MedImmune Assistance Program

MedImmune is proud to offer the MedImmune Assistance Program (MAP), designed to provide temporary assistance to individuals who need access to Synagis® (palivizumab), but who lack health insurance. The program can be reached by calling 1(877) 480-8082. By calling this number, a healthcare provider can review the patient's eligibility with a program specialist. In order to qualify for assistance, a patient must:

- be receiving Synagis for its FDA-approved indication,
- have no form of health insurance (including Medicare, Medicaid, or any other sponsored coverage); and,
- meet the income/asset/expense parameters of the program.

A final eligibility determination will be made upon the program's receipt of application materials.

If the patient is eligible, providers will receive product to be used for the treatment of the qualified patient.

If a patient is not eligible for assistance, all efforts will be made by program staff to direct the patient towards insurance programs or other funding sources that may be able to provide assistance.

Important Safety Information

Synagis® (palivizumab) is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease and is administered by intramuscular injection. Safety and efficacy were established in infants with bronchopulmonary dysplasia (BPD), infants with a history of premature birth (<35 weeks gestational age), and children with hemodynamically significant congenital heart disease (CHD). Synagis has been used in more than one million children in the U.S. since its introduction in 1998. The first dose of Synagis should be administered prior to commencement of the RSV season. Patients, including those who develop an RSV infection, should continue to receive monthly doses throughout the season.

Very rare cases (<1 per 100,000 patients) of anaphylaxis and rare (<1 per 1,000 patients) hypersensitivity reactions have been reported with Synagis. Cases of anaphylaxis were reported following re-exposure to Synagis and rare severe hypersensitivity reactions occurred on initial exposure or re-exposure. If a severe hypersensitivity reaction occurs, therapy with Synagis should be permanently discontinued. If milder hypersensitivity reaction occurs, caution should be used on re-administration of Synagis.

In clinical trials, the most common adverse events occurring at least 1% more frequently in Synagis-treated patients than controls were upper respiratory infection, otitis media, fever, and rhinitis. Cyanosis and arrhythmia were seen in children with CHD.

Please see enclosed full prescribing information *SYN07-024*

MedImmune Assistance Program
Patient Application

Patient Information

Patient Last Name | Patient First Name | Patient MI | Date of Birth

Parent/ Guardian First and Last Name | Address

City | State | Zip

Home Phone | Work Phone | Cell Phone

Check *all* that apply:

Applied	Has Benefits	Application Pending	Not Eligible	Has Not
Medicaid	❑	❑	❑	❑
Other State Medical Assistance (CHIP, Title V, etc.)	❑	❑	❑	❑
Medicare	❑	❑	❑	❑
Private Insurance	❑	❑	❑	❑
Other (specify)_____	❑	❑	❑	❑

Is this patient a U.S. Resident? ❑ Yes ❑ No

Primary Diagnosis (IDC-9-CM diagnosis codes are in parenthesis)

Patient's Gestational Age (GA)_____ Birth Weight _____kg/lbs

Current Weight _____kg/lbs Date Recorded _____

❑ Congenital Heart Disease (745.0-747.9)
❑ Chronic Respiratory Disease Arising in the Perinatal Period (CLD) (770.7)
❑ < 24 weeks' GA (765.21-765.22)
❑ 25-26 weeks' GA (765.23)
❑ 27-28 weeks' GA (765.24)
❑ 29-30 weeks' GA (765.25)
❑ 31-32 weeks' GA (765.26)
❑ 33-34 weeks' GA (765.27)
❑ 35-36 weeks' GA (765.28)
❑ 37 or more weeks' GA (765.29)
❑ Other Respiratory Conditions of Fetus and Newborn (770.0-770.9)
❑ Congenital Anomalies of Respiratory System (748)
❑ Other _____ Secondary diagnosis (if applicable) _____

MEDICAL CRITERIA

1. Diagnosis of chronic pulmonary disease (CLD/BPD) and less than 24 months of age? ❑ Yes ❑ No
   Has patient received or is currently on medical treatment (check all that apply and provide last date received):
   ❑ Oxygen Date _____ ❑ Corticosteroids Date _____
   ❑ Bronchodilators Date _____ ❑ Diuretics Date _____
2. Diagnosis of hemodynamically significant congenital heart disease and less than 24 months of age? ❑ Yes ❑ No
   Patient has following condition: ❑ Diagnosis of moderate-severe pulmonary hypertension
   ❑ Medications for CHD _____ Last Date Received _____
3. Prematurity:
   ❑ Gestational age of ≤ 28 weeks and ≤ 12 months of age at the start of RSV season
   ❑ Gestational age of 29-32 weeks and < 6 months of age at start of the RSV season
   ❑ Gestational age of 33-35 weeks and < 6 months of age at start of the RSV season

