

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

CARBODEX 150 mg/15 ml solution for IV infusion Sterile, Cytotoxic

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each 1 ml contains 10 mg carboplatin, 150 mg carboplatin in 15 ml (total volume)

Excipient(s):

For the full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Vial containing solution for infusion. 15 ml clear, colorless-pale yellow concentrated particle-free solution for infusion.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Ovarian carcinoma,
- Germ cell tumors,
- Small cell lung carcinoma,
- Other malignancies:

Non-small cell lung carcinoma, malign mesothelioma, breast carcinoma, head-neck carcinomas (Larynx carcinoma, nasopharynx carcinoma), esophagus carcinoma, stomach carcinoma, pancreas carcinoma, bladder carcinoma, soft tissue and bone sarcomas, lymphomas, malignancies of unknown primary, invasive squamous cell skin carcinoma, brain tumors, melanomas, neuroblastoma, myeloma, Wilm's tumor, hepatoblastoma.

4.2 Posology and method of administration

Posology/frequency and duration of administration:

The recommended dosage of carboplatin in previously untreated adult patients with normal kidney function is 400 mg/m² as a single IV dose administered by a 15 to 60

minutes infusion. Therapy should not be repeated until four weeks after the previous carboplatin course and/or until the neutrophil count is at least 2.000 cells/mm³ and the platelet count is at least 100.000 cells/mm³. Reduction of the initial dosage by 20-25% is recommended for those patients who present with risk factors such as prior myelosuppressive treatment and/or radiotherapy and significantly low performance status (ECOG-Zubrod 2-4 or Karnofsky below 80). Determination of the hematological nadir by weekly blood counts during the initial courses of treatment with carboplatin is recommended for future dosage adjustment. DEVA HOLDING A.S. Property-Strictly Confidential Page 1 of 11 CARBODEX 150 mg/15 ml Solution for IV Infusion

Combination chemotherapy:

The optimal use of carboplatin in combination with other myelosuppressive agents requires dosage adjustments according to the regimen and schedule to be adopted.

Method of administration:

Carboplatin is used by the intravenous route only. The solution must be administered by a shortterm intravenous infusion (15-60 minutes). The solution may be diluted in either 5% glucose or 0.9% sodium chloride. The safety measures for dangerous substances are to be complied with preparation and

administration. Preparation must be carried out by personnel who have been trained in the safe use

while wearing protective gloves, face mask and protective clothes. Needles or intravenous infusion sets containing aluminum parts that may come in contact with carboplatin injection should not be used for preparation or administration. Aluminum reacts with carboplatin injection causing precipitate formation and/or loss of potency. Additional information on special populations Renal/Hepatic impairment Patients with creatinine clearance values of less than 60 ml/min are at greater risk to develop myelosuppression (bone marrow suppression). The frequency of severe leucopenia, neutropenia, or thrombocytopenia has been maintained at about 25% level with the following dosage

recommendations:

Creatinine Clearance Initial Dose (Day 1) 41-59 ml/min. 250 mg/m² IV 16-40 ml/min. 200 mg/m² IV Insufficient data exist on the use of carboplatin in patients with creatinine clearance of 15 ml/min or less to permit a recommendation for treatment. All of the above dosing recommendations apply to the initial course of treatment. Subsequent dosages should be adjusted according to the patient's tolerance and to the acceptable level of myelosuppression.

Pediatric population:

There is insufficient experience available to recommend a dosage in the children.

Geriatric population:

In patients of more than 65 years of age, dosage adjustment may be necessary during the initial and the subsequent therapeutic courses depending on the physical condition of the patient.

4.3 Contraindications

CARBODEX is contraindicated in the following conditions.

- In patients with a history of hypersensitivity to carboplatin and/or platinum-containing compounds and any other excipients.

- In patients with severe myelosuppression,

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- In patients with pre-existing severe renal impairment (Creatinine clearance <30 ml/min),

- In pregnant women,

- During lactation,

- In patients with bleeding tumors,

- In children,

- Concomitant use with yellow fever vaccine (see section 4.5).

