

UDDERLY SMOOTH

**HIDRATAÇÃO DA PELE
LEVADA A SÉRIO.**





- ✓ **Creme de hidratação intensa/eficaz**
- ✓ **Casos que se exigem cuidado especial ou no uso diário**
- ✓ **Sem contraindicação (sem ureia)**
- ✓ **Todo tipo de pele (inclusive crianças e grávidas)**
- ✓ **Fabricado nos EUA há 45 anos**

Por que o **Udderly** é um dos melhores cremes hidratantes do mundo?



EFICÁCIA nos casos mais desafiadores

- apesar de não conter ureia

Indicado pelas **PRINCIPAIS INSTITUIÇÕES**

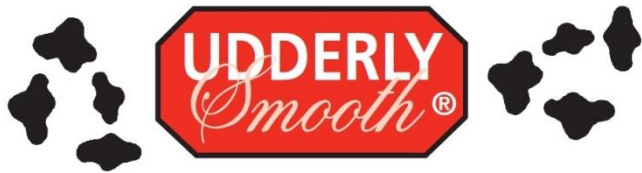
- hospitais, médicos, indústria farmacêutica

Vendido pelas **principais redes de drogarias**

- Walgreens, CVS, Rite Aid, Walmart (EUA)
- Venâncio, Onofre (Brasil)

SEGURANÇA

- não contém ingredientes prejudiciais
- muito usado em pacientes com cuidados especiais



EFICÁCIA



...“essa paciente usou doxorubicina lipossomal e teve uma síndrome mão pé grau IV. Fez uso do Udderly Smooth e a recuperação da pele foi excepcional”

Enfermeira Larissa Anielle
Centro de Oncologia RN

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Visual-aid - PFIZER

KIT BOAS-VINDAS

Para facilitar a utilização do medicamento, o paciente recebe um kit ao ser cadastrado no programa.

O kit contém:



› Bolsa



› Carta de boas-vindas



› Folheto explicativo sobre o programa



› Folheto de orientação sobre a doença



› Protetor solar FPS 15 que pode auxiliar no tratamento da pele seca



› Fio dental, escova e creme dental que podem auxiliá-lo no tratamento da mucosite



› Enxaguatório bucal que pode auxiliá-lo no tratamento da mucosite



› Creme de hidratação intensa que protege a pele contra o ressecamento causado por eventos que diminuem a hidratação, como: síndrome mão/pé, rash cutâneo



› Loção oleosa que pode auxiliar no tratamento da pele seca



› Lip Balm que pode auxiliar no tratamento da rachadura na boca

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HELPFUL TIPS FOR MANAGING SIDE EFFECTS

Mouth sores

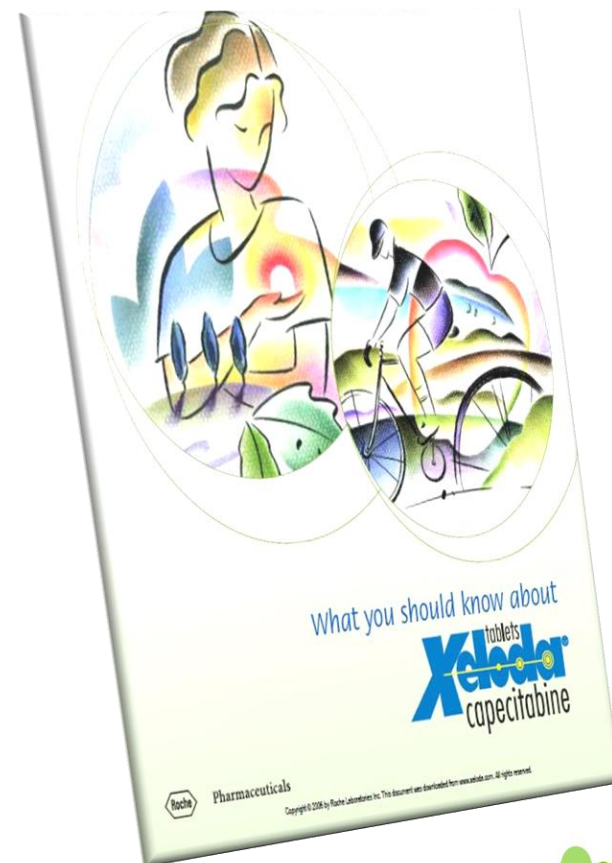
- Use good dental hygiene
 - Example: Swish and spit with salt water and soda mouthwash 3-4 times a day (1 tsp. salt and 1 tsp. baking soda dissolved in warm water)
- Avoid irritants to mouth such as citrus fruits and juices, tobacco, and spicy foods

