HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use VARIZIG® safely and effectively. See full prescribing information for VARIZIG.

VARIZIG® [Varicella Zoster Immune Globulin (Human)]
for intramuscular administration only.
Lyophilized Powder for Solution for Injection

Initial U.S. Approval: TBD

----------INDICATIONS AND USAGE----------
VARIZIG is a Varicella Zoster Immune Globulin (Human) indicated for post-exposure prophylaxis in high risk individuals (1). High risk groups include:

- immunocompromised children and adults,
- newborns of mothers with varicella shortly before or after delivery,
- premature infants,
- infants less than one year of age,
- adults without evidence of immunity,
- pregnant women.

VARIZIG administration is intended to reduce the severity of varicella.

----------DOSAGE AND ADMINISTRATION----------
Intramuscular use only.

Dosing of VARIZIG is based on body weight. Administer a single dose of VARIZIG intramuscularly as recommended in the following table (2.1):

Weight of Patient (kg)	Dose (IU)	Number of Vials
≤2.0	62.5	0.5
2.1–10.0	125	1
10.1–20.0	250	2
20.1–30.0	375	3
30.1–40.0	500	4
>40.1	625	5

Reconstitute prior to administration with the supplied Sterile Diluent only. Discard the remaining sterile diluents (2.2).
The intramuscular dose should be divided and administered in two sites, dependent on patient size. Do not exceed 3 mL per injection site. (2.3).

----------DOSAGE FORMS AND STRENGTHS----------
VARIZIG is supplied as a lyophilized powder for solution for intramuscular injection and is available in a single-use vial of 125 IU. VARIZIG is accompanied by a vial of 8.5 mL of Sterile Diluent used for reconstitution. Each vial of VARIZIG is reconstituted with 1.25 mL of Sterile Diluent (3).

----------CONTRAINDICATIONS----------

- History of anaphylactic or severe systemic reactions to human globulins (4).
- IgA-deficient patients with antibodies against IgA and a history of hypersensitivity (4).

----------WARNINGS AND PRECAUTIONS----------

- Thrombotic events (5.1)
- Coagulation disorders (5.2)
- Hypersensitivity (5.3)
- Transmissible infectious agents (5.4)

----------ADVERSE REACTIONS----------
Most common adverse reactions from clinical trials are pain at the injection site (2%) and headache (2%) (6).

To report SUSPECTED ADVERSE REACTIONS, contact Cangene Corporation at 1-800-768-2304 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------

- Efficacy of live attenuated virus vaccines may be impaired by immune globulin administration; revaccination may be necessary (7).

----------USE IN SPECIFIC POPULATIONS----------

- Pregnancy: Use only if clearly needed (8.1)
- Nursing Mothers: Caution should be exercised (8.3)

See 17 for PATIENT COUNSELING INFORMATION

Revised: [12/2012]

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed

1 INDICATIONS AND USAGE

VARIZIG® [Varicella Zoster Immune Globulin (Human)] is indicated for post-exposure prophylaxis of varicella in high risk individuals. High risk groups include:

- immunocompromised children and adults,
- newborns of mothers with varicella shortly before or after delivery,
- premature infants,
- neonates and infants less than one year of age,
- adults without evidence of immunity,
- pregnant women.

VARIZIG administration is intended to reduce the severity of varicella.

Administer VARIZIG as soon as possible following varicella zoster virus (VZV) exposure, ideally within 96 hours for greatest effectiveness.

- There is no convincing evidence that VARIZIG reduces the incidence of chickenpox infection after exposure to VZV.
- There is no convincing evidence that established infections with VZV can be modified by VARIZIG administration.
- There is no indication for the prophylactic use of VARIZIG in immunodeficient children or adults when there is a past history of varicella, unless the patient is undergoing bone marrow transplantation.

2 DOSAGE AND ADMINISTRATION

For intramuscular use only.

