

BELMEDPREPARATY RUE

Oncology medicines

manufactured by
Belmedpreperaty RUE



Temobel

capsules 20 mg, 100 mg, 250 mg

Trade name: Temobel.

International nonproprietary name: Temozolomide.

Pharmaceutical form: capsules 20 mg, 100 mg and 250 mg.

Composition: each capsule contains:

Active ingredients: temozolomide.

Excipients: stearic acid, tartaric acid, colloidal anhydrous silica, sodium starch glycolate type A, anhydrous lactose.

ATC code: L01AX03.

Indications for use

- ▶ Adult patients with newly-diagnosed glioblastoma multiforme concomitantly with radiotherapy and subsequently as monotherapy.



- ▶ Children over the age of 3 years and adult patients with malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy.

Alkylating agents

Temodex

powder for preparing gel for local use
100 mg

Trade name: Temodex.

International non-proprietary name: Temozolomide.

Description: powder from white to greenish-gray or brown.

Composition: each package contains: temozolomide (in the form of temodex (mixture of temozolomide and sodium dextran phosphate)) – 100 mg.

Dosage form: powder for gel preparation for topical use.

Pharmacotherapeutic group: Antitumor agent of alkylating action.

ATC code: L01AX03.

Indications for use

The newly discovered multiform glioblastoma (as part of combined treatment in combination with radiotherapy); Malignant glioma (glioblastoma multiforme or anaplastic astrocytoma).



Cyclophosphan

powder for preparing solution for injection

Trade name: Cyclophosphan.

International nonproprietary name: Cyclophosphamide.

Pharmaceutical form: powder for preparing solution for injections.

Composition: each vial contains:

Active substance: cyclophosphamide – 200 mg.

ATC code: L01AA01.

Indications for use

Small cell carcinoma of the lung, ovarian carcinoma, breast cancer, cancer of the neck and of the body of the uterus, urinary bladder cancer, prostate cancer, neuroblastoma,

retinoblastoma, lymphogranulomatosis, lymphosarcoma, non-Hodgkin lymphoma, reticulosarcoma, osteogenous sarcoma, multiple myeloma, chronic lympholeukemia and myeloleukemia and monoblastic leukemia, Wilms' tumor,

Ewing's tumor, granulosa sarcoma, testis; autoimmune disease: rheumatoid arthritis, psoriatic arthritis, systemic disorders of the connective tissue, autoimmune hemolytic anemia, nephritic syndrome, suppression of the host-against-transplant reaction.



Alkylating agents

Gemcitabine

*powder lyophilized for preparing solution
for injection 200 mg, 1000 mg*

Trade name: Gemcitabine.

**International nonproprietary
name:** Gemcitabine.

Composition: each 10 ml vial
contains:

Active substance: gemcitabine
(as gemcitabine hydrochloride) –
200 mg and 1000 mg.

Excipients: mannitol, sodium
acetate (as sodium acetate
trihydrate).

Dosage form: lyophilized
powder for solution for infusion.

ATC code: L01BC05.



Indications for use

- ▶ Treatment of localised or metastatic bladder cancer in combination with cisplatin.
- ▶ Treatment of localised or metastatic pancreatic adenocarcinoma.
- ▶ First-line therapy of localised or metastatic non-small cell lung cancer (NSCLC) in combination with cisplatin. Gemcitabine monotherapy is possible in elderly patients or patients with physical function 2.
- ▶ Treatment of localised or metastatic epithelial ovarian cancer in combination with carboplatin in relapse patients after at least 6 months of delaying time to relapse after the end of the first line of platinum-based therapy.
- ▶ Complex treatment with paclitaxel of localised unresectable or metastatic breast cancer in relapse patients after adjuvant/non-adjuvant chemotherapy. The primary therapy shall include anthracycline in absence of contraindications.

Cladribine

solution for injection 1 mg/ml

Trade name: Cladribine.

International nonproprietary name: Cladribine.

Dosage form: solution for injection 1 mg/ml.

Description: a clear colorless solution.