Hand-foot syndrome

- Avoid injury to feet and hands
 - Avoid tight-fitting shoes and repetitive rubbing, pressure, or prolonged heat to hands and feet
- Take Vitamin B6 (pyridoxine)
 - Ask your doctor how much Vitamin B6 is right for you
- Apply emollient cream
 - Example: Udderly Smooth® can be applied liberally and frequently to hands and feet

Udderly Smooth is a registered trademark of RedEx Industries, Inc.

Guia do paciente – Roche (EUA)



Please see XELODA prescribing information in pocket, including boxed WARNING.

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Primeira unidade distribuída no início de cada tratamento quimioterápico

The XELODA Patient Starter Kit



The XELODA Patient Starter Kit was developed to provide patients who have been prescribed XELODA a centralized resource of information regarding their XELODA therapy. The kit contains the following:

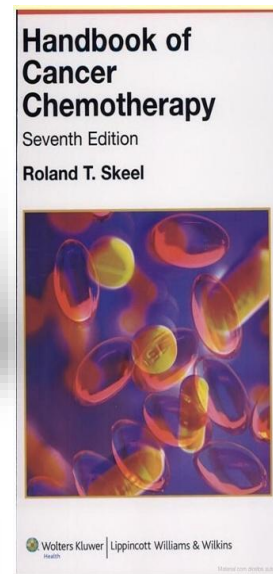
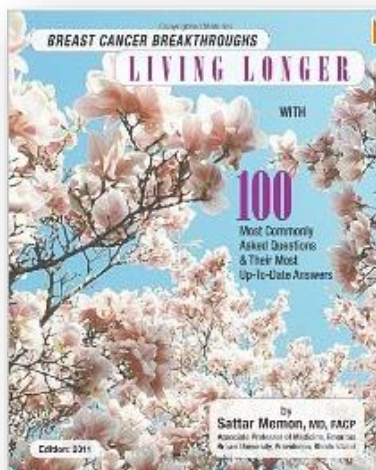
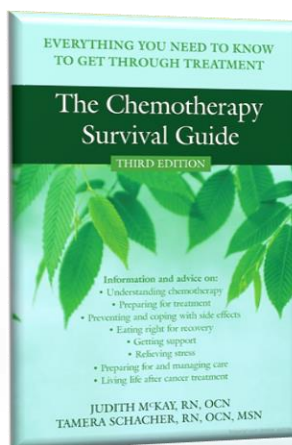
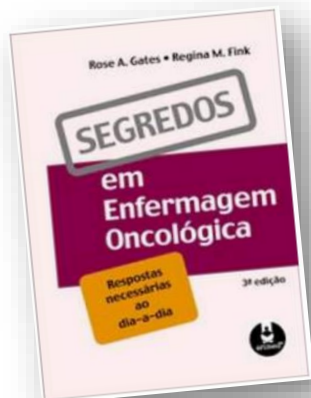
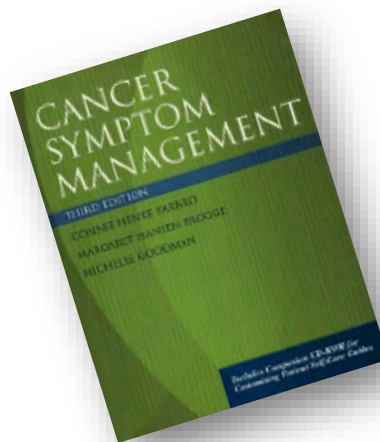
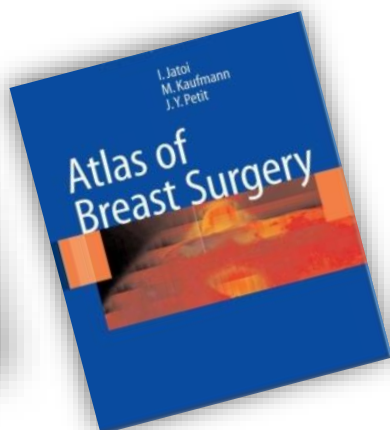
- > Patient video
- > Patient information booklet with diary
- > Patient brochure of the XTRA program with enrollment BRC
- > Laminated patient Product Insert

