

0100 Paclitaxel-Pack Inset-USA-B2

- hair loss
- numbness, tingling, or burning in your hands or feet (neuropathy)
- joint and muscle pain
- nausea and vomiting
- hypersensitivity reaction - trouble breathing, sudden swelling of your face, lips, tongue, throat, or other swelling, hives (raised bumps) on your skin
- diarrhea
- mouth- or lip sores (mucositis)
- infections - if you have a fever (temperature above 100.4°F) or other sign of infection, tell your healthcare provider right away
- swelling of your hands, face, or feet
- bleeding events
- irritation at the injection site
- low blood pressure (hypotension)

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of paclitaxel. For more information about your healthcare provider or pharmacist, call your doctor for medical advice about side effects to FDA at 1-800-FDA-1088 or go to www.fda.gov/medwatch or call 1-800-551-7176.

General information about the safe and effective use of paclitaxel.

Medicines are sometimes prescribed for purposes other than those listed in a patient information leaflet. Do not use paclitaxel for a condition for which it was not prescribed. Do not give paclitaxel to other people, even if they have the same symptoms that you have. If you have them.

This patient information leaflet summarizes the most important information about paclitaxel. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about paclitaxel that is written for health professionals. For more information go to www.fresenius-kabi.com, or call 1-800-551-7176.

What are the ingredients in paclitaxel?

Active ingredient: paclitaxel, USP.

Other ingredients include polydion 15 castor oil, NF and dehydrated alcohol, USP.

What is cancer?

Under normal conditions, the cells in your body divide and grow in an orderly, controlled way. Cell division and growth are necessary for the human body to perform its functions and to repair itself when necessary. Cancer cells are not able to control their own growth. The reasons for this abnormal growth are not yet fully understood.

A tumor is a mass of unhealthy cells that are dividing and growing fast and in an uncontrolled way. When a tumor invades surrounding healthy body tissue, it is known as a malignant tumor. A malignant tumor can spread (metastasize) from its original site to other parts of the body if not found and treated early.

FRENESEN KABI
 Lake Zurich, IL 60047
 For Product Inquiry
 1-800-551-7175 or www.fresenius-kabi.com
 45122SD Revised December 2017
 7202132602

Information for Patients (Patient Information Leaflet)

ADVERSE REACTIONS

Pooled Analysis of Adverse Event Experiences from Single-Agent Studies

Table 1A. Frequency of Important Adverse Events in the Phase 3 Second-Line Ovarian Carcinoma Study

Adverse Event	Percent of Patients (n/N)			
	ITT ¹ (n/N)	ITT ² (n/N)	ITT ³ (n/N)	ITT ⁴ (n/N)
Body Weight				
-Hypotension <2.00mmHg	76	98	78	80
-Hypotension <5.00mmHg	27	79	14	17
-Thrombocytopenia <100,000/mm ³	4	19	8	6
-Anemia <11 g/dL	84	90	68	88
-Hypotension <8 g/dL	31	12	36	10
-Hypotension <9 g/dL	16	12	36	10
-Hypotension <10 g/dL	2	1	1	1

TABLE 1B. SUMMARY OF ADVERSE EVENTS IN PATIENTS WITH SOLID TUMORS RECEIVING INTRAVENOUS PACLITAXEL

Adverse Event	Percent of Patients (n/N)			
	ITT ¹ (n/N)	ITT ² (n/N)	ITT ³ (n/N)	ITT ⁴ (n/N)
Body Weight				
-Hypotension <2.00mmHg	60	52	50	42
-Hypotension <5.00mmHg	17	50	11	12
-Thrombocytopenia <100,000/mm ³	9	20	2	2
-Anemia <11 g/dL	78	84	68	88
-Hypotension <8 g/dL	31	12	36	10
-Hypotension <9 g/dL	16	12	36	10
-Hypotension <10 g/dL	2	1	1	1

TABLE 1C. FREQUENCY OF IMPORTANT ADVERSE EVENTS IN THE PHASE 3 SECOND-LINE OVARIAN CARCINOMA STUDY

Adverse Event	Percent of Patients (n/N)			
	ITT ¹ (n/N)	ITT ² (n/N)	ITT ³ (n/N)	ITT ⁴ (n/N)
Body Weight				
-Hypotension <2.00mmHg	76	98	78	80
-Hypotension <5.00mmHg	27	79	14	17
-Thrombocytopenia <100,000/mm ³	4	19	8	6
-Anemia <11 g/dL	84	90	68	88
-Hypotension <8 g/dL	31	12	36	10
-Hypotension <9 g/dL	16	12	36	10
-Hypotension <10 g/dL	2	1	1	1

TABLE 1D. FREQUENCY OF IMPORTANT ADVERSE EVENTS IN THE PHASE 3 FIRST-LINE OVARIAN CARCINOMA STUDY

Adverse Event	Percent of Patients (n/N)			
	ITT ¹ (n/N)	ITT ² (n/N)	ITT ³ (n/N)	ITT ⁴ (n/N)
Body Weight				
-Hypotension <2.00mmHg	81	69	86	92
-Hypotension <5.00mmHg	29	59	19	20
-Thrombocytopenia <100,000/mm ³	21	30	26	30
-Anemia <11 g/dL	91	71	10	9
-Hypotension <8 g/dL	66	30	68	66
-Hypotension <9 g/dL	31	8	13	9
-Hypotension <10 g/dL	5	0	1	0
-Hypotension <11 g/dL	7	15	4	1