Composition: each vial contains:

Active ingredient: cladribine – 10 mg.

Excipients: potassium dihydrogen phosphate, sodium chloride, 1 M solution of sodium hydroxide, water for injection.

ATC Code: L01BB04.

Indications for use

- ▶ Hairy Cell Leukemia.
- ▶ Chronic lymphatic leukemia (progressing forms and the ones resistant to first line polychemotherapy drugs).
- ▶ Low-grade and intermediate magliant non-Hodgkin's lymphomas.



Mercaptopurine

tablets 50 mg

Trade name: Mercaptopurine.

International nonproprietary name:
Mercaptopurine.

Description: light yellow flat round beveled tablets.

Composition: each tablet contains:

Active ingredient: mercaptopurine – 50 mg.

Excipients: lactose monohydrate, sodium starch glycolate type A, calcium stearate, potato starch.

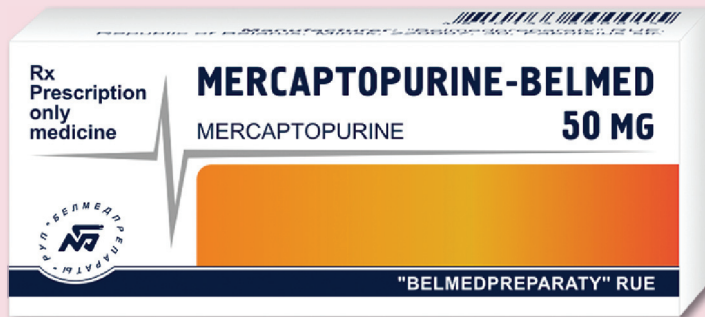
Pharmaceutical form: tablets.

ATC code: L01BB02.

Indications for use

Acute lymphatic leukemia, acute myeloleukemia (remission induction and supporting therapy).

Official instructions on proper treatment of the above diseases should be taken into account.



Methotrexate

tablets 2.5 mg and 5 mg

Trade name: Methotrexate.

International nonproprietary name: Methotrexate.

Description: biconvex, yellow film-coated tablets.

Composition: each tablet contains:

Active substance: methotrexate – 2.5 mg or 5 mg.

Excipients: lactose monohydrate, povidone, calcium stearate, potato starch, *coating:* opadry II color; *composition:* opadry II yellow: polyvinyl alcohol-part. hydrolyzed, macrogol / polyethylene glycol, quinoline yellow aluminum lake (E-104), sunny sunset yellow FCF aluminum lake (E-110), talc, titanium dioxide, iron oxide yellow (E-172).

Pharmaceutical form: film-coated tablet.

Pharmaceutical group: Anticancer drugs.
Antimetabolites.

ATC code: L01BA01.

Indications for use

Lympho- and myeloblastic leukosis, neuroleukemia, myelomatosis, trophoblastomas (uterine chorioepithelioma, cystic mole, incl. invasive mole), esophageal cancer, epidermoid cancer of head and neck, cancer of urinary bladder, cancer of lung, liver cancer, breast cancer, renal carcinoma, cancer of ureters, prostate cancer, cervical cancer, cancer of vulva, ovarian cancer, testicular cancer, Hodgkin's and non-Hodgkin's lymphoma (incl. Burkitt's lymphoma), mycosis fungoides (local treatment), non-metastatic osteogenic sarcoma. Rheumatoid arthritis (incl. Felty's syndrome), steroid-dependent bronchial asthma (if glucocorticoids are contraindicated), Crohn's disease, chronic nonspecific ulcerative colitis, lichen ruber planus, psoriasis, psoriatic arthritis, Reiter's syndrome, Sezary syndrome, disseminated sclerosis.



Antimetabolites



Methotrexate

*powder lyophilized for preparing solution
for injection 10 mg, 50 mg, 1000 mg*

Trade name: Methotrexate.

International non-proprietary name: Methotrexate.

Description: porous mass or powder of from yellow, orange to yellow-brown nonhomogenous color, hygroscopic.