- > Detachable pillbox for the XELODA tablets throughout the week
- > Sample of Udderly Smooth Cream for hands and feet

This kit is designed for each and every XELODA patient when he/she receives his/her first XELODA prescription. This kit is distributed to oncology offices and clinics via Roche Oncology Specialists. Please contact your local Roche oncology specialist if you need further information on the kit. OA

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Referenciado em inúmeros livros de Oncologia, Dermatologia e Enfermagem, publicações técnicas como *Journal of Clinical Oncology (ASCO)*, *Journal of Oncology Pharmacy Practice*, e *Journal of the American Academy of Dermatology*

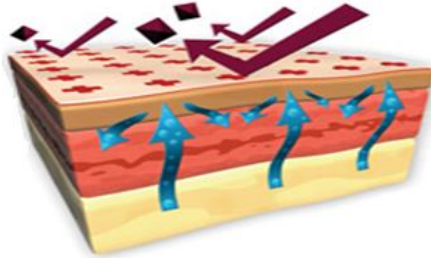


Ch. 27. Side Effects of Cancer Chemotherapy 687

untreated, grade 2 side effects may quickly progress to grade 3 or 4, requiring more intense medical concern and intervention. Depending on the drug used, recommendations are available for dose modifications. Education on preventative measures should be given to patients before beginning the drug where PPE is likely. Patients should be counseled to avoid tight-fitting shoes and rings or repetitive rubbing pressure to the hands or feet. Other precautionary measures include avoiding excessive pressure and heat on the skin for 3 to 5 days after treatment, avoidance of hot baths, showers, or hot tubs (hot water for 24 hours before and 72 hours after treatment), and friction-causing activities such as exercise for 3 to 5 days after treatment. Patients should also be advised to use emollients such as Bag Balm (Dairy Association Co., Lyndonville, VT), Udderly Smooth (Redex Industries, Salem, OH), or other petroleum- or lanolin-containing creams liberally and frequently. Patients should also be instructed to notify their health care providers at the first signs or symptoms of PPE. If the grade of toxicity worsens, supportive care related to analgesia and prevention of infection is important. Other anecdotal interventions include topical steroids and oral premedication with steroids, application of a nicotine patch, and oral administration of pyridoxine. Further studies need to be done to evaluate which interventions are helpful for PPE and do not exacerbate the skin toxicity.

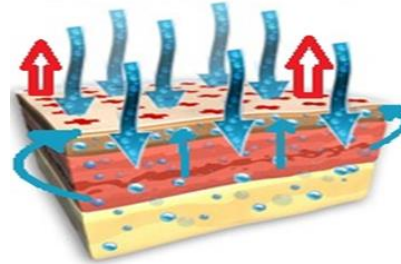
OCCLUSIVOS

- Reduz a evaporação transdérmica
- Cria barreira hidrofóbica sem oleosidade



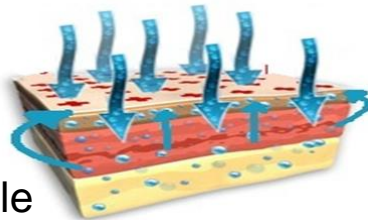
UMECTANTES

- Aumenta absorção de água da derme
- E do ambiente para a epiderme



EMOLIENTES

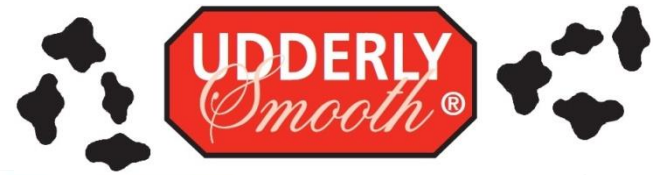
- Melhora aparência da pele
- Aumenta suavidade, elasticidade e maciez
- Preenchimento de rachaduras e reparação da pele
- Recuperação das funções naturais de retenção de água.



