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MICROMEDEX®

- 世界90カ国、9000以上の医療施設、機関が採用
- 医療薬学分野におけるEBMの先駆け
- 社内の専門家による編集と世界各国の編集委員 (総勢400名)
- 米国議会で医薬品情報の標準資料と認定されています。(Drugdex)
 - U.S. Code Subchapter XIX, "Grants to States for Medical Assistance Programs"
- 米国内の薬学部・医学部では実習教材として、多くの学生に使用されています

Product formation

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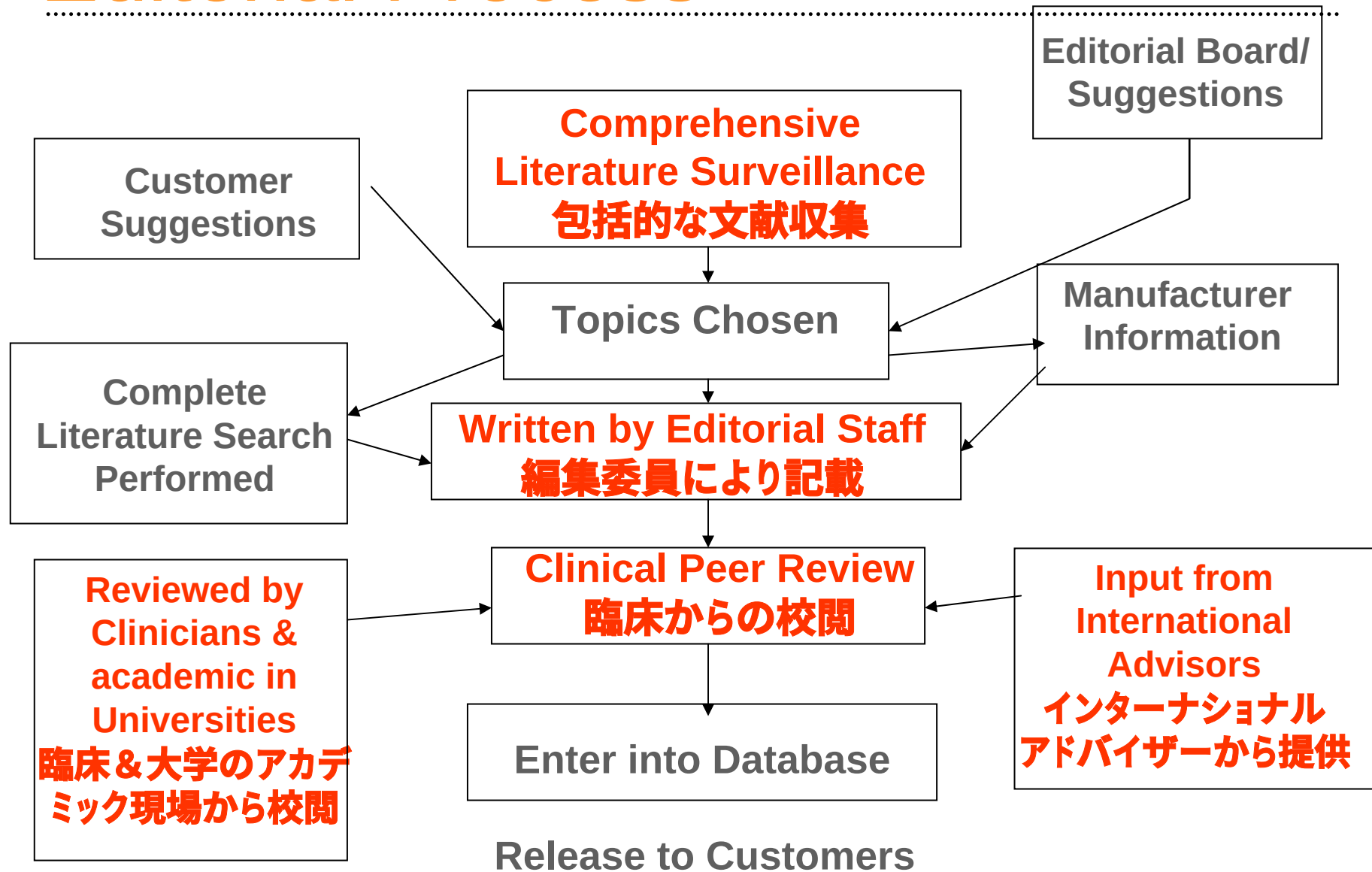
医薬情報
DRUGDEX

