

הודעה על החמרה (מידע בטיחות) בעלון לרופא
 (מעודכן 05.2013)

אושר – 3.16

תאריך: 23.02.2016

שם תכשיר באנגלית ומספר הרישום:

Dacogen, 143-65-31633-00

שם בעל הרישום: J-C Health Care Ltd.

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	טקסט נוכחי	פרק בעלון
<p>.....After aseptic reconstitution with 10mL of sterile water for injection, each mL of the concentrate of solution for infusion contains 5mg of decitabine.</p> <p>Each vial contains 0.5 mmol potassium (E340) and 0.29 mmol sodium (E524).</p>	<p>.....After aseptic reconstitution with 10mL of sterile water for injection, each mL of the concentrate of solution for infusion contains 5mg of decitabine.</p>	<p>Qualitative and quantitative composition</p>
<p>-Dacogen is contraindicated in patients with a known hypersensitivity to decitabine or any of the excipients. (see Section 6.1)</p> <p>-Pregnancy (see warnings and precautions)</p> <p>-Breast feeding (see warnings and precautions)</p>	<p>-Dacogen is contraindicated in patients with a known hypersensitivity to decitabine or any of the excipients. (see Section 6.1)</p> <p>-Pregnancy (see warnings and precautions)</p> <p>-Breast feeding (see warnings and precautions)</p>	<p>Contraindications</p>
<p><u>Myelosuppression</u> Myelosuppression and complications of myelosuppression, including infections and bleeding that occur in patients with MDS or AML may be exacerbated with</p>	<p><u>Myelosuppression</u> Myelosuppression and complications of myelosuppression, including infections and bleeding that occur in patients with MDS or AML may be exacerbated with</p>	<p>Special warnings and special precautions for use</p>

DACOGEN treatment. **Therefore patients are at increased risk for severe infections (due to any pathogen such as bacterial, fungal and viral), with potentially fatal outcome (see section 4.8). Patients should be monitored for signs and symptoms of infection and treated promptly....**

DACOGEN treatment.....

Undesirable effects:

..... **Table 3: Adverse Drug Reactions Identified with DACOGEN ²**

System Organ Class	Frequency (all Grades)	Adverse Drug Reaction	Frequency	
			All Grades ^a (%)	Grades 3-4 ^a (%)
Infections and infestations	Very common	pneumonia*	24	20
		urinary tract infection*	15	7
		All other infections (viral, bacterial, fungal)*b,c,d	63	39
	Common	septic shock*	6	4
		sepsis*	9	8
		sinusitis	3	1
Blood and lymphatic disorders	Very common	febrile neutropenia*	34	32
		neutropenia*	32	30
		thrombocytopenia ^b *	41	38
		anaemia	38	31
		leukopenia	20	18
	Uncommon	Pancytopenia*	<1	<1
Immune system disorders	Common	Hypersensitivity including anaphylactic reaction ^c	1	<1
Nervous system disorders	Very common	headache	16	1
Respiratory, thoracic and mediastinal disorders	Very common	epistaxis	14	2
Gastrointestinal disorders	Very common	diarrhoea	31	2
		vomiting	18	1
		nausea	33	<1
	Not known	Enterocolitis, including neutropaenic colitis, caecitis	Not known	Not known
	Common	stomatitis	7	1
Skin and subcutaneous	Uncommon	acute febrile neutrophilic dermatosis (Sweet's syndrome)	<1	NA

tissue disorders				
General disorders and administration site conditions	Very common	pyrexia	48	9

מצ"ב העלון, שבו מסומנות החמרות המבוקשות על רקע צהוב. שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע שונה. יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט.

הועבר בדואר אלקטרוני בתאריך...23.02.2016