Composition: each ampoule/vial contains:

Active substance: methotrexate (in the form of methotrexate sodium) – 10 mg, 50 mg, 1000 mg.

Pharmaceutical form: lyophilized powder for solution for injection.

ATC code: L01BA01.

Indications for use
Oncologic diseases.



Methotrexate is indicated for treatment of gestational choriocarcinoma, chorioadenoma destruens and hydatidiform mole.

In case of acute lymphoblastic leukemia, methotrexate is indicated for the prophylactics of meningeal leukemia and is used in maintenance therapy in combination with other chemotherapeutic agents. Methotrexate is also indicated for the treatment of meningeal leukemia.

Methotrexate is used alone or in combination with other anticancer agents in the treatment of breast cancer, epidermoid cancers of the head and neck, advanced mycosis fungoides (cutaneous T-cell lymphoma), and lung cancer, particularly squamous cell and small cell types. Methotrexate is also used in combination with other chemotherapeutic agents for treatment of advanced stage non-Hodgkin's lymphoma.

Methotrexate in high doses followed by calcium folinate rescue in combination with other chemotherapeutic agents is effective in prolonging relapse-free survival in patients with non-metastatic osteosarcoma who

have undergone surgical resection or amputation of the primary tumor.

Psoriasis

Methotrexate is indicated for the symptomatic control of severe, recalcitrant, disabling psoriasis in patients who do not have adequate response to other forms of therapy, but only when the diagnosis has been established, by biopsy and/or after dermatologic consultations. It is important to ensure that a psoriasis flare is not due to an undiagnosed disease affecting immune responses.

Rheumatoid arthritis including polyarticular-course juvenile rheumatoid arthritis

Methotrexate is indicated in the management of selected category of adult patients with severe, active rheumatoid arthritis (ACR criteria), or children with active polyarticular-course juvenile

rheumatoid arthritis, who have had an insufficient therapeutic response to, or are intolerant of, an adequate first-line therapy including a full dose of non-steroidal anti-inflammatory agents (NSAIDs).

Aspirin, (NSAIDs), and/or low dose steroids may be continued, although the possibility of increased toxicity with concomitant use of NSAIDs including salicylates has not been fully explored. Steroids may be reduced gradually in patients who respond to methotrexate. Combined use of methotrexate with gold, penicillamine, hydroxychloroquine, sulfasalazine, or cytotoxic agents, has not been studied and may increase the incidence of adverse effects. Rest and physiotherapy as indicated should be continued.



Cytarabine

powder lyophilized for preparing solution for injection / solution for injection 20 mg/ml

Trade name: Cytarabine.

International nonproprietary name: Cytarabine.

Pharmaceutical form:

Lyophilized powder injection, 100 mg, 1000 mg. Porous white mass in form of tablet

Solutions for injections 20 mg/ml.

Composition: each vial contains:

Active substance: cytarabine 1000 mg, 100 mg.

Excipients: low-molecular polyvinyl pyrrolidone medical grade Mr 12600 ± 2700 (povidone).

ATC code: L01BC01.

Indications for use

- ▶ Lymphoblast and myeloblast leukemia.
- ▶ Chronic myeloleukemia.
- ▶ Erythroleukemia, lymphogranulomatosis.

▶ Non-Hodgkin's lymphoma.

▶ Syndrome of bone marrow dysplasia.

The Cytarabine high-dose therapy is applied within the induction and consolidation programs under primary acute lymphoblast and myeloblast leukemia; under secondary leukemia developed either after the preceding

cytostatic and/or beam therapy or as a result of the MDS transformation; under primarily resistant forms of acute leukemia; under resistant relapses of acute leukemia; under a blast crisis of chronic myeloleukemia; under resistant forms of highly malignant Hodgkin's and non-Hodgkin's lymphomas.



Fludarabine-Belmed

*powder lyophilized for preparing solution
for injection 50 mg*

Trade name: Fludarabine-Belmed.

International nonproprietary name: Fludarabine.