Clinically has the following risk factors (check all that apply):

❑ School Age Siblings
❑ Exposure to Environmental Air Pollutants
❑ Daycare
❑ Severe Neuromuscular Disease
❑ Congenital Abnormality of Airway
❑ Other Medical History: _____
❑ Birth Weight Less Than 2500 g
❑ Crowded Living Conditions
❑ Multiple Birth
❑ Family History of Asthma

Gross Monthly Household Revenue Sources

List # in household: _____
(Applicant & Dependents)

All Salary/Wages/Pension	$ _____
Interest/Dividends/Annuities	$ _____
Unemployment Compensation	$ _____
Social Security/Supplement/Disability Income	$ _____
Other (Alimony, Capital Gains, Child Support, etc.)	$ _____
Total monthly household out-of-pocket medical expenses	$ _____

Household Cash Assets

Cash/Savings/Checking/Money Market	$ _____
CD's	$ _____
Stock/Bonds	$ _____
Total Household Cash Assets	$ _____

Prescription Information

❑ Synagis® (palivizumab)
Sig: ❑ Inject 15mg/kg IM one time per month

Monthly Quantity: ____100 mg vials ____50 mg vials
_____Refill _____ months
Other: _____

Provider Information

Physician Name (Include professional designation) | State License or DEA Number

Clinic or Hospital | Tax ID

Address | City | State | Zip

Contact Name | Office Phone | Office Fax

*Please note that the ***Physican Certification and Request*** and the ***Patient Authorization and Certification*** are included on the following page of the application form. The MedImmune Assistance Program will not be able to continue to process the application without these signed documents.*

Physician Certification and Request

I request on behalf of my patient the MedImmune product, Synagis® (palivizumab), and do so because my patient does not have insurance coverage. I certify that I am currently licensed to prescribe and receive medications and that the information provided by me herein is accurate and complete. I understand that the patient's eligibility under this program is subject to approval under the program guidelines, including meeting financial criteria, and that MedImmune reserves the right to change or terminate this program without prior notice. I understand that the assistance provided to the patient is temporary and the patient may be asked to reapply at designated intervals. I certify that, to the best of my knowledge, my patient has no access to medication benefit assistance, Medicare, Medicaid, government subsidized clinics, other government or private programs, or any other help to purchase medication. I attest to my patient's financial need and I certify that, to the best of my knowledge, my patient does not have the ability to pay for the Synagis injection to be administered. I certify that I have not received reimbursement for the Synagis being requested or previously administered. I understand that if the patient's income or insurance status changes, the patient may no longer be eligible under this program. I certify that no free vials provided under this program will be distributed for sale to any individual or organization and that I will not seek payment or reimbursement from the patient or any third–party payer. I certify that my patient is a resident of the US. I agree to immediately notify a program representative if the patient's insurance or income status changes. I understand that I am under no obligation to prescribe any MedImmune drug to participate in this program and that I have not received, nor will receive any benefit from MedImmune or the Lash Group for prescribing a MedImmune drug. I understand that the Lash Group and MedImmune are not responsible for filing any insurance claims. **I agree to abide by this certification throughout my participation in the program and to notify a program representative if aspects of this certification are no longer applicable.**

Original Signature of Physician **Date**

The patient or the patient's parent or guardian must sign both the certification and the authorization below in order to be eligible to participate in the Patient Assistance Program.

Patient Certification

I attest that the information supplied by me herein is complete and accurate. I understand that the patient's eligibility under this program is subject to approval under the program guidelines, and that MedImmune reserves the right to change or terminate the program without prior notice. I understand that this assistance is temporary and that I may be asked to reapply at designated intervals. I certify that the patient has no access to Medicare, Medicaid, government subsidized clinics, other government or private programs, or any other help to purchase the patient's medication. I certify that I do not have the ability to pay for the MedImmune product administered. I agree to inform my physician and/or program representative immediately if my income or insurance status changes. I understand that MedImmune and the consultants that are helping MedImmune administer this program are not responsible for filing any insurance claims. I agree to abide by this certification throughout my participation in the program and to notify a program representative if aspects of my certification are no longer applicable.

