

Participants with Severe Adverse Events  
(Incidence  $\geq 0\%$  in One or More Treatment Groups)  
(ASaT Population)

	Placebo		Xanomeline Low Dose		Xanomeline High Dose		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Participants in population	86		84		84		254	
with one or more severe AE	7	(8.14)	16	(19.05)	8	(9.52)	31	(12.20)
with no severe AE	79	(91.86)	68	(80.95)	76	(90.48)	223	(87.80)
<b>cardiac disorders</b>	<b>3</b>	<b>(3.5)</b>	<b>0</b>	<b>(0.0)</b>	<b>1</b>	<b>(1.2)</b>	<b>4</b>	<b>(1.6)</b>
atrial fibrillation	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
atrioventricular block second degree	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
myocardial infarction	2	(2.3)	0	(0.0)	0	(0.0)	2	(0.8)
<b>gastrointestinal disorders</b>	<b>0</b>	<b>(0.0)</b>	<b>0</b>	<b>(0.0)</b>	<b>2</b>	<b>(2.4)</b>	<b>2</b>	<b>(0.8)</b>
gastrointestinal haemorrhage	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
nausea	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
<b>general disorders and administration site conditions</b>	<b>0</b>	<b>(0.0)</b>	<b>7</b>	<b>(8.3)</b>	<b>0</b>	<b>(0.0)</b>	<b>7</b>	<b>(2.8)</b>
application site dermatitis	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
application site erythema	0	(0.0)	2	(2.4)	0	(0.0)	2	(0.8)
application site irritation	0	(0.0)	3	(3.6)	0	(0.0)	3	(1.2)
application site pruritus	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)

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<b>general disorders and administration site conditions</b>	<b>0</b>	<b>(0.0)</b>	<b>7</b>	<b>(8.3)</b>	<b>0</b>	<b>(0.0)</b>	<b>7</b>	<b>(2.8)</b>
application site warmth	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
sudden death	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
<b>infections and infestations</b>	<b>0</b>	<b>(0.0)</b>	<b>1</b>	<b>(1.2)</b>	<b>0</b>	<b>(0.0)</b>	<b>1</b>	<b>(0.4)</b>
nasopharyngitis	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
<b>injury, poisoning and procedural complications</b>	<b>1</b>	<b>(1.2)</b>	<b>0</b>	<b>(0.0)</b>	<b>1</b>	<b>(1.2)</b>	<b>2</b>	<b>(0.8)</b>
hip fracture	1	(1.2)	0	(0.0)	1	(1.2)	2	(0.8)
<b>musculoskeletal and connective tissue disorders</b>	<b>1</b>	<b>(1.2)</b>	<b>1</b>	<b>(1.2)</b>	<b>0</b>	<b>(0.0)</b>	<b>2</b>	<b>(0.8)</b>
arthritis	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
muscle spasms	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
<b>neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>	<b>0</b>	<b>(0.0)</b>	<b>1</b>	<b>(1.2)</b>	<b>1</b>	<b>(1.2)</b>	<b>2</b>	<b>(0.8)</b>
colon cancer	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
prostate cancer	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
<b>nervous system disorders</b>	<b>0</b>	<b>(0.0)</b>	<b>3</b>	<b>(3.6)</b>	<b>4</b>	<b>(4.8)</b>	<b>7</b>	<b>(2.8)</b>
dizziness	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
headache	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
partial seizures with secondary generalisation	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
stupor	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)

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<b>nervous system disorders</b>	<b>0</b>	<b>(0.0)</b>	<b>3</b>	<b>(3.6)</b>	<b>4</b>	<b>(4.8)</b>	<b>7</b>	<b>(2.8)</b>
syncope	0	(0.0)	2	(2.4)	1	(1.2)	3	(1.2)
transient ischaemic attack	0	(0.0)	1	(1.2)	1	(1.2)	2	(0.8)
<b>psychiatric disorders</b>	<b>1</b>	<b>(1.2)</b>	<b>1</b>	<b>(1.2)</b>	<b>0</b>	<b>(0.0)</b>	<b>2</b>	<b>(0.8)</b>
agitation	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
completed suicide	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
<b>reproductive system and breast disorders</b>	<b>1</b>	<b>(1.2)</b>	<b>0</b>	<b>(0.0)</b>	<b>0</b>	<b>(0.0)</b>	<b>1</b>	<b>(0.4)</b>
benign prostatic hyperplasia	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
<b>skin and subcutaneous tissue disorders</b>	<b>0</b>	<b>(0.0)</b>	<b>4</b>	<b>(4.8)</b>	<b>1</b>	<b>(1.2)</b>	<b>5</b>	<b>(2.0)</b>
blister	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
pruritus	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
rash	0	(0.0)	1	(1.2)	1	(1.2)	2	(0.8)
skin irritation	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
This is footnote 1								
This is footnote 2								

Source: [Study MK9999P001: adam-adac]