Description: white powder or porous mass compressed as a tablet.

Composition: each ampoule contains:

Active substance: fludarabine phosphate – 50 mg.

Excipients: mannitol, 1M sodium hydroxide solution.

Pharmaceutical form: lyophilized powder for solution for injection 50 mg.

ATC code: L01BB05.

Indications for use

B-cell chronic lymphocytic leukemia (CLL) in patients with sufficient bone marrow reserve. The therapy with the drug product as the essential one should be administered in patients with progressing disease of Rai stage III/IV (Binet C) or Rai stage I/II (Binet A/B) when the patient has the symptoms connected with the disease or attribute of progressing disease.



Docetaxel

*concentrate for preparing solution
for infusion 20 mg/ml*

Trade name: Docetaxel.

International nonproprietary name: Docetaxel.

Description: clear light yellow solution.

Composition: each vial with a capacity of 1 ml, 2 ml, 4 ml contains

Active substance: docetaxel, mg 20, 40, 80.

Excipients: anhydrous citric acid, mg 4, 8, 16, anhydrous ethanol pharmacopoeial, ml 0.5, 1, 2, polysorbate 80, ml to 1, to 2, to 4.

Pharmaceutical form: concentrate for solution for infusion.

ATC code: L01CD02.

Indications for use

► Breast cancer (BC)

Operable BC (adjuvant chemotherapy combined with doxorubicin and cyclophosphamide):

- involving regional lymph glands;
- without involving regional lymph glands in patients indicated for chemotherapy according to the established international selection criteria for initial chemotherapy at early stages of BC (in case of one or more factors of high risk of recurrence: tumor size more than 2 cm, negative status of estrogen and progesterone receptors, high histological level of tumor malignancy (level 2-3), age under 35 years old).

Metastatic and/or locally advanced BC:

- locally advanced or metastatic BC (first line therapy combined with doxorubicin);



- metastatic BC with tumor hyperexpression HER2 (first line therapy combined with trastuzumab);
- locally advanced or metastatic BC in non-effective previous chemotherapy including anthracyclines or alkalisng preparations (in monotherapy) or in non-effective previous chemotherapy including anthracyclines (combined with capecitabine).

- ▶ Non-small cell lung cancer non-operable, locally advanced or metastatic non-small cell lung cancer (combined with cisplatin or carboplatin) as first line therapy or in monotherapy as second line therapy.

- ▶ Metastatic ovarian cancer second line therapy.

- ▶ Head and neck cancer.

Locally advanced squamous cell carcinoma of head and neck (induction therapy combined with cisplatin and 5-fluorouracil).

- ▶ Prostate cancer.

metastatic prostate cancer, refractory to hormonal therapy (combined with or prednisone or prednisolone).

- ▶ Stomach cancer metastatic stomach cancer including cancer of esophagogastric transition zone (first line therapy combined with cisplatin and 5-fluorouracil).



Vinorelbine

*concentrate for preparing solution
for infusion 10 mg/ml*

Trade name: Vinorelbine.

International nonproprietary name: Vinorelbine.

Description: clear colorless or pale-yellow solution.

Composition: each vial contains:

Active substance: vinorelbine (as vinorelbine tartrate) –
10 mg or 50 mg.

Excipient: water for injections.

Pharmaceutical form: concentrate for solution for
infusion.

ATC code: L01CA04.

Indications for use

- ▶ Extensive inoperable non-small cell lung cancer of 3-4th grade.
- ▶ Disease breast cancer of 3-4th grade refractory or progressing after chemotherapy including anthracyclines.



Paclitaxel

*concentrate for preparing solution
for infusion 100 mg/16,7 ml and 30 mg/5 ml*

Trade Name: Paclitaxel.

International nonproprietary name: Paclitaxel.

Description: oily clear colorless or yellowish liquid.

Composition: 1 ml contains:

Active ingredients: semisynthetic paclitaxel – 6 mg.

Excipients: citric acid anhydrous, ethanol anhydrous, macrogolglycerol ricinoleate.