Signature of Parent of Legal Guardian **Date**

Patient Authorization to Use and Disclose Medical Information

By signing below, I also authorize the patient's doctor, health plan or other healthcare provider to release the patient's medical and insurance status information to MedImmune and its consultants for the sole purpose of assessing my eligibility for participation in the program and administering the program. I further authorize MedImmune and its consultants to re-disclose that information, and information in this application, to health insurance companies and other potential sources of funding for Synagis. I understand that this authorization will expire twelve (12) months from the date of signing it. I may revoke this authorization at any time by writing to the patient's doctor, except that information that has been disclosed before the patient's doctor receives my revocation will not be retrieved. I understand that I may receive a copy of this authorization upon request.

I understand the patient's doctor will treat the patient even if I do not sign this authorization. However, I understand that the patient cannot participate in the MedImmune Assistance Program if I do not sign this authorization, or if I revoke the authorization. I understand that once

the patient's health information has been disclosed in reliance on this authorization, the information may no longer be protected under federal privacy laws, and may be re-disclosed.

Signature of Legal Guardian **Date**

_____

Relationship to Patient

SYNAGIS® (PALIVIZUMAB) **Rx only**

for Intramuscular Administration

DESCRIPTION: Synagis (palivizumab) is a humanized monoclonal antibody (IgG1κ) produced by recombinant DNA technology, directed to an epitope in the A antigenic site of the F protein of respiratory syncytial virus (RSV). Synagis is a composite of human (95%) and murine (5%) antibody sequences. The human heavy chain sequence was derived from the constant domains of human IgG1 and the variable framework regions of the V_H genes Cor (1) and Cess (2). The human light chain sequence was derived from the constant domain of Cκ and the variable framework regions of the V_L gene K104 with Jκ-4 (3). The murine sequences were derived from a murine monoclonal antibody, Mab 1129 (4), in a process that involved the grafting of the murine complementarity determining regions into the human antibody frameworks. Synagis is composed of two heavy chains and two light chains and has a molecular weight of approximately 148,000 Daltons.

Synagis is supplied as a sterile, preservative-free liquid solution at 100 mg/mL to be administered by intramuscular injection (IM). Thimerosal or other mercury containing salts are not used in the production of Synagis. The solution has a pH of 6.0 and should appear clear or slightly opalescent.

Each 100 mg single-dose vial of Synagis liquid solution contains 100 mg of Synagis, 3.9 mg of histidine, 0.1 mg of glycine, and 0.5 mg of chloride in a volume of 1 mL.

Each 50 mg single-dose vial of Synagis liquid solution contains 50 mg of Synagis, 1.9 mg of histidine, 0.06 mg of glycine, and 0.2 mg of chloride in a volume of 0.5 mL.

CLINICAL PHARMACOLOGY: *Mechanism of Action:* Synagis exhibits neutralizing and fusion-inhibitory activity against RSV. These activities inhibit RSV replication in laboratory experiments. Although resistant RSV strains may be isolated in laboratory studies, a panel of 57 clinical RSV isolates were all neutralized by Synagis (5). Synagis serum concentrations of ≥40 mcg/mL have been shown to reduce pulmonary RSV replication in the cotton rat model of RSV infection by 100-fold (5). The *in vivo* neutralizing activity of the active ingredient in Synagis was assessed in a randomized, placebo-controlled study of 35 pediatric patients tracheally intubated because of RSV disease. In these patients, Synagis significantly reduced the quantity of RSV in the lower respiratory tract compared to control patients (6).

Pharmacokinetics: In pediatric patients <24 months of age without congenital heart disease (CHD), the mean half-life of Synagis was 20 days and monthly intramuscular doses of 15 mg/kg achieved mean ± SD 30 day trough serum drug concentrations of 37 ± 21 mcg/mL after the first injection, 57 ± 41 mcg/mL after the second injection, 68 ± 51 mcg/mL after the third injection and 72 ± 50 mcg/mL after the fourth injection (7). Trough concentrations following the first and fourth Synagis dose were similar in children with CHD and in non-cardiac patients. In pediatric patients given Synagis for a second season, the mean ± SD serum concentrations following the first and fourth injections were 61 ± 17 mcg/mL and 86 ± 31 mcg/mL, respectively.