4.4 Special warnings and precautions for use

Carboplatin for injection should be used by only physicians experienced with cancer chemotherapeutic drugs. Blood counts as well as renal and hepatic function tests must be done regularly and the drug should be discontinued if abnormal depression of the bone marrow or abnormal renal or hepatic function is seen.

Hematologic toxicity:

Leucopenia, neutropenia and thrombocytopenia are dose-dependent and dose-limiting. Peripheral blood count should be monitored during carboplatin injection treatment frequently and, in cases of toxicity, until recovery is achieved. Median day of nadir is day 21 in patients receiving single agent carboplatin injection and day 15 in patients receiving carboplatin injection in combination with other chemotherapeutic agents. In general, single intermittent carboplatin injection doses should not be repeated until leucocytes, neutrophil and platelet counts have returned to normal. Therapy should not be repeated until 4 weeks after the previous carboplatin injection course and/or until the neutrophil count is at least 2000 cells/mm³ and the platelet count is at least 100.000 cells/mm³. Anemia is frequent and cumulative requiring very rarely a transfusion. Severity of myelosuppression is increased in patients with prior treatment (in particular with

cisplatin) and/or impaired kidney function. Initial carboplatin injection dosages in these groups of

patients should be appropriately reduced (see section 4.2) and the effects carefully monitored through frequent blood counts between courses. Carboplatin injection combination therapy with other myelosuppressive forms of treatment must be planned very carefully with respect to dosages and timing in order to minimize additive effects.

Allergic reactions:

As with other platinum-based drugs, allergic reactions appearing most often during perfusion may occur and necessitate discontinuation of the perfusion and an appropriate symptomatic treatment. Cross reactions, sometimes fatal, have been reported with all the platinum compounds (see section

4.3 and section 4.8).

Renal toxicity:

In patients with impaired renal function, the effect of carboplatin on the hematopoietic system is more pronounced and longer-acting than in patients with normal renal function. In this risk group, therapy with carboplatin must be administered with special caution (see section 4.2)

Neurologic toxicity:

Although peripheral neurologic toxicity is generally common and mild, limited to paresthesia and decrease of osteotendinous reflexes, its frequency is increased in patients older than 65 years and/or in patients previously treated with cisplatin. Monitoring and neurological examinations should be DEVA HOLDING A.S. Property-Strictly Confidential Page 3 of 11 CARBODEX 150 mg/15 ml Solution for IV Infusion carried out at regular intervals. Visual disturbances, including loss of vision, have been reported after the use of carboplatin injection in doses higher than those recommended in patients with renal impairment. Vision appears to recover totally or to a significant extent within weeks of stopping these high doses.

Geriatric use:

In studies involving combination therapy with carboplatin and cyclophosphamide, elderly patients treated with carboplatin were more likely to develop severe thrombocytopenia than younger patients. Because renal function is often decreased in the elderly, renal function should be considered when determining dosage (see section 4.2).

Other:

Auditory defects have been reported during carboplatin therapy. Ototoxicity may be more pronounced in children. Cases of hearing loss with a delayed onset have been reported in pediatric

patients. A long-term audiometric follow-up in this population is recommended.

Administration of live or live-attenuated vaccines in patients immunocompromised by chemotherapeutic agents including carboplatin, may result in serious or fatal

infections. Vaccination with a live vaccine should be avoided in patients receiving carboplatin. Killed or inactivated vaccines may be administered; however, the response to such vaccines may be diminished.

4.5 Interaction with other medicinal products and other forms of interaction

Due to the increase of thrombotic risk in case of tumoral diseases, the use of anticoagulative treatment is frequent. The high intra-individual variability of the coagulability during diseases, and the eventuality of interaction between oral anticoagulants and anticancer chemotherapy, require, if it is decided to treat the patient with oral anticoagulants, to increase frequency of the control of the INR (International Normalized Ratio) monitoring. Concomitant use contraindicated

- Yellow fever vaccine: Risk of generalized fatal vaccine disease (see section 4.3).

Concomitant use not recommended

- Live attenuated vaccines (except yellow fever): risk of systemic, possibly fatal disease. This risk

is increased in patients who are already immunosuppressed by their underlying disease. Use an inactivated vaccine where this exist (poliomyelitis).

