes dermatitis, dermatitis acneiform, dermatitis bullous, exfoliative rash, rash erythematous, rash follicular, rash macular, rash maculo-papular, rash papular, rash pruritic and drug eruption. [d]Musculoskeletal pain is a composite term which includes back pain, bone pain, musculoskeletal chest pain, musculoskeletal discomfort, myalgia, neck pain, pain in extremity, spinal pain. [e]Frequencies of laboratory terms reflect the proportion of patients who experienced a worsening from baseline in laboratory measurements with the exception of weight decreased, blood cholesterol increased and hypertriglyceridaemia. Description of selected adverse reactions Data for the following reactions are based on patients who received CABOMETYX 60 mg orally once daily as monotherapy in the pivotal studies in RCC following prior VEGF-targeted therapy or in patients who received CABOMETYX 40 mg orally daily in combination with nivolumab in first-line advanced RCC (section Pharmacodynamic properties). ***Gastrointestinal (GI) perforation (see section Special warnings and precautions for use)*** In the study in RCC following prior VEGF-targeted therapy (METEOR), GI perforations were reported in 0.9% (3/331) of cabozantinib-treated RCC patients. Events were Grade 2 or 3. Median time to onset was 10.0 weeks. In the treatment-naïve RCC study (CABOSUN), GI perforations were reported in 2.6% (2/78) of cabozantinib-treated patients. Events were Grade 4 and 5. In the HCC study (CELESTIAL), GI perforations were reported in 0.9% of cabozantinib-treated patients (4/467). All events were Grade 3 or 4. Median time to onset was 5.9 weeks. In combination with nivolumab in advanced RCC in first-line treatment (CA2099ER) the incidence of GI perforations was 1.3% (4/320) treated patients. One event was grade 3, two events were grade 4 and one event was grade 5 (fatal). Fatal perforations have occurred in the cabozantinib clinical program. ***Hepatic encephalopathy (see section Special warnings and precautions for use)*** In the HCC study (CELESTIAL), hepatic encephalopathy (hepatic encephalopathy, encephalopathy, hyperammonaemic encephalopathy) was reported in 5.6% of cabozantinib-treated patients (26/467); Grade 3-4 events in 2.8%, and one (0.2%) Grade 5 event. Median time to onset was 5.9 weeks. No cases of hepatic encephalopathy were reported in the RCC studies (METEOR, CABOSUN and CA2099ER). ***Diarrhoea (see section Special warnings and precautions for use)*** In the study in RCC following prior VEGF-targeted therapy (METEOR), diarrhoea was reported in 74% of cabozantinib-treated RCC patients (245/331); Grade 3-4 events in 11%. Median time to onset was 4.9 weeks. In the treatment-naïve RCC study (CABOSUN), diarrhoea was reported in 73% of cabozantinib-treated patients (57/78); Grade 3-4 events in 10%. In the HCC study (CELESTIAL), diarrhoea was reported in 54% of cabozantinib-treated patients (251/467); Grade 3-4 events in 9.9%. Median time to onset of all events was 4.1 weeks. Diarrhoea led to dose modifications, interruptions and discontinuations in 84/467 (18%), 69/467 (15%) and 5/467 (1%) of subjects, respectively. In combination with nivolumab in advanced RCC in first-line treatment (CA2099ER), the incidence of diarrhoea was reported in 64.7% (207/320) of treated patients; Grade 3-4 events in 8.4% (27/320). Median time to onset of all events was 12.9 weeks. Dose delay or reduction occurred in 26.3% (84/320) and discontinuation in 2.2% (7/320) of patients with diarrhoea, respectively. ***Fistulas (see section Special warnings and precautions for use)*** In the study in RCC following prior VEGF-targeted therapy (METEOR), fistulas were reported in 1.2% (4/331) of cabozantinib-treated patients and included anal fistulas in 0.6% (2/331) cabozantinib-treated patients. One event was Grade 3; the remainder were Grade 2. Median time to onset was 30.3 weeks. In the treatment-naïve RCC study (CABOSUN), no cases of fistulas were reported. In the HCC study (CELESTIAL), fistulas were reported in 1.5% (7/467) of the HCC patients. Median time to onset was 14 weeks. In combination with nivolumab in advanced RCC in