Trastuzumab for Injection (r-DNA Origin)

**For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory**

**PRELIMINARY SAFETY DATA**

Trastuzumab is no longer indicated as an initial treatment for patients with metastatic breast cancer. In clinical trials in metastatic breast cancer, trastuzumab plus chemotherapy was associated with no statistically significant difference in overall survival compared with chemotherapy alone. Overall survival is a key endpoint for the registration of new anticancer drugs. Trastuzumab is currently indicated as palliative treatment for patients with HER2-overexpressing breast cancer who have received anthracyclines and taxanes and as first-line trastuzumab plus anastrozole treatment for patients with hormone receptor-positive HER2-overexpressing metastatic breast cancer. Trastuzumab should not be used as a first-line treatment for patients with HER2-overexpressing metastatic breast cancer. The benefit-risk balance for patients with HER2-overexpressing metastatic breast cancer who have received previous trastuzumab treatment is unknown. The benefit-risk balance for such patients is unknown, and treatment is not recommended.

**INDICATIONS**

- **Early-Stage Breast Cancer (BC)**: Trastuzumab is indicated for the treatment of HER2-overexpressing metastatic breast cancer in combination with cyclophosphamide, doxorubicin (Adriamycin®), and paclitaxel (Taxol®) as first-line therapy, followed by trastuzumab and anastrozole as second-line therapy. Trastuzumab is also indicated as rescue therapy for patients with HER2-overexpressing metastatic breast cancer who have received previous trastuzumab treatment.

- **Metastatic Breast Cancer (MBC)**: Trastuzumab is indicated for the treatment of HER2-overexpressing metastatic breast cancer in combination with chemotherapy.

**CONTRAINDICATIONS**

- Hypersensitivity to trastuzumab or any component of the formulation.
- Prior trastuzumab treatment.
- Concurrent use of emtansine (EMD) or pertuzumab (PZB).

**WARNING AND PRECAUTIONS**

- **Hypersensitivity Reactions**: Severe hypersensitivity reactions, including anaphylaxis, have been reported.
- **Thrombosis/Thrombocytopenia**: Thrombosis and thrombocytopenia may occur, particularly in patients treated with trastuzumab plus chemotherapy.
- **Bone Marrow Suppression**: Bone marrow suppression, including neutropenia, may occur.
- **Liver Function Tests**: Hepatic function tests may be altered.

**DOSAGE AND ADMINISTRATION**

- **Adults**: The recommended dosage of trastuzumab is 6 mg/kg administered as an intravenous infusion over 30 minutes on day 1 every 3 weeks.
- **Pediatric Patients**: The recommended dosage for pediatric patients is 4 mg/kg administered as an intravenous infusion over 30 minutes on day 1 every 3 weeks.

**SIDE EFFECTS**

- **Common**: Fatigue, constipation, diarrhea, nausea, vomiting, infections, and fever.
- **Uncommon**: Headache, rash, and pruritus.
- **Very Rare**: Severe hypersensitivity reactions, including anaphylaxis.

**PACKAGING INFORMATION**

- **Storage**: Store at 2°C to 8°C under refrigeration. Do not freeze.
- **Expiration Date**: The expiration date is 2 years from the date of manufacture.

**REFERENCES**