ALANTOÍNA

- Cicatrizante
- Acelera a regeneração celular
- Recuperação das irritações e asperezas da pele
- Possui propriedades anti-idade





Principais Ingredientes

Água

Óleo Mineral
Ácido Esteárico
Óleo de Lanolina

Oclusivos

PEG-2
Estearato
Propileloglicol

Alantoína

Umectantes

Dimeticona

Emolientes

Miristato
de Isopropila

HIDRATAÇÃO INTENSA



- . Síndrome Mão-Pé (quimioterapia)
 - . Radiodermite (radioterapia)
 - . Ressecamento severo
 - . Psoríase
 - . Dermatite
 - . Queimaduras leves
 - . Pés, mãos, rosto, joelho, etc
- Prevenção e gerenciamento



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ESTUDOS CIENTÍFICOS DAS MAIS RESPEITADAS INSTITUIÇÕES FUNDAMENTAM A EFICÁCIA, COMO YALE CANCER CENTER E NORTHWESTERN UNIVERSITY

The image displays three overlapping screenshots of scientific publications and clinical trial information. The top-left screenshot is from PubMed, showing a case report titled "Hand-foot syndrome variant in dihydrogenase-deficient patient" by Saif MW, Elfiky A, and Diasio R, published in *Clin Colorectal Cancer*. The top-right screenshot is from the *Journal of Clinical Oncology*, featuring a Phase I study titled "Phase I Study of Capecitabine With Concomitant Radiotherapy for Patients With Locally Advanced Pancreatic Cancer: Expression Analysis of Genes Related to Outcome" by M. Wasif Saif et al. The bottom screenshot is from ClinicalTrials.gov, showing the details for the study NCT00667589, which is a four-arm study evaluating treatments for hand-foot skin reaction related to the use of kinase inhibitor sorafenib.

PubMed
U.S. National Library of Medicine
National Institutes of Health

Display Settings: Abstract
Clin Colorectal Cancer, 2006 Sep;6(3):219-23.
Hand-foot syndrome variant in dihydrogenase-deficient patient
Saif MW, Elfiky A, Diasio R
Yale Cancer Center, New Haven, CT, USA. wasif.saif@yale.edu

PMID: 17026792 [PubMed - indexed for MEDLINE]
Publication Types, MeSH Terms, Substances
LinkOut - more resources

ClinicalTrials.gov archive
A member of the U.S. National Institutes of Health
— History of this study | Current version of this study
View of NCT00667589 on 2010_04_02
ClinicalTrials Identifier: NCT00667589
Updated: 2010_04_02

Descriptive Information
Brief title: Sorafenib-induced Hand-Foot Skin Reaction Treatment
Official title: Four-arm Study to Evaluate Urea 40% Cream, Fluocinonide 0.05% Cream, Tazarotene 0.1% Cream, and an Emollient Cream in the Treatment of Hand-Foot Skin Reaction Related to the Use of Kinase Inhibitor Sorafenib.
Brief summary: The purpose of this study is to evaluate treatments for a rash caused by sorafenib.
Detailed description: This study will compare the effectiveness of four creams (fluocinonide 0.05% cream, tazarotene 0.1% cream, and Uddery smooth® Udder Cream) in treating hand-foot skin reaction, a rash caused by sorafenib.
Phase 1: Interventional, Treatment, Randomized, Double Blind (Subject, Investigator), Uncontrolled, Parallel Assignment, Efficacy Study
Phase 2: Interventional, Treatment, Randomized, Double Blind (Subject, Investigator), Uncontrolled, Parallel Assignment, Efficacy Study
Study design: Primary outcome
Measure: To compare the duration of HFSR for sorafenib 40% cream, fluocinonide 0.05% cream, tazarotene 0.1% cream, and Uddery smooth® Udder Cream
Time Frame: 8 weeks
Safety Issue? No
Measure: To compare patient reported outcomes for sorafenib 40% cream, fluocinonide 0.05% cream, tazarotene 0.1% cream, and Uddery smooth® Udder Cream
Time Frame: 8 weeks

Official Journal of the American Society of Clinical Oncology
HOME | SEARCH | BROWSE BY TOPIC | ARCHIVE | EARLY RELEASE | MEETING ABSTRACTS | RESOURCES | ALERTS
Journal of Clinical Oncology, Vol 23, No 34 (December 1), 2005: pp. 8679-8687
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DOI: 10.1200/JCO.2005.02.0628