2.1 Dosage

Dosing of VARIZIG is based on body weight. Administer a single dose of VARIZIG intramuscularly as recommended in Table 1.

The minimum dose is 62.5 International Units (IU) for small infants under two kilograms body weight; the maximum dose of 625 IU should be administered for all patients greater than 40 kilograms in weight.

Table 1 VARIZIG Dose and Volume of Administration

Weight of Patient		VARIZIG Dose		Volume to Administer* (milliliters)
Kilograms	**Pounds**	**IU**	**Number of Vials**	
≤2.0	≤4.4	62.5	0.5	0.6
2.1–10.0	4.5–22.0	125	1	1.2
10.1–20.0	22.1–44.0	250	2	2.4
20.1–30.0	44.1–66.0	375	3	3.6
30.1–40.0	66.1–88.0	500	4	4.8
≥40.1	≥88.1	625	5	6.0

*Volume of VARIZIG to be administered after reconstitution.

Consider a second full dose of VARIZIG for high risk patients who have additional exposures to varicella greater than three weeks after initial VARIZIG administration.

2.2 Reconstitution

Reconstitute VARIZIG according to Table 2. Only use the accompanying Sterile Diluent with aseptic technique throughout. Reconstitute shortly before use.

Table 2 Recommendations for Reconstitution of VARIZIG

Route of Administration	Number of VARIZIG Vials	Volume of Sterile Diluent	Concentration of Reconstituted VARIZIG
Intramuscular	1 vial (125 IU)	1.25 milliliters	100 IU/milliliter

To reconstitute:

1. Remove caps from the Sterile Diluent and VARIZIG vials.
2. Wipe exposed central portion of each rubber stopper with suitable disinfectant.
3. Withdraw 1.25 milliliter of the Sterile Diluent using a suitable syringe and needle.
4. Inject diluent slowly into the VARIZIG vial at an angle so that the liquid is directed onto the inside glass wall of the vial containing the freeze-dried pellet.
5. Wet pellet by gently tilting and inverting the vial. Avoid frothing. Gently swirl upright vial until dissolved (less than ten minutes). Do not shake.

- Inspect VARIZIG visually for particulate matter and discoloration prior to administration.
- Do not use if turbid and/or discoloration is observed.
- Reconstituted product can be stored for up to 12 hours at 2 to 8°C (36 to 46ºF) prior to use.
- Do not freeze. Solutions that have been frozen should not be used.

VARIZIG is for single use only. Partially used vials, including the remaining Sterile Diluent, should be discarded.

2.3 Administration

For intramuscular use only.

Divide the intramuscular dose and administer in two or more injection sites, depending on patient size. Do not exceed 3 milliliters per injection site.

Inject into the deltoid muscle or the anterolateral aspects of the upper thigh. Due to the risk of sciatic nerve injury, do not use the gluteal region as a routine injection site. If the gluteal region is used, only use the upper, outer quadrant.

To prevent the transmission of infectious agents from one person to another, use a new disposable sterile syringe and needle for each individual patient.

3 DOSAGE FORMS AND STRENGTHS

VARIZIG is supplied as a sterile lyophilized powder for solution for intramuscular injection and is available in a single-use vial of 125 IU. VARIZIG is accompanied by a vial containing 8.5 milliliters of Sterile Diluent for reconstitution. Each 125 IU vial of VARIZIG contains less than 250 milligrams of total protein, mostly human immunoglobulin G (IgG). VARIZIG contains no preservative and is intended for single use only. VARIZIG does not contain mercury.

4 CONTRAINDICATIONS

- Individuals known to have anaphylactic or severe systemic (hypersensitivity) reactions to human immune globulin preparations should not receive VARIZIG.
- IgA-deficient patients with antibodies against IgA and a history of hypersensitivity may have an anaphylactoid reaction.
- VARIZIG contains less than 40 micrograms per milliliter of IgA.