中毒情報
POISINDEX

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Editorial Process



DRUGDEX® System

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 - 各国の商品名リスト

DRUGDEX® Evaluation

医薬品評価のモノグラフ

- **レアケースの臨床報告を簡単に入手可能**
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DRUGDEX® Evaluation outline

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活用例 1

“capecitabine”の胃癌への適応外投与のデータを検索する場合

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Main Keyword Search:
Search Drug, Toxicology, Disease, and Labs databases for:

capecitabine Search

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Summary Documents

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DRUGDEX® Tradename List	Search Related Tradenames
PDR® Physicians' Desk Reference	Results (2)
MARTINDALE - The Complete Drug Reference	Capecitabine
Martindale Products	Search Related Products
Index Nominum	Capecitabine (Rec.INN)
Detailed Drug Information for the Consumer	CAPECITABINE (Oral route) - kap-e-SYE-ta-been
MSDS	CAPECITABINE

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CAPECITABINE
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DRUGDEX® Evaluations - Titles

Titles (1 results)

CAPECITABINE

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"capecitabine" is in DRUGDEX® Evaluations under these topics:

- [comparison with](#) (4 results)
- [dose, adult](#) (1 results)
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comparison with (4 results) [\(back to top\)](#)

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DRUGDEX® Evaluations

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0.0 Overview

- 1) Class
 - a) This drug is a member of the following class(es):
 - Antimetabolite
 - Antineoplastic Agent
- 2) Dosing Information
 - a) Adult
 - 1) Colon cancer, Adjuvant therapy, Duke's Stage C, when treatment with a fluoropyrimidine alone is preferred
 - a) 1,250 mg/m(2) ORALLY twice daily for 2 wks followed by 1 wk off, given as 3 wk cycles for a total of 8 cycles (6 mo) (Prod Info Xeloda(R), 2005)
 - 2) Colorectal cancer, Nonresectable, advanced, or metastatic; first-line In combination with oxaliplatin
 - a) XELOX: oxaliplatin 130 mg/m(2) IV on day 1 plus **capecitabine** 1000 mg/m(2) orally twice daily, starting the evening of day 1 and ending the morning of day 15; repeat every 3 weeks until disease progression or unacceptable toxicity (Cassidy et al, 2004)
 - 3) Esophagogastric cancer, First-line therapy for advanced or metastatic disease, in combination with epirubicin and oxaliplatin or cisplatin
 - a) 625 mg/m(2) ORALLY twice daily; in combination with epirubicin 50 mg/m(2) IV on day 1 and either oxaliplatin 130 mg/m(2) IV on day 1 or cisplatin 60 mg/m(2) IV (with hydration) on day 1; repeat every 3 weeks for up to 8 cycles has been used in a clinical trial (Cunningham et al, 2003)
 - b) Advanced or metastatic disease, in combination with epirubicin and oxaliplatin or cisplatin; in combination with epirubicin 50 mg/m(2) IV on day 1 and either oxaliplatin 130 mg/m(2) IV (with hydration) on day 1; repeat every 3 weeks for up to 8 cycles has been used in a clinical trial (Cunningham et al, 2003)
- 3) Therapy when resistant to paclitaxel/anthracycline-containing regimens or resistant to paclitaxel and not a candidate for further anthracycline therapy
 - a) 1,250 mg/m(2) ORALLY twice daily for 2 wks followed by 1 wk off, given as 3 wk cycles (Prod Info Xeloda(R), 2001e)
- 6) Metastatic breast cancer, In combination with docetaxel after failure of prior anthracycline-containing regimens
 - a) 1,250 mg/m(2) ORALLY twice daily for 2 wks followed by 1 wk off, given as 3 wk cycles in combination with docetaxel 75 mg/m(2) IV over 1 hour every 3 weeks. Premedication for docetaxel should be initiated prior to starting therapy (Prod Info Xeloda(R), 2003b)
- 7) Metastatic colorectal cancer, First-line therapy, in combination with bevacizumab and oxaliplatin
 - a) 1000 mg/m(2) orally twice daily days 1 to 14 repeated every 3 weeks was used, in combination with bevacizumab and oxaliplatin, in a clinical trial (Saltz et al, 2008)

Therapeutic Use
をクリック

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(Cunningham et al, 2008).

