



PERJETA 420 MG/14 ML VIAL C/1

ROCHE FARMA

ESPECIFICACIONES TECNICAS PROCEDIMIENTO NEGOCIADO: PERTUZUMAB

Evaluable y seleccionado por la Comisión de Farmacia y Terapéutica, e incluido en la Guía Farmacoterapéutica del Área 4.

GRUPO TERAPÉUTICO: L01XC – Otros citostáticos: anticuerpos monoclonales

Presentación en viales de vidrio de tipo I, con tapón de caucho butílico, que contienen 14 mL de solución (420 mg de pertuzumab), perfectamente identificados con:

- Nombre comercial
 - Nombre del principio activo
 - Dosis en miligramos
 - Lista de excipientes
 - Forma farmacéutica
 - Vía de administración
 - Lote
 - Caducidad
 - Condiciones de conservación
 - Código Nacional
 - Laboratorio fabricante
-
- Información técnica complementaria relativa a:
 - Posología y forma de administración
 - Nivel de información sobre utilización del medicamento en situaciones especiales: geriatría, pediatría, embarazo, lactancia, insuficiencia renal y hepática, diálisis, patologías concomitantes e interacciones.



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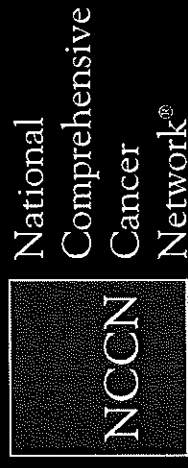
Comunidad de Madrid

- Nivel de información sobre vigilancia farmacológica y toxicológica: medidas preventivas de efectos adversos potencialmente graves y medidas a tomar en caso de intoxicación con el medicamento.
- Compatibilidad con fármacos de uso concomitante habitual.
- Envase acondicionado a las características técnicas de la especialidad: cartonaje y eliminación (impacto ambiental); embalaje exterior identificado lote y caducidad.

La Guía de tratamiento del cáncer de mama de The National Comprehensive Cancer Network (NCCN) (2.2017) recomienda el uso de pertuzumab asociado a los regímenes de quimioterapia convencionales en el tratamiento neoadyuvante, adyuvante o metastásico del cáncer de mama en pacientes que presentan sobreexpresado el receptor HER2.

Se adjunta bibliografía.

Fdo Teresa Bermejo Vicedo
Jefe Servicio de Farmacia



NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

Breast Cancer

Version 2.2017 — April 6, 2017

NCCN.org

NCCN Guidelines for Patients® available at www.nccn.org/patients

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PREOPERATIVE/ADJUVANT THERAPY REGIMENS 1,2,3,4

Regimens for HER2-negative disease^{5,6}

Preferred regimens:

- Dose-dense AC (doxorubicin/cyclophosphamide) followed by paclitaxel every 2 weeks
- Dose-dense AC (doxorubicin/cyclophosphamide) followed by weekly paclitaxel
- TC (docetaxel and cyclophosphamide)

Other regimens:

- Dose-dense AC (doxorubicin/cyclophosphamide)
- AC (doxorubicin/cyclophosphamide) every 3 weeks (category 2B)
- CMF (cyclophosphamide/methotrexate/fluorouracil)
- AC followed by docetaxel every 3 weeks
- AC followed by weekly paclitaxel
- EC (epirubicin/cyclophosphamide)
- TAC (docetaxel/doxorubicin/cyclophosphamide)

Regimens for HER2-positive disease^{6,7,8,9}

Preferred regimens:

- AC followed by T + trastuzumab ± **pertuzumab**¹⁰ (doxorubicin/cyclophosphamide followed by paclitaxel plus trastuzumab ± pertuzumab, various schedules)
- TCH (docetaxel/carboplatin/trastuzumab) ± **pertuzumab**

Other regimens:

- AC followed by docetaxel + trastuzumab ± **pertuzumab**¹⁰
- Docetaxel + cyclophosphamide + trastuzumab
- FEC (fluorouracil/epirubicin/cyclophosphamide) followed by docetaxel + trastuzumab + **pertuzumab**¹⁰
- FEC followed by paclitaxel + trastuzumab + **pertuzumab**¹⁰
- Paclitaxel + trastuzumab¹¹
- Pertuzumab + trastuzumab + docetaxel followed by FEC¹⁰
- Pertuzumab + trastuzumab + paclitaxel followed by FEC¹⁰