- Phenytoin, fosphenytoin: Risk of exacerbation of convulsions (resulting from the decrease of

phenytoin digestive absorption by the cytotoxic drug), risk of toxicity enhancement or loss of efficacy of the cytotoxic drug (due to increased hepatic metabolism by phenytoin). Concomitant use to take into consideration

- Cyclosporin (and by extrapolation tacrolimus and sirolimus): Excessive immunosuppression

with risk of lymphoproliferation.

- Aminoglycosides: Concurrent therapy with nephrotoxic or ototoxic drugs such as aminoglycosides, vancomycin, capreomycin and diuretics, may increase or exacerbate toxicity, particularly in renal failure patients, due to carboplatin induced changes in renal clearance.

- Loop diuretics: The concomitant use of carboplatin with loop diuretic should be approached with

caution due to the cumulative nephrotoxicity and ototoxicity. DEVA HOLDING A.S.
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Renal/hepatic impairment:

Patients with creatinine clearance values of less than 60 ml/min are at greater risk to develop myelosuppression (bone marrow suppression). The frequency of severe leucopenia, neutropenia, or thrombocytopenia has been maintained at about 25% level with the following dosage

recommendations:

Creatinine Clearance Initial Dose (Day 1) 41-59 ml/min. 250 mg/m² IV 16-40 ml/min. 200 mg/m² IV Insufficient data exist on the use of carboplatin in patients with creatinine clearance of 15 ml/min or less to permit a recommendation for treatment. All of the above dosing recommendations apply to the initial course of treatment. Subsequent dosages should be adjusted according to the patient's tolerance and to the acceptable level of myelosuppression.

Pediatric population:

There is insufficient experience available to recommend a dosage in the children.

4.6 Fertility, pregnancy and lactation

General Principles Pregnancy category is D. Women of child-bearing potential/Contraception Women of childbearing potential should be warned to avoid becoming pregnant during treatment and should use effective contraceptive methods. Pregnancy Carboplatin has harmful pharmacologic effects on pregnancy and/or the fetus/new born. Carboplatin injection has been shown to be embryotoxic and teratogenic in rats receiving the drug during organogenesis. No controlled studies in pregnant women have been conducted. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus. CARBODEX should not be used in pregnancy unless necessary. Breast-feeding It is not known whether

carboplatin is excreted in human milk. If treatment becomes necessary during the lactation period, breastfeeding must be stopped. Fertility Gonadal suppression resulting in amenorrhea or azospermia may occur in patients receiving antineoplastic therapy. These effects appear to be related to dose and length of therapy and may be

irreversible. Prediction of the degree of testicular or ovarian function impairment is complicated by

the common use of combinations of several antineoplastics, which makes it difficult to assess the effects of individual agents. Men of sexually mature age treated with carboplatin are recommended not to father a child during DEVA HOLDING A.S. Property-Strictly Confidential Page 5 of 11 CARBODEX 150 mg/15 ml Solution for IV Infusion treatment and up to 6 month afterwards and to ask advice about spermatic preservation prior to initiation of the therapy because of the possibility of irreversible infertility due to therapy with carboplatin. Women with child-bearing potential should be advised to avoid becoming pregnant during their treatment with carboplatin.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. However, CARBODEX may cause nausea, vomiting, vision abnormalities and ototoxicity; therefore, patients should be warned on the potential effect of these events on the ability to drive or to use machines.

4.8 Undesirable effects

The frequency of adverse reactions reported is based on a cumulative database of 1,893 patients receiving single agent carboplatin injection and post-marketing experience. The list is presented by system organ class, MedDRA preferred term, and frequency using the following frequency categories: Very common ($\geq 1/10$); common ($\geq 1/100$, $< 1/10$); uncommon ($\geq 1/1,000$, $< 1/10,000$); not known (cannot be estimated from the available data). System Organ Class Frequency MedDRA Term Infections and infestations Common Infections* Neoplasms, benign and Not known Treatment related secondary malignancy malignant (including cysts and polyps) Blood and lymphatic system Very common Thrombocytopenia, neutropenia,