4.5.E Gastric cancer, First-line therapy for advanced or metastatic

1) Overview

FDA Approval: Adult, no; Pediatric, no
 Efficacy: Adult, Evidence favors efficacy
 Recommendation: Adult, Class IIb
 Strength of Evidence: Adult, Category B

See Drug Consult reference: [RECOMMENDATION AND EVIDENCE RATINGS](#)

2) Summary:

As monotherapy, **capecitabine** produced overall response rates in phase 2 clinical trials ranging from 26% to 32% with median overall survivals of approximately 9.5 to 10 months (Sakamoto et al, 2006; Hong et al, 2004)

In a large, randomized, phase 3 clinical trial (the Randomized ECF for Advanced and Locally Advanced Esophagogastric Cancer 2 (REAL-2) trial) (n=1002), substitution of **capecitabine** (epirubicin/cisplatin/**capecitabine** vs epirubicin/cisplatin/fluorouracil) for fluorouracil and oxaliplatin for cisplatin (epirubicin/oxaliplatin/fluorouracil vs epirubicin/oxaliplatin/**capecitabine**) was noninferior as first-line therapy for esophageal, gastroesophageal junction, or gastric cancer (Cunningham et al, 2008)

Combination therapy with **capecitabine** and cisplatin produced response rates of 28% to 55% and median overall survivals of 10.1 to 11.2 months in phase 2 clinical trials (Kang et al, 2005; Kim et al, 2002)

Combination therapy with **capecitabine** and weekly or every-3-week docetaxel produced response rates ranging from 21% to 60% and median overall survivals ranging from 7.7 to 12 months in phase 2 clinical trials (Orditura et al, 2006; Chun et al, 2005; Kim et al, 2005; Park et al, 2004)

Combination therapy with **capecitabine** and irinotecan produced a response rate of approximately 46% and a median survival of 8.6 months in a phase 2 clinical trial (Baek et al, 2006)

Combination therapy with **capecitabine** and oxaliplatin in a phase 2 clinical trial produced a response rate of 65% and a median survival that had not yet been reached after a median follow-up of 11.1 months (Park et al, 2006)

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As monotherapy or in combination with various chemotherapy agents, is an acceptable option for treatment of patients with advanced gastric cancer (Sakamoto et al, 2006; Hong et al, 2004; Orditura et al, 2006; Chun et al, 2005; Kim et al, 2005; Park et al, 2004). As a single agent, **capecitabine** has produced overall response rates ranging from 26% to 32% with median overall survivals of approximately 9.5 to 10 months (Sakamoto et al, 2006; Hong et al, 2004). In a large, randomized, phase 3 clinical trial (the Randomized ECF for Advanced and Locally Advanced Esophagogastric Cancer 2 (REAL-2) trial) (n=1002), substitution of **capecitabine** (epirubicin/cisplatin/**capecitabine** vs epirubicin/cisplatin/fluorouracil) for fluorouracil and oxaliplatin for cisplatin (epirubicin/oxaliplatin/fluorouracil vs epirubicin/oxaliplatin/**capecitabine**) was noninferior as first-line therapy for esophageal, gastroesophageal junction, or gastric cancer (Cunningham et al, 2008). Combination therapy with **capecitabine** and cisplatin produced response rates of 28% to 55% and median overall survivals of 10.1 to 11.2 months in phase 2 clinical trials (Kang et al, 2005; Kim et al, 2002). Combination therapy with **capecitabine** and weekly or every-3-week docetaxel produced response rates ranging from 21% to 60% and median overall survivals ranging from 7.7 to 12 months in phase 2 clinical trials (Orditura et al, 2006; Chun et al, 2005; Kim et al, 2005; Park et al, 2004). Combination therapy with **capecitabine** and irinotecan produced a response rate of approximately 46% and a median survival of 8.6 months (Baek et al, 2006). Combination therapy with **capecitabine** and oxaliplatin in a phase 2 clinical trial produced a response rate of 65% and a median overall survival that had not yet been reached after a median follow-up of 11.1 months (Park et al, 2006). The ranges of responses within combinations may have varied due to differences in dosing regimens, inclusion of patients with prior adjuvant chemotherapy and/or radiotherapy, and extent of metastatic disease. The regimens were overall well-tolerated and toxicities reflected those commonly seen with each agent (Sakamoto et al, 2006; Hong et al, 2004).

