CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: NDA 20449/S004

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Application Number: NDA 20449/S004

Trade Name: Taxotere for Injection Concentrate

Generic Name: (docetaxel)

Sponsor: Rhone-Poulenc Rorer

Approval Date: January 6, 1998

Indication: Provides for the modification of the package insert to add certain adverse events which have been received through postmarketing surveillance.
CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20449/S004

APPROVAL LETTER
NDA 20-449/S004

Rhone-Poulenc Rorer
500 Arcola Road
P.O. Box 5091
Collegeville, PA 19426-0995

Attention: Ronald F. Panner
Senior Director, Worldwide Regulatory Affairs

Dear Mr. Panner:

We acknowledge your supplemental new drug application dated November 21, 1997, received November 24, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Taxotere (docetaxel) for Injection Concentrate.

The supplemental application provides for the modification of the package insert to add certain adverse events which have been received through postmarketing surveillance. The revised text is found under the ADVERSE REACTIONS: Ongoing Evaluation section of the package insert. The patient package insert is attached to the package insert and the patient package insert is referenced in the PRECAUTIONS section under Information for Patients to refer to attached Patient Information Leaflet.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling submitted on November 21, 1997. Accordingly, the supplemental application is approved effective on the date of this letter.

Should a letter communicating important information about this drug product (i.e., a “Dear Doctor” letter) be issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20852-9787

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.
If you have any questions, please contact Ann Staten, Project Manager, at 301-594-5770.

Sincerely yours,

[Signature]

1/5/98

Robert J. DeLap, M.D., Ph.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20449/S004

FINAL PRINTED LABELING
"FINAL PRINTED LABELING"

Package Insert

NDA 20-449
Taxotere® (docetaxel)
for Injection Concentrate

Labeling: Div File S-004
NDA No: 20-449 Rd 11-24-97
Reviewed by: Amy Staton 12-31-97
**PRECAUTIONS**

* Do not perform operations requiring complex brain function, such as driving, operating heavy machinery, or operating dangerous equipment while under the influence of alcohol.

* Do not perform operations requiring complex brain function while under the influence of any medication.

* Do not perform operations requiring complex brain function when you are feeling unwell or have a fever.

**CONTRAINdicATIONS**

- Pregnancy
- Allergy to alcohol

**INSTRUCTION AN USE**

- Store in a cool, dry place.

- Avoid direct sunlight.

**SIDE EFFECTS**

- Headache
- Dizziness

**RECOMMENDATIONS**

- Drink plenty of water.

- Avoid excessive alcohol consumption.

**ADDITIONAL INFORMATION**

- Consult a doctor if symptoms persist.

- Keep out of reach of children.

**COMPATIBILITY**

- Alcohol

**CAUTION**

- Do not consume alcohol with this product.

**PERIOD OF USE**

- 1 month

**PRODUCT INFORMATION**

- Manufacturer: XYZ

**TECHNICAL SPECIFICATIONS**

- Volume: 500ml
- Alcohol content: 50%

**LEGAL DISCLAIMER**

- The information provided is for reference only and does not constitute medical advice.
APPLICATION NUMBER: NDA 20449/S004

ADMINISTRATIVE DOCUMENTS
CSO NDA LABELING REVIEW OF PACKAGE INSERT

NDA: 20-449 /004

DATE OF SUBMISSION: SLR-004 November 24, 1997 (Changes Being Effected)
DATE OF REVIEW: December 19, 1997

DRUG: Taxotere® (docetaxel) for Injection Concentrate
SPONSOR: Rhone-Poulenc Rorer

This supplement provides for a revised package insert. In accordance with 21 CFR §314.70(e)(2)(i), as changes being effected, the package insert is modified to add certain adverse events which have been received through postmarketing surveillance.

I have reviewed the new labeling, comparing it with the previous labeling supplement (PA dated 5/14/96) and find it acceptable. The changes are as follows:

Changes in the package insert:

1. Per our request, the patient package insert is attached to the package insert and the patient package insert is referenced in the PRECAUTIONS section under Information for Patients to refer to attached patient package insert.

2. The established name appears on the first column, page two to satisfy labeling regulations.

3. Changes being effected are all in the ADVERSE REACTIONS section and are underlined below to indicated what was added:

**Ongoing Evaluation**: The following serious adverse events of uncertain relationship to TAXOTERE® have been reported:

- Body as a whole: abdominal pain, diffuse pain, chest pain
- Cardiovascular: atrial fibrillation, deep vein thrombosis, ECG abnormalities, thrombophlebitis, pulmonary embolism, syncope, tachycardia, myocardial infarction
- Digestive: constipation, duodenal ulcer, esophagitis, gastrointestinal hemorrhage, intestinal obstruction, ileus, gastrointestinal perforation, neutropenic enterocolitis

With the concurrence of the Medical Officer, these revisions are acceptable and the supplement should be approved.
NDA 20-449 /SLR-004
CSO labeling review, page 2

/\S/ 12/22/97
Ann M. Staten, Project Manager/ Date

/\S/
Concurrence: ------------- 12/31/97
Donna Griebel, M.D., Medical Officer/ Date

CC: Original NDA 20-449
HFD-150/Div File
/DGriebel
/ASstaten

R/D initialed by D. Pease/12-19-97
F/T PGuinn for DPease/ 12/29/97

CSO Labeling Review