leucopenia, anemia disorders Common Hemorrhage* Not known Bone marrow failure, febrile neutropenia, hemolyticuremic syndrome Immunity system disorders Common Hypersensitivity, anaphylactoid reaction Metabolism and nutrition Not known Dehydration, anorexia, hyponatremia disorders Nervous system disorders Common Neuropathy peripheral, paresthesia, decrease of osteotendinous reflexes, sensory disturbance, dysgeusia Not known Cerebrovascular accident* Eye disorders Common Visual disturbance Rare cases of loss of vision Ear and labyrinth disorders Common Ototoxicity Cardiac disorders Common Cardiovascular disorder* Not known Cardiac failure* Vascular disorders Not known Embolism*, hypertension, hypotension Respiratory, thoracic and Common Respiratory disorder, interstitial lung disease, mediastinal disorders bronchospasm Gastrointestinal disorders Very common Vomiting, nausea, abdominal pain Common Diarrhea, constipation, mucous membrane disorder Not known Stomatitis Skin and subcutaneous tissue Common Alopecia, skin disorder disorders Not known Urticaria, rash, erythema, pruritus Musculoskeletal and Common Musculoskeletal disorder connective tissue disorders Renal and urinary disorders Common Urogenital disorder

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General disorders and Common Asthenia administration site conditions Not known Injection site necrosis, Injection site reaction, Injection site extravasation, Injection site erythema, malaise Investigations Very common Creatinine renal clearance decreased, blood urea increased, blood alkaline phosphatase increased, aspartate aminotransferase increased, liver function test abnormal, blood sodium decreased, blood potassium decreased, blood calcium decreased, blood magnesium decreased. Common Blood bilirubin increased, blood creatinine increased, blood uric acid increased *Fatal in <1%, fatal cardiovascular events in <1% included cardiac failure, embolism and cerebrovascular accident combined. Blood and lymphatic system disorders Myelosuppression is the dose-limiting toxicity of carboplatin injection. In patients with normal baseline values, thrombocytopenia with platelet counts below 50.000/mm³ occurs in 25% of patients, neutropenia with granulocyte counts below 1.000/mm³ in 18% of patients, and leucopenia with WBC counts below 2000/mm³ in 14% of patients. The nadir usually occurs on day 21. Myelosuppression can be worsened by combination of carboplatin injection with other myelosuppressive compounds or forms of

treatment. Myelotoxicity is more severe in previously treated patients, in particular in patients previously treated with cisplatin and in patients with impaired renal function. Patients with poor performance status have also experienced increased leucopenia and thrombocytopenia. These effects, although usually reversible, have resulted in infectious and hemorrhagic complications in 4% and 5% of patients given carboplatin injection, respectively. These complications have led to death in less than 1% of patients. Anemia with hemoglobin values below 8 g/dl has been observed in 15% of patients with normal baseline values. The incidence of anemia is increased with increasing exposure to carboplatin injection. Immunity system disorders Anaphylactic-type reactions, sometimes fatal, may occur in the minutes following injection of the product: facial edema, dyspnea, tachycardia, low blood pressure, urticaria, anaphylactic shock, bronchospasm. Nervous system disorders Peripheral neuropathy (mainly paresthesias and decrease of osteotendinous reflexes) has occurred in 4% of patients administered carboplatin injection. Patients older than 65 years and patients previously treated with cisplatin, as well as those receiving prolonged treatment with carboplatin injection, appear to be at increased risk. Clinically significant sensory disturbances (i.e., visual disturbances and taste modifications) have occurred in 1% of patients. The overall frequency of neurologic side effects seems to be increased in patients receiving carboplatin injection in combination. This may also be related to longer cumulative exposure. Ear and labyrinth disorders Auditory defects out of the speech range with impairments in the high-frequency range (4.000-