ATC code: L01CD01.

Indications for use

- ▶ Ovarian Cancer (the 1st line therapy (in combination with cisplatin) in patients with advanced metastatic or residual tumor (more than 1 cm) after laparotomy and the 2nd line therapy in patients with advanced metastatic ovarian cancer after unsuccessful standard therapy).
- ▶ Breast cancer (adjuvant therapy in patients with lymph nodes metastasis after standard combination therapy, the 1st line therapy in metastatic cancer and the disease aggravation after adjuvant therapy with anthracyclines, the 2nd line therapy with the disease aggravation after combination chemotherapy with anthracycline antitumor antibiotics).
- ▶ Non-small cell lung cancer (the 1st line therapy in combination with cisplatin or monotherapy in patients who haven't been planned for surgery and/or radiation therapy with the chance to be cured).
- ▶ Kaposi's sarcoma in AIDS patients: the 2nd line therapy.
- ▶ Squamous cell carcinoma of head and neck.
- ▶ Transitional cell carcinoma of the bladder.



Vincristine-Belmed

solution for injection 1 mg/2 ml

Trade name: Vincristine-Belmed.

International nonproprietary name: Vincristine.

Description: clear, colorless or light yellow solution.

Composition: each vial contains:

Active substance: vincristine sulfate 0.5 mg (1 ml vial) or 1 mg (2 ml vial);

Excipients: mannitol (E421), sulfuric acid (E513), sodium hydroxide (E524), water for injection.

Pharmaceutical form: solution for intravenous administration.

Pharmacotherapeutic group: Antineoplastic drugs. Vinca alkaloids and their analogues.

ATC code: L01CA02.

Indications for use

- ▶ Leukemia, including acute lymphocytic leukemia, chronic lymphocytic leukemia, acute myeloblastic

leukemia and blast crisis of chronic myelogenous leukemia.

- ▶ Malignant lymphomas, including Hodgkin's disease and non-Hodgkin's lymphoma.
- ▶ Multiple myeloma.
- ▶ Solid tumors, including breast cancer, small cell lung cancer, head and neck tumors and soft tissue sarcoma.
- ▶ Solid tumors of children, including Ewing's sarcoma, embryonic rhabdomyosarcoma, neuroblastoma, Wilms tumor, retinoblastoma and medulloblastoma.
- ▶ Idiopathic thrombocytopenic purpura (with resistance to corticosteroids and ineffectiveness of splenectomy). It is not recommended to use vincristine as a first-line preparation. The recommended weekly doses of vincristine from 3 to 4 weeks in some patients led to a stable remission. If the patient does not respond to vincristine after 3 to 6 doses, then the probability of positive dynamics for additional doses is small.



Doxorubicin hydrochloride

powder lyophilized for preparing solution for injection 10 mg

Trade name: Doxorubicin hydrochloride.

International nonproprietary name: Doxorubicin.

Composition: one vial contains:

Active ingredients: doxorubicin hydrochloride – 10 mg.

Excipients: mannitol.

Pharmaceutical form: lyophilized powder for injection, 10 mg.

ATC code: L01DB01.

Indications for use

- ▶ Acute lymphoblastic and myeloblastic leukemia, chronic lymphatic leukemia, myelomatosis, lymphogranulomatosis, non-Hodgkin's lymphoma.
- ▶ Breast cancer.
- ▶ Carcinoma of lung (especially small cell carcinoma), urinary bladder (treatment and secondary

prophylaxis after surgical procedures), thyroid gland, ovaries.



▶ Osteogenic sarcomata and soft tissue sarcomata; Ewing's sarcoma; neuroblastoma; Wilms' tumor, cancer of endometrium, Kaposi's sarcoma in case of AIDS, retinoblastoma.

▶ Malignant thymoma, hepatoblastoma, primary hepatocellular carcinoma.

▶ Other solid tumors: cancer of endometrium, neck of uterus, malignant ovary tumors, cancer of prostate gland, cancer of esophagus, cancer of stomach, cancer of adrenal glands, cancer of liver and cancer of pancreas.