¹Retrospective evidence suggests that anthracycline-based chemotherapy regimens may be superior to non-anthracycline-based regimens in patients with HER2-positive tumors.
²Randomized clinical trials demonstrate that the addition of a taxane to anthracycline-based chemotherapy provides an improved outcome.
³CMF and radiation therapy may be given concurrently, or the CMF may be given first. All other chemotherapy regimens should be given prior to radiotherapy.
⁴Chemotherapy and endocrine therapy used as adjuvant therapy should be given sequentially with endocrine therapy following chemotherapy.
⁵The regimens listed for HER2-negative disease are all category 1 (except where indicated) when used in the adjuvant setting.
⁶Nab-paclitaxel may be substituted for paclitaxel or docetaxel due to medical necessity (ie, hypersensitivity reaction). If substituted for weekly paclitaxel or docetaxel, then the weekly dose of nab-paclitaxel should not exceed 125 mg/m².

Note: All recommendations are category 2A unless otherwise indicated.

Clinical Trials: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.

⁷In patients with HER2-positive and axillary node-positive breast cancer, trastuzumab should be incorporated into the adjuvant therapy (category 1). Trastuzumab should also be considered for patients with HER2-positive node-negative tumors ≥1 cm (category 1).

⁸Trastuzumab should optimally be given concurrently with paclitaxel as part of the AC followed by paclitaxel regimen, and should be given for one year total duration.

⁹A pertuzumab-containing regimen can be administered to patients with ≥T2 or ≥N1, HER2-positive, early-stage breast cancer preoperatively. Patients who have not received a pertuzumab-containing regimen can receive adjuvant pertuzumab.

¹⁰Trastuzumab given in combination with an anthracycline is associated with significant cardiac toxicity. Concurrent use of trastuzumab and pertuzumab with an anthracycline should be avoided.

¹¹Paclitaxel + trastuzumab may be considered for patients with low-risk stage I, HER2-positive disease, particularly those not eligible for other standard adjuvant regimens due to comorbidities.

DOSING SCHEDULE FOR COMBINATIONS FOR HER2-POSITIVE DISEASE: PREFERRED REGIMENS

AC followed by T chemotherapy with trastuzumab⁹

- Doxorubicin 60 mg/m² IV day 1
 - Cyclophosphamide 600 mg/m² IV day 1
- Cycled every 21 days for 4 cycles.

Followed by:

Paclitaxel 80 mg/m² by 1 h IV weekly for 12 wks

With:

- Trastuzumab 4 mg/kg IV with first dose of paclitaxel

Followed by:

- Trastuzumab 2 mg/kg IV weekly to complete 1 y of treatment. As an alternative, trastuzumab 6 mg/kg IV every 21 days may be used following the completion of paclitaxel, and given to complete 1 y of trastuzumab treatment.

Evaluate left ventricular ejection fraction (LVEF) prior to and during treatment.*

AC followed by T chemotherapy with trastuzumab + **pertuzumab**

- Doxorubicin 60 mg/m² IV day 1
 - Cyclophosphamide 600 mg/m² IV day 1
- Cycled every 21 days for 4 cycles.

Followed by:

- **Pertuzumab 840 mg IV day 1 followed by 420 mg IV**
 - Trastuzumab 8 mg/kg IV day 1 followed by 6 mg/kg IV
 - Paclitaxel 80 mg/m² IV days 1, 8, and 15
- Cycled every 21 days for 4 cycles
- Trastuzumab 6 mg/kg IV day 1

Cycled every 21 days to complete 1 y of trastuzumab therapy

Evaluate LVEF prior to and during treatment.*

*The optimal frequency of LVEF assessment during adjuvant trastuzumab therapy is not known. The FDA label recommends LVEF measurements prior to initiation of trastuzumab and every 3 mo during therapy.

The selection, dosing, and administration of anti-cancer agents and the management of associated toxicities are complex. Modifications of drug dose and schedule and initiation of supportive care interventions are often necessary because of expected toxicities and individual patient variability, prior treatment, and comorbidity. The optimal delivery of anti-cancer agents therefore requires a health care delivery team experienced in the use of anti-cancer agents and the management of associated toxicities in patients with cancer.