8.000 Hz) were found in serial audiometric investigations with a frequency of 15%. Very rare cases

of hypoacusia have been reported. In patients who have been previously treated with cisplatin and have a hearing organ predamaged DEVA HOLDING A.S. Property-Strictly Confidential Page 7 of 11 CARBODEX 150 mg/15 ml Solution for IV Infusion due to cisplatin, a further exacerbation in the hearing function sometimes occurs during treatment with carboplatin. Gastrointestinal disorders Vomiting occurs in 65% of patients, in one-third of whom it is severe. Nausea occurs in an additional 15%. Previously treated patients (in particular patients previously treated with cisplatin) appear to be more prone to vomiting. Nausea and vomiting usually

disappear within 24 hours after treatment and are generally responsive to or prevented by antiemetic medication. Vomiting is more likely when carboplatin injection is given in combination with other emetogenic compounds. The other gastro-intestinal complaints corresponded to pain in 8% of patients, diarrhea, and constipation in 6% of patient. Renal and urinary disorders When given in usual doses, development of abnormal renal function has been uncommon, despite the fact that carboplatin injection has been administered without high-volume fluid hydration and/or forced diuresis. Elevation of serum creatinine occurs in 6% of patients, elevation of blood urea nitrogen in 14%, and of uric acid in 5% of patients. These are usually mild and are reversible in about one-half the patients. Creatinine clearance has proven to be the most sensitive renal function measure in patients receiving carboplatin injection. 27% of patients who have a baseline value of 60 ml/min or greater, experience a reduction in creatinine clearance during carboplatin injection therapy. Investigations Decreases in serum sodium, potassium, calcium, and magnesium occur in 29%, 20%, 22%, and 29% of patients, respectively. In particular, cases of early hyponatremia have been reported. The electrolyte losses are minor and mostly take a course without any clinical symptoms. Modification of liver function in patients with normal baseline values was observed, including elevation of total bilirubin in 5%, SGOT in 15%, and alkaline phosphatase in 24% of patients. These modifications were generally mild and reversible in about one-half the patients. In a limited series of patients receiving very high dosages of carboplatin injection and autologous bone marrow transplantation, severe elevation of liver function tests has occurred. Cases of an acute, fulminant liver cell necrosis occurred after high-dosed administration of carboplatin.

Other undesired effects:

Secondary acute malignancies after cytostatic combination therapies containing carboplatin have been reported. Alopecia, fever and chills, mucositis, asthenia, malaise as well as dysgeusia have occasionally been observed. In isolated cases, a hemolytic-uremic syndrome occurred. Isolated cases of cardiovascular incidents (cardiac insufficiency, embolism) as well as isolated cases of cerebrovascular accidents have been reported. Cases of hypertension have been reported.

Local reactions:

Injection site reactions (Burning, pain, redness, swelling, hives, and necrosis with extravasation) were reported. DEVA HOLDING A.S. Property-Strictly Confidential
Page 8 of 11 CARBODEX 150 mg/15 ml Solution for IV Infusion Reporting of suspected adverse reactions Reporting suspected adverse reactions after authorization 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 to Turkey Pharmacovigilance Centre (TÜFAM). (www.titck.gov.tr; e-mail: tufam@titck.gov.tr; phone number: 0 800 314 00 08; fax: 0 312 218 35 99)

4.9 Overdose

There is no specific antidote for carboplatin. Overdose may lead to impaired renal, hepatic and auditory functions as well as myelosuppression. Use of higher than recommended doses of carboplatin injection may cause loss of vision (see section 4.4).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antineoplastic agents (Platinum compounds) ATC code: L01XA02 Carboplatin is a cytotoxic, inorganic heavy metal complex. Carboplatin binds to DNA to produce intra- and interstrand crosslinks which inhibit DNA synthesis. Cross-resistance was developed by continuous cisplatin in animal studies.

5.2 Pharmacokinetic properties

Absorption:

After intravenous administration the highest plasma level as well as the AUC (area under the curve) value of unchanged carboplatin, ultrafiltrated platinum and total platinum content corresponds linearly with the administered dose.

Distribution:

After IV administration as short term infusion (<1 hour) the plasma concentrations decreases biphasically following first order kinetics. Initial half-life ($T_{1/2}$) for unchanged carboplatin and free platinum is 90 minutes, for total platinum 100

minutes. Terminal half-life ($T_{1/2}$) for free platinum is 6 hours and for total platinum 24-40 hours. After repeated administrations (5 days consecutive intravenous administration of carboplatin single

doses) accumulation of platinum in plasma is not found. Pharmacokinetic parameters on first day of

administration are almost same as those after 2-5 days of administration.