Photolon®

*powder lyophilized for preparing solution
for injection 100 mg*



Trade name: Photolon®.

International nonproprietary name (INN): none.

Description: Greenish black porous mass. Violet tint is allowed.

Composition: each bottle/vial contains:

Active ingredient: chlorin E6 (trisodium salt of chlorin E6) – 100 mg.

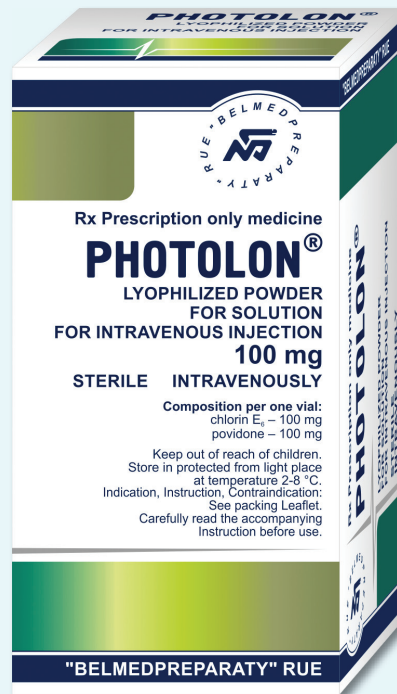
Excipients: low-molecular polyvinyl pyrrolidone medical grade Mr 12600±2700 (povidone).

Pharmaceutical form: lyophilized powder for injection, 100 mg.

ATC code: L01XD.

Indications for use

Oncology: photodynamic therapy of pre-cancerous lesions and malignant tumors: skin cancers



(squamous cell carcinoma, basal cell carcinoma), melanoma and intracutaneous metastases of breast cancer, superficial mucosal tumors (vulva, esophagus, rectum); intraoperative photodynamic therapy of malignant tumors of the brain (in the combination therapy); diagnostics of malignant tumors by spektrofluorescent method.

Ophthalmology: photodynamic therapy of ophthalmologic diseases, diseases of organ of vision accompanied by the development of vascular neoplasms in its structure: subretinal neovascular membranes in under central involutinal chorioretinal dystrophy and myopic maculopathy.

Oxaliplatin

*powder lyophilized for preparing solution
for infusion 50 mg and 100 mg*

Trade name: Oxaliplatin.

International nonproprietary name: Oxaliplatin.

Description: white or almost white powder or porous mass.

Composition: one bottle/vial contains:

Active substance: oxaliplatin – 50 mg and 100 mg.

Excipients: lactose monohydrate.

Pharmaceutical form: lyophilized powder for infusion.

ATC code: L01XA03.

Indications for use

- ▶ III stage colorectal cancer (Dukes' stage C) adjuvant therapy after the primary tumor radical resection in combination with 5-fluorouracil and folic acid;
- ▶ disseminated colorectal cancer (monotherapy or combined therapy with 5-fluorouracil and folic acid).



Hydroxycarbamide

capsules 250 mg

Trade name: Hydroxycarbamide.

International nonproprietary name: Hydroxycarbamide.

Description: White hard gelatin capsules No. 0. Capsule content – white or white with yellowish tint powder. Allowed presence seals the capsule mass in form of a column or tablets which, when pressing a glass rod disintegrate.

Composition: each capsule contains:

Active ingredients: hydroxycarbamide – 250 mg.

Excipients: citric acid monohydrate, disodium phosphate anhydrous, calcium stearate, sodium laurilsulfate, sodium citrate 5.5-hydrate.

Hard gelatin capsule composition: gelatin, glycerin, purified water, titanium dioxide, sodium laurilsulfate.

Pharmaceutical form: capsules 250 mg.

ATC code: L01XX05.



Indications for use

Melanoma, resistant chronic myeloid leukemia, recurrent metastatic or unresectable ovarian cancer, cervical cancer, head and neck cancer with exception of lips (simultaneously with radiation therapy).