Phase I Study of Capecitabine With Concomitant Radiotherapy for Patients With Locally Advanced Pancreatic Cancer: Expression Analysis of Genes Related to Outcome
M. Wasif Saif, Mohammed A. Eloubeidi, Suzanne Russo, Adam Steg, Jennifer Thornton, John Fiveash, Mark Carpenter, Carmello Blaquicett, Robert B. Diasio, Martin R. Johnson
From the Department of Medicine, Division of Hematology-Oncology, Division of Gastroenterology and Division of Radiation Oncology, Department of Pharmacology/Toxicology, and University of Alabama Comprehensive Cancer Center, University of Alabama at Birmingham, Birmingham, Department of Medical Statistics, Auburn University, Auburn, AL.
Address reprint requests to M. Wasif Saif, MD, MBBS, Yale University School of Medicine, Section of Medical Oncology, 333 Cedar St, New Haven, CT 06520, e-mail: wasif.saif@yale.edu

ABSTRACT
PURPOSE: To establish the feasibility of capecitabine with concurrent radiotherapy (XRT) in patients with locally advanced (LA) pancreatic cancer and evaluate the effect of XRT on thymidine phosphorylase (TP), dihydroxyimidine dehydrogenase (DPD), and tumor necrosis factor-alpha (TNF-α).
PATIENTS AND METHODS: Fifteen patients with LA pancreatic cancer received three-

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doi: 10.1200/JCO.2005.02.0628
JCO December 1, 2005 vol. 23 no. 34 8679-8687
Abstract: Free
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Gastrointestinal Cancer
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ESTUDO DE CASO

Yale Cancer Center
Biblioteca Nacional de Medicina dos Estados Unidos
Instituto Nacional de Saúde

Clínica: Câncer colorretal é uma [neoplasia](#) maligna que afeta o [intestino grosso](#) e/ou o [reto](#), acometendo a [parede intestinal](#), e que dependendo do grau de invasão desta, pode comprometer outros órgãos, quer directamente, quer através de [metástases](#).

Data: 6 de Setembro de 2006

Variante: Paciente com Deficiência Dihidropirimidina Desidrogenase (DPD), tratado com Capecitabina manifestando Síndrome Mão-Pé (HFS)

Realizado por: Saif MW, Elfiky A, Diasio R. (wasif.saif@yale.edu)

Local do estudo: Yale Cancer Center, New Haven, CT, USA.

Síntese:

Apresentamos um caso com deficiência dihidropirimidina desidrogenase (DPD) que se manifestou a variante da Síndrome Mão-Pé (HFS).

Um homem de 52 anos recebeu Capecitabina para tratamento do câncer colorretal. No nono dia do primeiro ciclo, ele apresentou uma erupção sobre o dorso de ambas as mãos acompanhados por sintomas de dor, eritema, edema e descamação consistente com grau 3 de Síndrome Mão-Pé (HFS).

As palmas das mãos e plantas dos pés estavam apenas sensíveis sem aparente erupção ou descoloração.

A atividade de Dihidropirimidina Desidrogenase foi avaliada através do teste de rádio usando células mononucleares do sangue periférico. O resultado foi abaixo do normal: 0,12 de nmol/minuto/mg proteína.

A Capecitabina não foi retomada e a erupção avermelhada foi resolvida em três semanas com o uso de Vitamina B6 Piridoxina e do **Udderly Smooth®**.

Curiosamente, a Síndrome Mão-Pé (HFS) raramente é vista com esquemas de 5-fluorouracil (5-FU ou f5U, vendido sob as marcas *Adrucil*, *Carac*, *Efudex* e *Fluoroplex*) contendo inibidores de DPD.

A farmacologia necessita mais investigação para o desenvolvimento da Síndrome Mão-Pé (HFS) em pacientes com Deficiência Dihidropirimidina Desidrogenase (DPD).

A DPD se não for diagnosticada pode levar à morte. Além de grave ameaça para a vida, toxicidades semelhante ao 5-Fluorouracil e a Capecitabina podem levar a variantes incluindo HFS, em pacientes com DPD.

Publicado em PubMed - index MEDLINE

PMID: 17026792



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ESTUDO CLÍNICO

Northwestern University
Instituto Nacional de Saúde dos EUA
Biblioteca Nacional de Medicina dos EUA

Informação Descritiva

Título:

Tratamento da Reação da Pele das Mãos e dos Pés induzida pelo Sorafenibe

Título Oficial:

Estudo para avaliar Creme com 40% de Uréia, Creme Fluocinonide 0.05%, Creme Tazarotene 0.1%, e um creme emoliente para o tratamento das reações de Mão-Pé relacionadas com o uso de Tyrosine Kinase – inibidor do Sorafenibe.