In 139 pediatric patients ≤24 months of age with hemodynamically significant CHD who received Synagis and underwent cardio-pulmonary bypass for open-heart surgery, the mean ± SD serum Synagis concentration was 98 ± 52 mcg/mL before bypass and declined to 41 ± 33 mcg/mL after bypass, a reduction of 58% (see *DOSAGE AND ADMINISTRATION*). The clinical significance of this reduction is unknown.

Specific studies were not conducted to evaluate the effects of demographic parameters on Synagis systemic exposure. However, no effects of gender, age, body weight or race on Synagis serum trough concentrations were observed in a clinical study with 639 pediatric patients with CHD (≤24 months of age) receiving five monthly intramuscular injections of 15 mg/kg of Synagis.

The pharmacokinetics and safety of Synagis liquid solution and Synagis lyophilized formulation administered IM at 15 mg/kg were studied in a cross-over trial of 153 pediatric patients ≤6 months of age with a history of prematurity. The results of this trial indicated that the trough serum concentrations of palivizumab were comparable between the liquid solution and the lyophilized formulation, which was the formulation used in the clinical studies described below.

CLINICAL STUDIES: The safety and efficacy of Synagis were assessed in two randomized, double-blind, placebo-controlled trials of prophylaxis against RSV infection in pediatric patients at high risk of an RSV-related hospitalization. Trial 1 was conducted during a single RSV season and studied a total of 1,502 patients ≤24 months of age with bronchopulmonary dysplasia (BPD) or infants with premature birth (≤35 weeks gestation) who were ≤6 months of age at study entry (7). Trial 2 was conducted over four consecutive seasons among a total of 1,287 patients ≤24 months of age with hemodynamically significant congenital heart disease. In both trials participants received 15 mg/kg Synagis or an equivalent volume of placebo IM monthly for five injections and were followed for 150 days from randomization. In Trial 1, 99% of all subjects completed the study and 93% completed all five injections. In Trial 2, 96% of all subjects completed the study and 92% completed all five injections. The incidence of RSV hospitalization is shown in Table 1.

Table 1: Incidence of RSV Hospitalization by Treatment Group

Trial		Placebo	Synagis	Difference Between Groups	Relative Reduction	p-Value
Trial 1	N	500	1002			
Impact-RSV	Hospitalization	53 (10.6%)	48 (4.8%)	5.8%	55%	<0.001
Trial 2	N	648	639			
CHD	Hospitalization	63 (9.7%)	34 (5.3%)	4.4%	45%	0.003

In Trial 1, the reduction of RSV hospitalization was observed both in patients with BPD (34/266 [12.8%] placebo vs. 39/496 [7.9%] Synagis), and in premature infants without BPD (19/234 [8.1%] placebo vs. 9/506 [1.8%] Synagis). In Trial 2, reductions were observed in acyanotic (36/305 [11.8%] placebo versus 15/300 [5.0%] Synagis) and cyanotic children (27/343 [7.9%] placebo versus 19/339 [5.6%] Synagis).

The clinical studies do not suggest that RSV infection was less severe among RSV hospitalized patients who received Synagis compared to those who received placebo.

INDICATIONS AND USAGE: Synagis is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease. Safety and efficacy were established in infants with bronchopulmonary dysplasia (BPD), infants with a history of premature birth (≤35 weeks gestational age), and children with hemodynamically significant congenital heart disease (CHD) (see *CLINICAL STUDIES*).

CONTRAINDICATIONS: Synagis should not be used in pediatric patients with a history of a severe prior reaction to Synagis or other components of this product.

WARNINGS: Very rare cases of anaphylaxis (<1 case per 100,000 patients) have been reported following re-exposure to Synagis (see *ADVERSE REACTIONS, Post-Marketing Experience*). Severe acute hypersensitivity reactions, estimated to be rare, (<1 case per 1,000 patients) have also been reported on initial exposure or re-exposure to Synagis (see *ADVERSE REACTIONS, Post-Marketing Experience*). If a severe hypersensitivity reaction occurs, therapy with Synagis should be permanently discontinued. If milder hypersensitivity reactions occur, caution should be used on readministration of Synagis. **If anaphylaxis or severe allergic reactions occur, administer appropriate medications (e.g., epinephrine) and provide supportive care as required.**

PRECAUTIONS: General: Synagis is for intramuscular use only. As with any intramuscular injection, Synagis should be given with caution to patients with thrombocytopenia or any coagulation disorder.