Elimination:

Plasma protein binding rate of carboplatin is 20-25% after 4 hours, and >90% after 24 hours. Carboplatin is mainly eliminated by the kidneys. 60-80% of administered dose found in urine after 24 hours. Elimination rate of carboplatin mainly depends on glomerular filtration rate. In patients with impaired renal function the carboplatin dosage must be reduced according to the reduced clearance otherwise the myelosuppressive activity of carboplatin increases.

5.3 Preclinical safety data

Carboplatin has been shown to be cytotoxic, mutagenic and embryotoxic in the preclinical studies. The product is essentially similar to other products authorized in EU countries. Use of this DEVA HOLDING A.S. Property-Strictly Confidential Page 9 of 11 CARBODEX 150 mg/15 ml Solution for IV Infusion medicinal product is well-known and its efficiency was established by several publications.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections

6.2 Incompatibilities

In order to reduce risk of decreased antineoplastic activity of carboplatin and precipitate formation; needles, syringes, catheters or intravenous sets containing aluminum parts that may come into contact with carboplatin should not be used for preparation or administration of carboplatin.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at room temperature below 25°C. Store in its original package to protect from light. See section 6.6 for storage conditions and shelf life after dilution.

6.5 Nature and contents of container

Each box contains amber colored Type I glass single-use vial with rubber stopper sealed flip-off aluminum cap with plastic disc.

6.6 Special precautions for disposal and other handling

For single use only. Exposure to CARBODEX and other cytotoxic drugs should be avoided by pregnant women. It should not be administered and transferred by pregnant staff. Infusion solution should be prepared and disposed by personnel who have been trained in the safe use of cytotoxics. Preparation should be performed in a designated aseptic area. Personnel should wear appropriate clothing, mask, protective goggles and gloves. In the event of contamination with eyes, eyes should be rinsed with plenty of water and asked for a physician if needed. Adequate care and precautions should be taken in disposal of materials (needle, syringe etc.) used to reconstitute cytotoxic drugs. Waste materials and body waste must be disposed of by placing in double sealed polyethylene bags and incinerating at a temperature of 1000°C. Liquid waste should be flushed with copious amounts of pressurized water. Any unused product or waste material should be disposed of in accordance with local disposal regulations. Any unused solution should be discarded.

Disposal of the medicine or contaminated materials:

Incineration: 1000°C Chemical: Dilute in large volumes of water; allow to stand for 48 hours. DEVA HOLDING A.S. Property-Strictly Confidential Page 10 of 11
CARBODEX 150 mg/15 ml Solution for IV Infusion Contact with skin: Wash with water. Liquid waste should be flushed with copious amounts of water.

Instructions for dilution:

CARBODEX should be diluted before use. The solution may be diluted with either 5% glucose or 0.9% sodium chloride. From a microbiological point of view, the diluted solution should be used immediately. If not used immediately, in-use storage conditions are the responsibility of the user (would normally not be longer

than 24 hours at 2-8°C, unless dilution has taken place under controlled and validated aseptic conditions). The following stability data (physical and chemical) is valid for diluted solution when that process

is performed under aseptic conditions:

Carboplatin Stability Duration Vehicles Conditions Concentration (mg/ml) (hours)
Room temperature/ protect 5% glucose solution 0.4-2 72 from light 0.9% sodium chloride solution 2 2-8°C/ protect from light 24 However, infusion solution diluted with 0.9% sodium chloride solution is recommended to be used immediately after preparation. Carboplatin is for intravenous use only. The solution must be administered by a short-term intravenous infusion (15-60 minutes). Needles, syringes or intravenous sets containing aluminum parts that may come into contact with carboplatin should not be used for preparation or administration of carboplatin. Aluminum reacts with carboplatin injection causing precipitate formation and/or loss of potency.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

H2025/CTD9329/15769

9. DATE OF FIRST AUTHORIZATION/ RENEWAL OF THE AUTHORIZATION

2025 July 14

10. DATE OF REVISION OF THE TEXT

2025 July 14