Skip to main content

Atracurium Besylate (Tracrium)

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

Observed in Controlled Clinical Studies

TRACRIUM (atracurium besylate) was well tolerated and produced few adverse reactions during extensive clinical trials. Most adverse reactions were suggestive of histamine release. In studies including 875 patients, TRACRIUM (atracurium besylate) was discontinued in only one patient (who required treatment for bronchial secretions), and six other patients required treatment for adverse reactions attributable to TRACRIUM (atracurium besylate) (wheezing in one, hypotension in five). Of the five patients who required treatment for hypotension, three had a history of significant cardiovascular disease. The overall incidence rate for clinically important adverse reactions, therefore, was 7/ 875 or 0.8%. Table 1 includes all adverse reactions reported attributable to TRACRIUM (atracurium besylate) during clinical trials with 875 patients.

Table 1: Percent of Patients Reporting Adverse Reactions Initial Dose of TRACRIUM (atracurium besylate) (mg/kg)

Adverse Reaction	Initial Dose of TRACRIUM (atracurium besylate) (mg/ kg)			
	Total (n = 875)	0.60≥ (n = 24)	0.31-0.50* (n = 366)	0.00-0.30 (n = 485)
Skin Flush				
Erythema	5.0%	29.2%	8.7%	1.0%
Itching	0.6%	0%	0.5%	0.6%
Wheezing/Bronchial Secretions	0.2%	0%	0%	0.4%
Hives	0.2%	0%	0.3%	0.2%
	0.1%	0%	0%	0.2%

* Includes the recommended initial dosage range for most patients.

Most adverse reactions were of little clinical significance unless they were associated with significant hemodynamic changes. Table 2 summarizes the incidences of substantial vital sign changes noted during clinical trials of TRACRIUM (atracurium besylate) with 530 patients, without cardiovascular disease, in whom these parameters were assessed.

Table 2: Percent of Patients Showing >30% Vital Sign Changes Following Administration of TRACRIUM (atracurium besylate)

Vital Sign Change	Initial Dose of TRACRIUM (atracurium besylate) (mg/ kg)			
	Total (n = 530)	0.60≥ (n = 21)	0.31-0.50* (n = 144)	0.00-0.30 (n = 365)
Mean Arterial Pressure				
Increase	2.1%	0%	2.8%	1.9%
Decrease	1.9%	14.3%	2.1%	1.1%
Heart Rate				

					Increase
2.1%	4.8%	2.8%	1.6%		Decrease
0.6%	0%	0%	0.8%		

* Includes the recommended initial dosage range for most patients.

Observed in Clinical Practice

Based on initial clinical practice experience in approximately 3 million patients who received TRACRIUM (atracurium besylate) in the US and in the United Kingdom, spontaneously reported adverse reactions were uncommon (approximately 0.01% to 0.02%). The following adverse reactions are among the most frequently reported, but there are insufficient data to support an estimate of their incidence:

Allergic reactions (anaphylactic or anaphylactoid responses) which, in rare instances, were severe (e.g., cardiac arrest). ***General:***

Inadequate block, prolonged block. ***Musculoskeletal:***

Hypotension, vasodilatation (flushing), tachycardia, bradycardia. ***Cardiovascular:***

Dyspnea, bronchospasm, laryngospasm. ***Respiratory:***

Rash, urticaria, reaction at injection site. ***Integumentary:***

There have been rare spontaneous reports of seizures in ICU patients following long-term infusion of atracurium to support mechanical ventilation. There are **PRECAUTIONS: Long-Term Use in Intensive Care Unit** insufficient data to define the contribution, if any, of atracurium and/or its metabolite laudanosine. (See).**[ICU]**