The safety and efficacy of Synagis have not been demonstrated for treatment of established RSV disease.

The single-dose vial of Synagis does not contain a preservative. Administration of Synagis should occur immediately after dose withdrawal from the vial. The vial should not be re-entered. Discard any unused portion.

Drug Interactions: No formal drug-drug interaction studies were conducted. In Trial 1, the proportions of patients in the placebo and Synagis groups who received routine childhood vaccines, influenza vaccine, bronchodilators or corticosteroids were similar and no incremental increase in adverse reactions was observed among patients receiving these agents.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenesis, mutagenesis and reproductive toxicity studies have not been performed.

Pregnancy: Pregnancy Category C: Synagis is not indicated for adult usage and animal reproduction studies have not been conducted. It is also not known whether Synagis can cause fetal harm when administered to a pregnant woman or could affect reproductive capacity.

ADVERSE REACTIONS: The most serious adverse reactions occurring with Synagis treatment are anaphylaxis and other acute hypersensitivity reactions (see *WARNINGS*). The adverse reactions most commonly observed in Synagis-treated patients were upper respiratory tract infection, otitis media, fever, rhinitis, rash, diarrhea, cough, vomiting, gastroenteritis, and wheezing. Upper respiratory tract infection, otitis media, fever, and rhinitis occurred at a rate of 1% or greater in the Synagis group compared to placebo (Table 2).

Because clinical trials are conducted under widely varying conditions, adverse event rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The adverse reaction information does, however, provide a basis for identifying the adverse events that appear to be related to drug use and a basis for approximating rates.

The data described reflect Synagis exposure for 1,641 pediatric patients of age 3 days to 24.1 months in Trials 1 and 2. Among these patients, 496 had bronchopulmonary dysplasia, 506 were premature birth infants less than 6 months of age, and 639 had congenital heart disease. Adverse events observed in the 153 patient crossover study comparing the liquid and lyophilized formulations were similar between the two formulations, and similar to the adverse events observed with Synagis in Trials 1 and 2.

Table 2 - Adverse Events Occurring at a Rate of 1% or Greater More Frequently in Patients' Receiving Synagis

Event	Synagis (n=1641) n (%)	Placebo (n=1148) n (%)
Upper respiratory infection	830 (50.6)	544 (47.4)
Otitis media	597 (36.4)	397 (34.6)
Fever	446 (27.1)	289 (25.2)
Rhinitis	439 (26.8)	282 (24.6)
Hernia	68 (4.1)	30 (2.6)
SGOT Increase	49 (3.0)	20 (1.7)

[1]Cyanosis (Synagis [9.1%]/placebo [6.9%]) and arrhythmia (Synagis [3.1%]/placebo [1.7%]) were reported during Trial 2 in CHD patients.

Immunogenicity

In Trial 1, the incidence of anti-Synagis antibody following the fourth injection was 1.1% in the placebo group and 0.7% in the Synagis group. In pediatric patients receiving Synagis for a second season, one of the fifty-six patients had transient, low titer reactivity. This reactivity was not associated with adverse events or alteration in serum concentrations. Immunogenicity was not assessed in Trial 2.

These data reflect the percentage of patients whose test results were considered positive for antibodies to Synagis in an ELISA assay, and are highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody positivity in an assay may be influenced by several factors including sample handling, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to Synagis with the incidence of antibodies to other products may be misleading.

With any monoclonal antibody, the possibility exists that a liquid solution may be more immunogenic than a lyophilized formulation. The relative immunogenicity rates between the lyophilized formulation, used in Trials 1 and 2 above, and the liquid solution have not yet been established.

Post-Marketing Experience

The following adverse reactions have been identified and reported during post-approval use of Synagis. Because the reports of these reactions are voluntary and the population is of uncertain size, it is not always possible to reliably estimate the frequency of the reaction or establish a causal relationship to drug exposure.

Rare severe acute hypersensitivity reactions (<1 case per 1,000 patients) have been reported on initial or subsequent exposure. Very rare cases of anaphylaxis (<1 case per 100,000 patients) have also been reported following re-exposure (see *WARNINGS*). None of the reported hypersensitivity reactions were fatal. Hypersensitivity reactions may include dyspnea, cyanosis, respiratory failure, urticaria, pruritus, angioedema, hypotonia and unresponsiveness. The relationship between these reactions and the development of antibodies to Synagis is unknown.

