

## Background

Numerous monoclonal antibody products have recently been approved to aid in the treatment and diagnosis of a wide variety of diseases.

Most currently available monoclonal antibody-based medications utilize a murine (mouse) source. An unfortunate side effect of using mouse antibody-based products is the occasional development of Human Anti-Murine Antibodies (HAMA) in patients administered these drugs.

## An Immune Response

A HAMA reaction occurs when the immune system recognizes the mouse antibody as a foreign protein.

In an attempt to reduce the incidence of HAMA, scientists have employed new technologies to produce monoclonal antibodies (e.g., Chimeric, Humanized, and Recombinant DNA) that have less murine components and more human components. However, all still have the potential to elicit a HAMA response

## Potential for Concern

Patients with HAMA have an increased risk of allergic or serious hypersensitivity reactions during administration of murine monoclonal antibody products.

## Altered Clearance and Biodistribution

Undetectable HAMA serum levels can alter the clearance and biodistribution of monoclonal antibodies. In nuclear medicine procedures, this may lead to an inconclusive diagnostic study or a failed therapy.

## Patient Screening

Prior to administration, patients who have previously received any murine antibody-based product should be tested for HAMA.

## Time Frame for HAMA Response

Patients that develop HAMA usually do so after about 4 weeks post mouse antibody administration.

In one clinical trial, HAMA decreased to an undetectable level after 4 to 12 months in about half of all HAMA positive patients.

## Laboratory Test Interactions

The presence of HAMA in serum may interfere with some antibody-based immunoassays. For example: PSA, CEA, CA-125, and digoxin

## Monoclonal Antibodies in the Future

At present there are many monoclonal antibody-based medications in clinical trials and other stages of development. It is important to be aware of a patient's medical history with regard to the use of these medications and the potential impact on future diagnostic tests and therapies.

**If you have questions regarding this, or any other procedure, don't hesitate to call us at (812) 421-1002 or (800) 755-5889 or visit us online at: [www.radiopharmacy.com](http://www.radiopharmacy.com)**



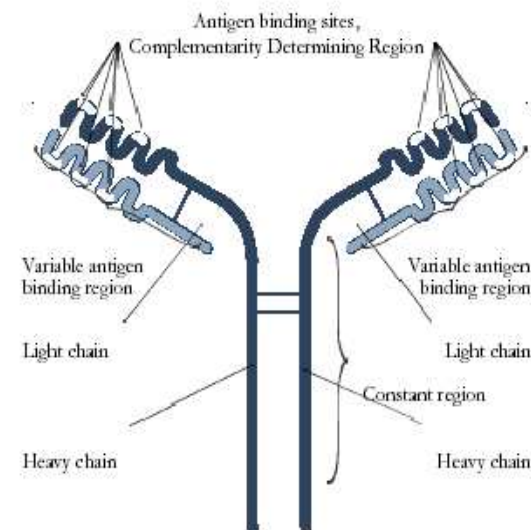
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# MONOCLONAL ANTIBODY-BASED MEDICATIONS AND HAMA

A DISCUSSION OF MEDICATIONS THAT MAY INDUCE THE PRODUCTION OF HUMAN ANTI-MURINE ANTIBODIES

2003



The antibody molecule

# Monoclonal Antibody-Based Medications and HAMA

Drug	Generic Name	Antibody Type	HAMA	Indication/Use
Bexxar®	I-131 Tositumomab	Murine	11%	B-cell NHL Treatment
Campath®	Alemtuzumab	Recombinant DNA	1.9%	B-cell CLL Treatment
CEA-Scan®	Tc-99m Arcitumomab	Murine (antibody fragment)	<1.0%	Colorectal Cancer Imaging
Herceptin®	Trastuzumab	Recombinant DNA	0.1%	Breast Cancer Treatment
Humira™	Adalimumab	Recombinant DNA	5.0%	Rheumatoid Arthritis
Mylotarg®	Gemtuzumab Ozogamicin	Recombinant Humanized	1.4%	AML Treatment
MyoScint®	In-111 Imciromab Pentetate	Murine (antibody fragment)	0.1%	Cardiac Imaging
OncoScint®	In-111 Satumomab Pendetide	Murine	55%	Colorectal and Ovarian Cancer Imaging
ProstaScint®	In-111 Capromab Pendetide	Murine	8%	Prostate Cancer Imaging
Remicade®	Infliximab	Chimeric (murine/human)	10%	Rheumatoid Arthritis/Crohn's Disease
Reopro®	Abciximab	Chimeric (murine/human antibody fragment)	5.8%	Anticoagulant
Rituxan®	Rituximab	Chimeric (murine/human)	1.1%	B-cell NHL Treatment
Simulect®	Basiliximab	Chimeric (murine/human)	2.6%	Immunosuppression for Organ Transplant
Synagis®	Palivizumab	Humanized Murine	0.7%	RSV Prophylaxis
Verluma®	Tc-99m Nofetumomab Merpentan	Murine (antibody fragment)	6.0%	Lung Cancer Imaging
Xolair®	Omalizumab	Recombinant DNA	<0.1%	Asthma
Zenapax®	Daclizumab	Humanized Murine	14%	Immunosuppression for Organ Transplant
Zevalin™	In-111/Y-90 Ibritumomab Tiuxetan	Murine	3.8%	B-cell NHL Treatment

\*HAMA Incidence as reported in clinical trials.

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