first-line treatment (CA2099ER) the incidence of fistula was reported in 0.9% (3/320) of treated patients and the severity was Grade 1. Fatal fistulas have occurred in the cabozantinib clinical program. ***Haemorrhage (see section Special warnings and precautions for use)*** In the study in RCC following prior VEGF-targeted therapy (METEOR), the incidence of severe haemorrhagic events (Grade ≥ 3) was 2.1% (7/331) in cabozantinib-treated RCC patients. Median time to onset was 20.9 weeks. In the treatment-naïve RCC study (CABOSUN), the incidence of severe haemorrhagic events (Grade ≥ 3) was 5.1% (4/78) in cabozantinib-treated RCC patients. In the HCC study (CELESTIAL), the incidence of severe haemorrhagic events (Grade ≥ 3) was 7.3% in cabozantinib-treated patients (34/467). Median time to onset was 9.1 weeks. In combination with nivolumab in advanced RCC in first-line treatment (CA2099ER) the incidence of ≥ Grade 3 haemorrhage was in 1.9% (6/320) of treated patients. Fatal haemorrhages have occurred in the cabozantinib clinical program. ***Posterior Reversible Encephalopathy Syndrome (PRES) (see section Special warnings and precautions for use)*** No case of PRES was reported in the METEOR or CABOSUN or CA2099ER or CELESTIAL studies, but PRES has been reported rarely in other clinical trials (in 2/4872 subjects; 0.04%). ***Elevated liver enzymes when cabozantinib is combined with nivolumab in RCC*** In a clinical study of previously untreated patients with RCC receiving cabozantinib in combination with nivolumab, a higher incidence of Grades 3 and 4 ALT increased (10.1%) and AST increased (8.2%) were observed relative to cabozantinib monotherapy in patients with advanced RCC (ALT increased of 3.6% and AST increased of 3.3% in METEOR study). The median time to onset of grade > 2 increased ALT or AST was 10.1 weeks (range: 2 to 106.6 weeks; n=85). In patients with grade ≥ 2 increased ALT or AST, the elevations resolved to Grades 0-1in 91% with median time to resolution of 2.29 weeks (range: 0.4 to 108.1 weeks). Among the 45 patients with Grade ≥2 increased ALT or AST who were rechallenged with either cabozantinib (n=10) or nivolumab (n=10) administered as a single agent or with both (n=25), recurrence of Grade ≥2 increased ALT or AST was observed in 4 patients receiving cabozantinib, in 3 patients receiving nivolumab and 8 patients receiving both cabozantinib and nivolumab. ***Hypothyroidism*** In the study in RCC following prior VEGF-targeted therapy (METEOR), the incidence of hypothyroidism was 21% (68/331). In the treatment-naïve RCC study (CABOSUN), the incidence of hypothyroidism was 23% (18/78) in cabozantinib-treated RCC patients. In the HCC study (CELESTIAL), the incidence of hypothyroidism was 8.1% (38/467) in cabozantinib-treated patients and Grade 3 events in 0.4% (2/467). In combination with nivolumab in advanced RCC in first-line treatment (CA2099ER) the incidence of hypothyroidism was 35.6% (114/320) of treated patients. Reporting of suspected adverse reactions Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via, Belgium: Federal Agency for Medicines and Health Products, Vigilance Division, Postbus 97, 1000 Brussel, Madou. Website: www.eenbijwerkingmelden.be E-mail: adr@faggs.be Luxembourg: Direction de la Santé, Division de la Pharmacie et des Médicaments, 20, rue de Bitbourg, L-1273 Luxembourg-Hamm, Tél.: (+352) 2478 5592. E-mail: pharmacovigilance@ms.etat.lu. Link pour le formulaire : https://guichet.public.lu/fr/entreprises/sectoriel/sante/medecins/notification-effets-indesirables-medicaments.html. **MARKETING AUTHORISATION HOLDER** Ipsen Pharma, 65 quai Georges Gorse, 92100 Boulogne-Billancourt, France. Local representative: Ipsen nv **MARKETING AUTHORISATION NUMBER(S)** Cabometyx 20 mg film-coated tablets EU/1/16/1136/002 Cabometyx 40 mg film-coated tablets EU/1/16/1136/004 Cabometyx 60 mg film-coated tablets EU/1/16/1136/006 **DELIVERY** prescription only medicine **DATE OF FIRST AUTHORISATION** 9 September 2016 **DATE OF RENEWAL OF THE AUTHORISATION** 21/04/2021 **DATE OF REVISION OF THE TEXT** 11/2021

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