Limited information from post-marketing reports suggests that, within a single RSV season, adverse events after a sixth or greater dose of Synagis are similar in character and frequency to those after the initial five doses.

OVERDOSAGE: No data from clinical studies are available on overdosage. No toxicity was observed in rabbits administered a single intramuscular or subcutaneous injection of Synagis at a dose of 50 mg/kg.

DOSAGE AND ADMINISTRATION: The recommended dose of Synagis is 15 mg/kg of body weight. Patients, including those who develop an RSV infection, should continue to receive monthly doses throughout the RSV season. The first dose should be administered prior to commencement of the RSV season. In the northern hemisphere, the RSV season typically commences in November and lasts through April, but it may begin earlier or persist later in certain communities.

Synagis serum levels are decreased after cardio-pulmonary bypass (see *CLINICAL PHARMACOLOGY*). Patients undergoing cardio-pulmonary bypass should receive a dose of Synagis as soon as possible after the cardio-pulmonary bypass procedure (even if sooner than a month from the previous dose). Thereafter, doses should be administered monthly.

Synagis should be administered in a dose of 15 mg/kg intramuscularly using aseptic technique, preferably in the anterolateral aspect of the thigh. The gluteal muscle should not be used routinely as an injection site because of the risk of damage to the sciatic nerve. The dose per month = patient weight (kg) x 15 mg/kg ÷ 100 mg/mL of Synagis. Injection volumes over 1 mL should be given as a divided dose.

Administration of Synagis

- **DO NOT DILUTE THE PRODUCT**
- **DO NOT SHAKE OR VIGOROUSLY AGITATE THE VIAL**
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not use any vials exhibiting particulate matter or discoloration.
- Using aseptic techniques, attach a sterile needle to a sterile syringe. Remove the flip top from the Synagis vial, and wipe the rubber stopper with a disinfectant (e.g., 70% isopropyl alcohol). Insert the needle into the vial, and withdraw into the syringe an appropriate volume of solution. Administer immediately after drawing the dose into the syringe.
- Synagis is supplied as a single-dose vial and does not contain preservatives. Do not re-enter the vial after withdrawal of drug; discard unused portion. Only administer one dose per vial.
- To prevent the transmission of hepatitis viruses or other infectious agents from one person to another, sterile disposable syringes and needles should be used. DO NOT reuse syringes and needles.

HOW SUPPLIED: Synagis is supplied in single-dose vials as a preservative-free, sterile liquid solution at 100 mg/mL for IM injection.

50 mg vial NDC 60574-4114-1
The 50 mg vial contains 50 mg Synagis in 0.5 mL.

100 mg vial NDC 60574-4113-1
The 100 mg vial contains 100 mg Synagis in 1 mL.

There is no latex in the rubber stopper used for sealing vials of Synagis. Upon receipt and until use, Synagis should be stored between 2°C and 8°C (35.6°F and 46.4°F) in its original container. DO NOT freeze. DO NOT use beyond the expiration date.

REFERENCES:

1. Press E, and Hogg N. The Amino Acid Sequences of the Fd Fragments of Two Human Gamma-1 Heavy Chains. Biochem. J. 1970; 117:641-660.
2. Takahashi N, Noma T, and Honjo T. Rearranged Immunoglobulin Heavy Chain Variable Region (V_H) Pseudogene that Deletes the Second Complementarity-Determining Region. Proc. Nat. Acad. Sci. USA 1984; 81:5194-5198.
3. Bentley D, and Rabbitts T. Human Immunoglobulin Variable Region Genes - DNA Sequences of Two Vκ Genes and a Pseudogene. Nature 1980; 288:730-733.
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5. Johnson S, Oliver C, Prince GA, et al. Development of a Humanized Monoclonal Antibody (MEDI-493) with Potent In Vitro and In Vivo Activity Against Respiratory Syncytial Virus. J. Infect. Dis. 1997; 176:1215-1224.
6. Malley R, DeVincenzo J, Ramilo O, et al. Reduction of Respiratory Syncytial Virus (RSV) in Tracheal Aspirates in Intubated Infants by Use of Humanized Monoclonal Antibody to RSV F Protein. J. Infect. Dis. 1998; 178:1555-1561.
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MedImmune

Manufactured by:

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