Breve Resumo

O objetivo deste estudo é avaliar tratamentos para erupções cutâneas causada por Sorafenibe.

Descrição

Este estudo irá comparar a eficácia dos quatro cremes (creme de **uréia 40%**, creme **fluocinonide 0.05% [corticoide]**, **creme tazarotene 0.1%** e o creme **Udderly Smooth®**) no tratamento das reações de pele de mão-pé, uma erupção cutânea causada por sorafenib.

ClinicalTrials Identifier: NCT00667589

FONTE: ClinicalTrials.gov

Link: <http://clinicaltrials.gov/ct2/show/NCT00667589>



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JOURNAL OF CLINICAL ONCOLOGY
Official Journal of the American Society of Clinical Oncology

Journal of Clinical Oncology, Vol 23, No 34 (December 1), 2005: pp. 8679-8687
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DOI: 10.1200/JCO.2005.02.0628

Phase I Study of Capecitabine With Concomitant Radiotherapy for Patients With Locally Advanced Pancreatic Cancer: Expression Analysis of Genes Related to Outcome

M. Wasif Saif, Mohammed A. Eloubeidi, Suzanne Russo, Adam Steg, Jennifer Thornton, John Fiveash, Mark Carpenter, Carmello Blanquicett, Robert B. Diasio, Martin R. Johnson

From the Department of Medicine, Division of Hematology-Oncology, Division of Gastroenterology and Hepatology, Division of Radiation Oncology, Department of Pharmacology/Toxicology, and University of Alabama at Birmingham Comprehensive Cancer Center, University of Alabama at Birmingham, Birmingham, Department of Mathematics and Statistics, Auburn University, Auburn, AL

Address reprint requests to M. Wasif Saif, MD, MBBS, Yale University School of Medicine, Section of Medical Oncology, 333 Cedar St, New Haven, CT 06520; e-mail: wasif.saif@yale.edu

Jornal de Oncologia Clínica (Jornal Oficial da Sociedade Americana de Oncologia Clínica)
Fase I – Estudo do Capecitabina com concomitante radioterapia para pacientes com avançado câncer de pâncreas

can be delivered safely. We did not observe any patient developing grade 3 HFS, the most common DLT observed in rectal cancer studies.^{34,35} All the patients enrolled on our study were administered pyridoxine 50 mg orally tid^{36,37} and Udderly Smooth Udder Cream (Reddex Industries Inc, Salem, OH) or Bag Balm (Dairy Association, Lyndonville, VT)

Nós não observamos nenhum paciente desenvolvendo grau 3 de síndrome mão-pé, a mais comum toxina redutora de dosagem observada em estudos de câncer retal. Todos os pacientes em nosso estudo foram administrados com piridoxina 50mg oral 3 vezes por dia e **Udderly Smooth Udder Cream** ou Bag Balm.

Fonte:

<http://jco.ascopubs.org/content/23/34/8679.full>



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HOW WE DO IT

Identifying and Treating Fluoropyrimidine-Associated Hand-and-Foot Syndrome in White and Non-White Patients

Muhammad Wasif Saif, MD, MBBS, and Aymen A. Elfiky, MD

Classified as an antimetabolite, fluorouracil (5-FU) is used to treat many different types of cancer, such as cancer of the colon, rectum, breasts, stomach, and pancreas.¹ Typically, it may also be used to treat skin cancer.² Bolus intravenous (IV) administration of 5-FU and leucovorin was established in the 1980s as an efficacious treatment of advanced colorectal cancer, providing median survival times of approximately 1 year.³ Subsequent studies of prolonged 5-FU infusions reported lower toxicity than with bolus regimens but only modest improvements in efficacy.⁴

The unpredictable and highly variable bioavailability of 5-FU makes it unsuitable for oral administration.⁵ As a result, two strategies have been explored in the development of oral agents. The first approach is to combine an oral fluoropyrimidine, such as the 5-FU prodrug tegafur, with a substance of dihydropyrimidine dehydrogenase (DPD), the rate-limiting enzyme in the catabolism of 5-FU.⁶ Tegafur combinations include UFT (tegafur and uracil) and S-1 (tegafur, 5-chloro-2,4-dihydropyridine and oxonic acid).