TABLE 1E. FREQUENCY OF IMPORTANT ADVERSE EVENTS IN THE PHASE 3 FIRST-LINE OVARIAN CARCINOMA STUDY

Adverse Event	Percent of Patients (n/N)			
	ITT ¹ (n/N)	ITT ² (n/N)	ITT ³ (n/N)	ITT ⁴ (n/N)
Body Weight				
-Hypotension <2.00mmHg	80	81	81	81
-Hypotension <5.00mmHg	28	19	19	19
-Thrombocytopenia <100,000/mm ³	11	3	2	2
-Anemia <11 g/dL	95	87	68	67
-Hypotension <8 g/dL	53	23	15	15
-Hypotension <9 g/dL	22	15	15	15
-Hypotension <10 g/dL	2	1	1	1

TABLE 1F. FREQUENCY OF IMPORTANT ADVERSE EVENTS IN THE PHASE 3 FIRST-LINE OVARIAN CARCINOMA STUDY

Adverse Event	Percent of Patients (n/N)			
	ITT ¹ (n/N)	ITT ² (n/N)	ITT ³ (n/N)	ITT ⁴ (n/N)
Body Weight				
-Hypotension <2.00mmHg	80	81	81	81
-Hypotension <5.00mmHg	28	19	19	19
-Thrombocytopenia <100,000/mm ³	11	3	2	2
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-Hypotension <9 g/dL	22	15	15	15
-Hypotension <10 g/dL	2	1	1	1

TABLE 1G. FREQUENCY OF IMPORTANT ADVERSE EVENTS IN THE PHASE 3 FIRST-LINE OVARIAN CARCINOMA STUDY

Adverse Event	Percent of Patients (n/N)			
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Body Weight				
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-Hypotension <9 g/dL	22	15	15	15
-Hypotension <10 g/dL	2	1	1	1

TABLE 1H. FREQUENCY OF IMPORTANT ADVERSE EVENTS IN THE PHASE 3 STUDY FOR FIRST-LINE OVARIAN CARCINOMA

Adverse Event	Percent of Patients (n/N)			
	ITT ¹ (n/N)	ITT ² (n/N)	ITT ³ (n/N)	ITT ⁴ (n/N)
Body Weight				
-Hypotension <2.00mmHg	80	86	84	84
-Hypotension <5.00mmHg	29	65	55	55
-Thrombocytopenia <100,000/mm ³	11	6	6	6
-Anemia <11 g/dL	94	82	12	16
-Hypotension <8 g/dL	58	36	36	36
-Hypotension <9 g/dL	22	19	29	29
-Hypotension <10 g/dL	3	3	3	3

TABLE 1I. FREQUENCY OF IMPORTANT ADVERSE EVENTS IN THE PHASE 3 STUDY FOR FIRST-LINE OVARIAN CARCINOMA

Adverse Event	Percent of Patients (n/N)			
	ITT ¹ (n/N)	ITT ² (n/N)	ITT ³ (n/N)	ITT ⁴ (n/N)
Body Weight				
-Hypotension <2.00mmHg	80	86	84	84
-Hypotension <5.00mmHg	29	65	55	55
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-Hypotension <9 g/dL	22	19	29	29
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TABLE 1J. FREQUENCY OF IMPORTANT ADVERSE EVENTS IN THE PHASE 3 STUDY FOR FIRST-LINE OVARIAN CARCINOMA

Adverse Event	Percent of Patients (n/N)			
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TABLE 1K. FREQUENCY OF IMPORTANT ADVERSE EVENTS IN THE PHASE 3 STUDY FOR FIRST-LINE OVARIAN CARCINOMA

Adverse Event	Percent of Patients (n/N)			
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-Hypotension <10 g/dL	3	3	3	3

TABLE 1L. FREQUENCY OF IMPORTANT ADVERSE EVENTS IN THE PHASE 3 STUDY FOR FIRST-LINE OVARIAN CARCINOMA

Adverse Event	Percent of Patients (n/N)			
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Body Weight				
-Hypotension <2.00mmHg	80	86	84	84
-Hypotension <5.00mmHg	29	65	55	55
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-Hypotension <9 g/dL	22	19	29	29
-Hypotension <10 g/dL	3	3	3	3

TABLE 1M. FREQUENCY OF IMPORTANT ADVERSE EVENTS IN THE PHASE 3 STUDY FOR FIRST-LINE OVARIAN CARCINOMA

Adverse Event	Percent of Patients (n/N)			
	ITT ¹ (n/N)	ITT ² (n/N)	ITT ³ (n/N)	ITT ⁴ (n/N)
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-Hypotension <10 g/dL	3	3	3	3

TABLE 1N. FREQUENCY OF IMPORTANT ADVERSE EVENTS IN THE PHASE 3 STUDY FOR FIRST-LINE OVARIAN CARCINOMA

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-Hypotension <10 g/dL	3	3	3	3

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TABLE 1Q. FREQUENCY OF IMPORTANT ADVERSE EVENTS IN THE PHASE 3 STUDY FOR FIRST-LINE OVARIAN CARCINOMA

Adverse Event	Percent of Patients (n/N)			
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