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Dose-dense AC followed by paclitaxel chemotherapy with trastuzumab¹⁰

- Doxorubicin 60 mg/m² IV day 1
 - Cyclophosphamide 600 mg/m² IV day 1
- Cycled every 14 days for 4 cycles.

Followed by:

- Paclitaxel 175 mg/m² by 3 h IV infusion day 1
- Cycled every 14 days for 4 cycles.

With:

- Trastuzumab 4 mg/kg IV with first dose of paclitaxel

Followed by:

- Trastuzumab 2 mg/kg IV weekly to complete 1 y of treatment. As an alternative, trastuzumab 6 mg/kg IV every 21 days may be used following the completion of paclitaxel, and given to complete 1 y of trastuzumab treatment.
- Evaluate LVEF prior to and during treatment.*

(All cycles are with myeloid growth factor support, See NCCN Guidelines for MGF)

TCH chemotherapy¹¹

- Docetaxel 75 mg/m² IV day 1
 - Carboplatin AUC 6 IV day 1
- Cycled every 21 days for 6 cycles

With:

- Trastuzumab 4 mg/kg IV wk 1

Followed by:

- Trastuzumab 2 mg/kg IV for 17 wks

Followed by:

- Trastuzumab 6 mg/kg IV every 21 days to complete 1 y of trastuzumab therapy

OR

- Trastuzumab 8 mg/kg IV wk 1

Followed by:

- Trastuzumab 6 mg/kg IV every 21 days to complete 1 y of trastuzumab therapy
- Evaluate LVEF prior to and during treatment.*

TCH chemotherapy + **pertuzumab**¹²

- Trastuzumab 8 mg/kg IV day 1 followed by 6 mg/kg IV
 - **Pertuzumab 840 mg IV day 1 followed by 420 mg IV**
 - Docetaxel 75 mg/m² IV day 1
 - Carboplatin AUC 6 IV day 1
- Cycled every 21 days for 6 cycles

Followed by:

- Trastuzumab 6 mg/kg IV every 21 days to complete 1 y of trastuzumab therapy
- Evaluate LVEF prior to and during treatment.*

CHEMOTHERAPY REGIMENS FOR RECURRENT OR METASTATIC BREAST CANCER^{1,2}

Preferred single agents:

Anthracyclines

- Doxorubicin
- Pegylated liposomal doxorubicin

Taxanes

- Paclitaxel

Anti-metabolites

- Capecitabine
- Gemcitabine

Other microtubule inhibitors

- Vinorelbine
- Eribulin

Other single agents:

- Cyclophosphamide
- Carboplatin
- Docetaxel
- Albumin-bound paclitaxel
- Cisplatin
- Epirubicin
- Ixabepilone

Chemotherapy combinations:

- CAF/FAC (cyclophosphamide/doxorubicin/fluorouracil)
- FEC (fluorouracil/epirubicin/cyclophosphamide)
- AC (doxorubicin/cyclophosphamide)
- EC (epirubicin/cyclophosphamide)
- CMF (cyclophosphamide/methotrexate/fluorouracil)
- Docetaxel/capecitabine
- GT (gemcitabine/paclitaxel)
- Gemcitabine/carboplatin
- Paclitaxel/bevacizumab³

Preferred first-line agents for HER2-positive disease:

- **Pertuzumab + trastuzumab + docetaxel (category 1)⁴**
- **Pertuzumab + trastuzumab + paclitaxel⁴**

Other agents for HER2-positive disease:

- Ado-trastuzumab emtansine (T-DM1)
- Trastuzumab + paclitaxel ± carboplatin
- Trastuzumab + docetaxel
- Trastuzumab + vinorelbine
- Trastuzumab + capecitabine

Agents for trastuzumab-exposed HER2-positive disease:

- Lapatinib + capecitabine
- Trastuzumab + capecitabine
- Trastuzumab + lapatinib (without cytotoxic therapy)
- Trastuzumab + other agents^{4,5,6}

¹There is no compelling evidence that combination regimens are superior to sequential single agents.

²Nab-paclitaxel may be substituted for paclitaxel or docetaxel due to medical necessity (ie, hypersensitivity reaction). If substituted for weekly paclitaxel or docetaxel, then the weekly dose of nab-paclitaxel should not exceed 125 mg/m².