The second approach, illustrated by capecitabine (Xeloda), another 5-FU prodrug, is the design of a molecule that precludes activation within the gut, thereby reducing local toxicity. Capecitabine is rapidly and almost completely absorbed in the upper gastrointestinal tract as an inactive molecule before being converted to 5-FU via a three-step enzymatic cascade. The enzyme that mediates the final step in the conversion process, thymidine phosphorylase, is significantly more active in tumor tissue than in normal tissue, resulting in tumor-selective generation of 5-FU.⁷

Correspondence to: M. Wasif Saif, MD, Associate Professor of Medicine, Medical Oncology, 313 Cedar Street, PO Box 208023, New Haven, CT 06510; telephone: (203) 773-1809; fax: (203) 773-2811; e-mail: ms21@med.nyu.edu

© Supportive Oncology 2007, 05(07):337-343

The recent introduction of oral 5-FU analogs has permitted development of dosing regimens with pharmacokinetics similar to those of long IV infusions, but without the need for indwelling venous access. Oral regimens provide improved convenience and safety and are preferred by a majority of patients.⁸ Fluoropyrimidine analogs alone or in various combinations remain the chemotherapeutic mainstay for the management of patients with advanced colorectal cancer.⁹

Hand-Foot Syndrome

Common toxicities associated with oral fluoropyrimidine therapy include mucositis, granulocytopenia, nausea, diarrhea, and skin toxicities.¹⁰ Hand-Foot Syndrome (HFS) is the most severe manifestation of skin toxicity and is associated more frequently with capecitabine therapy than with other oral fluoropyrimidines, with rates reported as high as 68%.¹¹ HFS is characterized by tingling, numbness, pain, erythema, dryness, rash, swelling, increased pigmentation, and/or pruritus of the palmar and plantar surfaces of the hands and/or feet.¹² Most patients with HFS present with dysesthesia, usually with a tingling sensation in the palms and soles of the hands and feet. This can progress in 3-4 days to burning pain and well-defined symmetric swelling and erythema. The hands tend to be more commonly affected than the feet, and in some patients may be the only area affected.¹³

Comparative trials of capecitabine versus 5-FU/IV in metastatic colorectal cancer have shown that hand-foot syndrome (HFS) was the only clinical adverse event occurring more frequently with capecitabine.¹⁴ Earlier, when compared with IV 5-FU, capecitabine caused less grade 3 HFS (1% vs 16%-18%) than has been observed with capecitabine in other trials (Table 1).¹⁵

PATHOPHYSIOLOGY

To date, the pathophysiology of HFS is not fully understood.

Dr. Saif is the Director, Gastrointestinal Malignancy Program, and Associate Professor of Medicine, Yale University School of Medicine, New Haven, Connecticut. Dr. Elfiky is a fellow in Medical Oncology, Yale University School of Medicine, New Haven, Connecticut.

Yale University School of Medicine

Identificando e Tratando Síndrome
→ Mão-Pé associada à Fluoropirimidina em
Pacientes Brancos e Não Brancos

dryness.¹⁶ Furthermore, patients should keep the affected skin well-hydrated with a mild moisturizer and regular use of salves such as Bag Balm (Dairy Association Co., Lyndonville, Vermont) or Udderly Smooth Udder Cream (Redex Industries Inc., Salem, Ohio). Patients should be instructed to soak their

in the foot pads of mice.²⁹ In our own trial of capecitabine and concomitant radiotherapy for locally advanced pancreatic cancer,³⁰ the use of prophylactic pyridoxine and Udderly Smooth Udder Cream may have played a role in reducing the number of cases of HFS, but further analysis is required.


started during cycle 4. He progressed to grade 3 at the end of sixth cycle despite his use of vitamin B₆ and Udderly Smooth balm cream. The skin toxicity was thought secondary to the

was held until improvement of HFS to grade 1. He went on to tolerate subsequent treatment cycles of capecitabine after a 25% dose reduction and continuation of supportive care measures with pyridoxine and Udderly Smooth balm.

areas (Figure 2c). He continued on treatment for 8 months with conservative management of his HFS and skin rash with pyridoxine and Udderly Smooth cream.

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