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Caverject Powder (Alprostadil Sterile Powder for Injection)

??? ??????: 30 ??????/?????? 2017

The following local adverse reaction information was derived from con- trolled and uncontrolled studies, including an uncontrolled **Local Adverse Reactions:** 18-month safety study.

Local Adverse Reactions Reported by ? 1% of Patients Treated with CAVERJECT for up to 18 Months*

CAVERJECT N = 1861	Event	CAVERJECT N = 1861	Event
3%	Penis disorder***	37%	Penile pain
2%	Injection site ecchymosis	4%	Prolonged erection
1%	Penile rash	3%	Penile fibrosis**
1%	Penile edema	3%	Injection site hematoma
* Except for penile pain (2%), no significant local adverse reactions were reported by 294 patientswho received 1 to 3 injections of placebo.			
.**General Precautions** ** See			
*** Includes numbness, yeast infection, irritation, sensitivity, phimosis, pruritus, erythema, venous leak, penile skin tear, strange feeling of penis, discoloration of penile head, itch at tip of penis.			

Penile pain after intracavernosal administration of CAVERJECT was reported at least once by 37% of patients in clinical studies of up to 18 months in **Penile Pain:** duration. In the majority of the cases, penile pain was rated mild or moderate in intensity. Three percent of patients discontinued treatment because of penile pain. The frequency of penile pain was 2% in 294 patients who received 1 to 3 injections of placebo.

In clinical trials, prolonged erection was defined as an erection that lasted for 4 to 6 hours; priapism was defined as erection that **Prolonged Erection/Priapism:** lasted 6 hours or longer. The frequency of prolonged erection after intracavernosal administration of CAVERJECT was 4%, while the frequency of priapism was 0.4%. In the majority of cases, spontaneous detumescence occurred. To minimize the chances of prolonged erection or priapism, CAVERJECT should be titrated). The patient must be instructed to immediately report to his physician or, if **DOSAGE AND ADMINISTRATION section**slowly to the lowest effective dose (see unavailable, to seek immediate medical assistance for any erection that persists for longer than 4 hours. If priapism is not treated immediately, penile tissue damage and permanent loss of potency may result.

The frequency of hematoma and ecchymosis was 3% and 2%, respectively. In most cases, hematoma/ecchymosis was judged to be a **Hematoma/Ecchymosis:** complication of a faulty injection technique. Accordingly, proper instruction of the patient in self-injection is of importance to minimize the potential of).**DOSAGE AND ADMINISTRATION**hematoma/ecchymosis (see

The following local adverse reactions were reported by fewer than 1% of patients after injection of CAVERJECT: balanitis, injection site hemorrhage, injection site inflammation, injection site itching, injection site swelling, injection site edema, urethral bleeding, penile warmth, numbness, yeast infection, irri tation, sensit ivity, phimosis, pruritus, erythema, venous leak, painful erect ion, and abnormal ejaculat ion.

The following systemic adverse event information was derived from controlled and uncontrolled studies, including an uncontrolled **Systemic Adverse Events:** 18-month safety study.

Systemic Adverse Events Reported by ? 1% of Patients Treated with CAVERJECT for up to 18 Months*

CAVERJECT N = 1861	Body System/Reaction (continued)	CAVERJECT N = 1861	Body System/Reaction

	Urogenital System		Cardiovascular System
2%	Prostatic Disorder**	2%	Hypertension
	Miscellaneous		**Central Nervous System**
2%	Localized pain***	2%	Headache
2%	Trauma****	1%	Dizziness
			Musculoskeletal System
		1%	Back pain
			Respiratory System
		4%	Upper respiratory infection
		2%	Flu syndrome
		2%	Sinusitis
		1%	Nasal congestion
		1%	Cough

* No significant adverse events were reported by 294 patients who received 1 to 3 injections ofplacebo.
** prostatitis, pain, hypertrophy, enlargement
*** pain in various anatomical structures other than injection site
**** injuries, fractures, abrasions, lacerations, dislocat ions

The following systemic events, which were reported for < 1% of patients in clinical studies, were judged by investigators to be possibly related to use of CAVERJECT: testicular pain, scrotal disorder, scrotal edema, hematuria, testicular disorder, impaired urination, urinary frequency, urinary urgency, pelvic pain, hypotension, vasodilation, peripheral vascular disorder, supraventricular extrasystoles, vasovagal reactions, hypesthesia, non-generalized weakness, diaphoresis, rash, non-application site pruritus, skin neoplasm, nausea, dry mouth, increased serum creatinine, leg cramps, and mydriasis.

Hemodynamic changes, manifested as decreases in blood pressure and increases in pulse rate, were observed during clinical studies, principally at doses above 20 micrograms and above 30 micrograms of alprostadil, respectively, and appeared to be dose-dependent. However, these changes were usually clinically unimportant; only three patients discont inued the treatment because of symptomatic hypotension.

CAVERJECT had no clinically important effect on serum or urine laboratory tests.