³Randomized clinical trials in metastatic breast cancer document that the addition of bevacizumab to some first- or second-line chemotherapy agents modestly improves time to progression and response rates but does not improve overall survival. The time-to-progression impact may vary among cytotoxic agents and appears greatest with bevacizumab in combination with weekly paclitaxel.

Note: All recommendations are category 2A unless otherwise indicated.

Clinical Trials: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.

⁴Patients previously treated with chemotherapy plus trastuzumab in the absence of pertuzumab in the metastatic setting may be considered for one line of therapy including both trastuzumab plus pertuzumab in combination with or without cytotoxic therapy (such as vinorelbine or taxane). Further research is needed to determine the ideal sequencing strategy for anti-HER2 therapy.

⁵Trastuzumab given in combination with an anthracycline is associated with significant cardiac toxicity. Concurrent use of trastuzumab and pertuzumab with an anthracycline should be avoided.

⁶Trastuzumab may be safely combined with all non-anthracycline containing preferred and other single agents listed above for recurrent or metastatic breast cancer.

DOSING SCHEDULES FOR CHEMOTHERAPY REGIMENS FOR HER2-POSITIVE RECURRENT OR METASTATIC BREAST CANCER

Preferred first-line agents for HER2-positive disease:

- **Pertuzumab + trastuzumab + docetaxel**³⁰
 - **Pertuzumab 840 mg IV day 1 followed by 420 mg IV**
 - **Trastuzumab 8 mg/kg IV day 1 followed by 6 mg/kg IV**
 - **Docetaxel 75–100 mg/m² IV day 1**
- Cycled every 21 days.

Pertuzumab + trastuzumab + paclitaxel³¹

- **Pertuzumab 840 mg IV day 1 followed by 420 mg IV cycled every 21 days**
- **Trastuzumab**
 - ▶ 4 mg/kg IV day 1 followed by 2 mg/kg IV weekly
- or
- ▶ 8 mg/kg IV day 1 followed by 6 mg/kg IV cycled every 21 days³²
- **Paclitaxel 80 mg/m² IV day 1 weekly**³¹
- or
- **Paclitaxel 175 mg/m² day 1 cycled every 21 days**

Other agents for HER2-positive disease:

Ado-trastuzumab emtansine (T-DM1)³³

- 3.6 mg/kg IV day 1
- Cycled every 21 days.

Paclitaxel/carboplatin + trastuzumab³⁴

- Carboplatin AUC 6 IV day 1
 - Paclitaxel 175 mg/m² IV day 1
- Cycled every 21 days.

Trastuzumab

- ▶ 4 mg/kg IV day 1 followed by 2 mg/kg IV weekly
- or
- ▶ 8 mg/kg IV day 1 followed by 6 mg/kg IV every 21 days³²

Weekly paclitaxel/carboplatin + trastuzumab³⁵

- Paclitaxel 80 mg/m² IV days 1, 8, & 15
 - Carboplatin AUC 2 IV days 1, 8, & 15
- Cycled every 28 days.

Trastuzumab

- ▶ 4 mg/kg IV day 1 followed by 2 mg/kg IV weekly

or

- ▶ 8 mg/kg IV day 1 followed by 6 mg/kg IV every 21 days³²

Trastuzumab + paclitaxel

- Paclitaxel
- ▶ 175 mg/m² IV day 1 cycled every 21 days³⁶

or

- ▶ 80–90 mg/m² IV day 1 weekly³⁷

Trastuzumab

- ▶ 4 mg/kg IV day 1 followed by 2 mg/kg IV weekly
- or
- ▶ 8 mg/kg IV day 1 followed by 6 mg/kg IV every 21 days³²

Trastuzumab + docetaxel

- Docetaxel
- ▶ 80–100 mg/m² IV day 1 cycled every 21 days³⁸

or

- ▶ 35 mg/m² IV days 1, 8, and 15 weekly³⁹

Trastuzumab

- ▶ 4 mg/kg IV day 1 followed by 2 mg/kg IV weekly
- or
- ▶ 8 mg/kg IV day 1 followed by 6 mg/kg IV every 21 days³²

Note: All recommendations are category 2A unless otherwise indicated.

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