Anastrozole

tablets 1 mg

Trade name: Anastrozole.

International nonproprietary name: Anastrozole.

Description: White or off-white round, biconvex film-coated tablets. Coating roughness on tablets surface is permissible.

Composition: each tablet contains:

Active substance – anastrozole – 1 mg.

Excipients – sodium starch glycolate (A type), povidone K-25, calcium stearate, sodium lauryl sulfate, lactose monohydrate, opadry II white (85 F).

Composition of coating substance (opadry II white (85 F)): partially hydrolyzed polyvinyl alcohol, macrogol/polyethyleneglycol, talc (E553b); titanium dioxide (E171).

Pharmaceutical form: film-coated tablets.

Pharmacotherapeutic group: antineoplastic agent, estrogen synthesis inhibitor.

ATC code: L02BG03.

Indications for use

Adjuvant therapy of early hormone-positive breast cancer in postmenopausal period.



Advanced breast cancer in postmenopausal women.
Adjuvant therapy of early hormone-positive breast cancer in postmenopausal period after taking tamoxifen during 2-3 years.

Other medicines for oncological diseases therapy

Calcium folinate

powder lyophilized for preparing solution for injection 50 mg and 100 mg

Trade name: Calcium folinate.

International nonproprietary name: Calcium folinate.

Pharmaceutical form: lyophilized powder for solution for intravenous and intramuscular injection.

Description: light yellow to yellow porous mass, non-uniform color. Hygroscopic.

Composition: each vial contains:

Active ingredient: calcium folinate (calculated as folinic acid) – 50 mg or 100 mg.

Excipient: methylparahydroxybenzoate.

Pharmaceutical group: Folic acid antagonist antidote, 5-fluorouracil biological action modifier, vitamin.

ATC code: V03AF03.

Indications for use

- ▶ Intoxications caused by folic acid antagonists (methotrexate, trimethoprim, and pyrimetamine).
- ▶ Prevention of the methotrexate toxic effect when it is administered in elevated and high doses.



- ▶ Colorectal cancer (as a part of the combined therapy with fluorouracil).
- ▶ Megaloblastic anemia on the background of folic acid deficit (including one on the background of malabsorption syndrome, undernutrition, pregnancy, sprue, in infancy in case of hereditary dihydrofolate reductase deficiency).



Zoledronic acid

*powder lyophilized for solution
for infusion 4 mg*



Trade name: Zoledronic acid.

International nonproprietary name: Zoledronic acid.

Description: white powder or porous mass. Hygroscopic.

Contents: 1 vial contains:

Active substance: zoledronic acid (as zoledronic acid monohydrate) – 4 mg.

Excipients: mannitol, sodium citrate 5, 5-hydrate.

Pharmaceutical form: lyophilized powder for solution for infusion.

Pharmacotherapeutic group: drug products for bone treatment. Bisphosphonates.

ATC code: M05BA08.

Indications for use

Treatment of hypercalcemia caused by malignant tumor (at blood serum concentration of calcium adjusted by the albumin level >12 mg/ml or 3 mmole/l).

Treatment of patients with metastases in bones with malignant solid tumors and multiple myeloma in combination with standard antineoplastic therapy.



Other medicines for oncological diseases therapy

Tropisetron

solution for injection 1 mg/ml

Trade name: Tropisetron.

International not patented name: Tropisetron.

Pharmacotherapeutic group: serotonergic preparations, anti-vomiting preparations.

Composition: each ampoule of 5 ml contents:

Active ingredient: tropisetron hydrochloride – 5 mg.

Excipient: sodium citrate, citric acid monohydrate, water for injection.

ATC code: A04AA03.

Indications for use

Preventing nausea and vomiting developing because of anti-tumor chemotherapy.

Stopping nausea and vomiting developing in the postoperative period.

Preventing nausea and vomiting developing after gynecologic intra-abdominal surgeries. When the preparation is prescribed for optimizing the ratio “effect/risk” it should be applied exclusively by the females having data about postoperative nausea and vomiting in the anamnesis.