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Capecitabine and oxaliplatin for advanced esophagogastric cancer.

[Cunningham D, Starling N, Rao S, Iveson T, Nicolson M, Coxon F, Middleton G, Daniel F, Oates J, Norman AR; Upper Gastrointestinal Clinical Studies Group of the National Cancer Research Institute of the United Kingdom.](#)

Royal Marsden Hospital National Health Service Foundation Trust, Surrey and London, United Kingdom.

BACKGROUND: We evaluated capecitabine (an oral fluoropyrimidine) and oxaliplatin (a platinum compound) as alternatives to infused fluorouracil and cisplatin, respectively, for untreated advanced esophagogastric cancer. METHODS: In a two-by-two design, we randomly assigned 1002 patients to receive triplet therapy with epirubicin and cisplatin plus either fluorouracil (ECF) or capecitabine (ECX) or triplet therapy with epirubicin and oxaliplatin plus either fluorouracil (EOF) or capecitabine (EOX). The primary end point was noninferiority in overall survival for the triplet therapies containing capecitabine as compared with fluorouracil and for those containing oxaliplatin as compared with cisplatin. RESULTS: For the capecitabine-fluorouracil comparison, the hazard ratio for death in the

randomised multicentre phase III study co [Br J Cancer. 2005]

- ▶ A phase I and pharmacokinetic study of capecitabine in combination with epirubicin and cisplatin in [Ann Oncol. 2002]
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References

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妊婦への投与は乳汁移行のデータはこちらをクリック

1) This drug is a member of the following class(es):

- Antimetabolite
- Antineoplastic Agent

2) Dosing Information

a) Adult

C, when treatment with a fluoropyrimidine alone is preferred
2 wks followed by 1 wk off, given as 3 wk cycles for a total of 8 cycles (6 mo) (Prod Info

or metastatic; first-line In combination with oxaliplatin

1 plus **capecitabine** 1000 mg/m² orally twice daily, starting the evening of day 1

ending the morning of day 15; repeat every 3 weeks until disease progression or unacceptable toxicity (Cassidy et al, 2004)
Esophagogastric cancer, First-line therapy for advanced or metastatic disease, in combination with epirubicin and oxaliplatin or

cisplatin

a) 625 mg/m² ORALLY twice daily; in combination with epirubicin 50 mg/m² IV on day 1 and either oxaliplatin 130 mg/m² IV on day 1 or cisplatin 60 mg/m² IV (with hydration) on day 1; repeat every 3 weeks for up to 8 cycles has been used in a clinical trial (Cunningham et al, 2008)

4) Gastric cancer, First-line therapy for advanced or metastatic disease, in combination with epirubicin and oxaliplatin or cisplatin
a) 625 mg/m² ORALLY twice daily; in combination with epirubicin 50 mg/m² IV on day 1 and either oxaliplatin 130 mg/m² IV on day 1 or cisplatin 60 mg/m² IV (with hydration) on day 1; repeat every 3 weeks for up to 8 cycles has been used in a clinical trial (Cunningham et al, 2008)

5) Metastatic breast cancer, As monotherapy when resistant to paclitaxel/anthracycline-containing regimens or resistant to paclitaxel and not a candidate for further anthracycline therapy

a) 1,250 mg/m² ORALLY twice daily for 2 wks followed by 1 wk off, given as 3 wk cycles (Prod Info Xeloda(R), 2001e)

6) Metastatic breast cancer, In combination with docetaxel after failure of prior anthracycline-containing regimens

a) 1,250 mg/m² ORALLY twice daily for 2 wks followed by 1 wk off, given as 3 wk cycles in combination with docetaxel 75 mg/m² IV over 1 hour every 3 weeks. Premedication for docetaxel should be initiated prior to starting therapy (Prod Info Xeloda(R), 2003b)

7) Metastatic colorectal cancer, First-line therapy, in combination with bevacizumab and oxaliplatin

a) 1000 mg/m² orally twice daily days 1 to 14 repeated every 3 weeks was used, in combination with bevacizumab and

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