5 WARNINGS AND PRECAUTIONS

5.1 Thrombotic Events

Thrombotic events may occur during or following treatment with immune globulin products (1, 2, 3). Patients at risk include those with a history of atherosclerosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, coagulation disorders, prolonged periods of immobilization, and/or known/suspected hyperviscosity. Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity including those with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides), or monoclonal gammopathies.

5.2 Coagulation Disorders

Administer VARIZIG intramuscularly only. In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, only administer VARIZIG if the expected benefits outweigh the potential risks.

5.3 Hypersensitivity

Severe hypersensitivity reactions may occur following VARIZIG administration. Administer VARIZIG in a setting with appropriate equipment, medication and personnel trained in the management of hypersensitivity, anaphylaxis and shock. In the case of hypersensitivity, discontinue administration of VARIZIG immediately and provide appropriate treatment.

VARIZIG contains trace amounts of IgA (less than 40 micrograms per milliliter). Patients with known antibodies to IgA have a greater risk of severe hypersensitivity and anaphylactic reactions. VARIZIG is contraindicated in IgA deficient patients with antibodies against IgA and history of hypersensitivity reactions [see 4 *CONTRAINDICATIONS*].

5.4 Transmissible Infectious Agents

Because VARIZIG is made from human plasma, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. The plasma donors are screened for the presence of certain infectious agents and the manufacturing process for VARIZIG includes measures to inactivate and remove certain viruses [see *11 DESCRIPTION*]. Despite these measures, products derived from human plasma can still potentially transmit diseases. No cases of transmission of viral diseases, vCJD or CJD have been associated with the use of VARIZIG.

Report all infections thought by a physician to have been transmitted by VARIZIG to Cangene Corporation at 1-800-768-2304. Discuss the risks and benefits of this product with the patient before administering it to the patient [see *17 PATIENT COUNSELING INFORMATION*].

6 ADVERSE REACTIONS

The most common adverse drug reactions observed in clinical trials for all subjects and patients are the following:

- injection site pain (2%)
- headache (2%).

Less common adverse drug reactions reported include the following:

- chills,
- fatigue,
- rash and
- nausea.

The following serious adverse reaction is described elsewhere [5 *WARNINGS AND PRECAUTIONS, 6.1 Clinical Trial Experience*]:

- thrombosis.

6.1 Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction 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.

Three hundred and seventy seven high risk individuals received VARIZIG intramuscularly in two clinical trials which included pregnant women, infants and immunocompromised pediatric and adult patients. The highest incidence of adverse reactions occurred in pregnant women (n=90), including injection site pain (9%), headache (4%), chills (2%) and fatigue (2%). All other adverse reactions occurred in 1% or less of clinical trial subjects within each high risk group. A single incidence of serum sickness (approximately one in 400 patients treated with VARIZIG) was observed in an immunocompromised adolescent patient.

There were six reported adverse events related to the coagulation system (one deep vein thrombosis) in 372 subjects in the open-label, Expanded Access Protocol (EAP); the study was not designed to differentiate between adverse events attributed to the underlying medical condition and adverse reactions to VARIZIG.

7 DRUG INTERACTIONS

The passive transfer of antibodies with immune globulin administration may impair the efficacy of live attenuated virus vaccines such as measles, rubella, mumps and varicella. Defer vaccination with live virus vaccines until approximately three months after VARIZIG administration. Inform the immunizing physician of recent therapy with VARIZIG so that appropriate measures can be taken [see *17 PATIENT COUNSELING INFORMATION*].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy category C. Animal reproduction studies have not been conducted with VARIZIG. It also is not known whether VARIZIG can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. VARIZIG should be given to a pregnant woman only if clearly needed.

8.3 Nursing Mothers

It is not known whether VARIZIG is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when VARIZIG is administered to a nursing mother.

8.4 Pediatric Use

The dosing recommendations in the treatment of pediatric patients are by body weight [see 2 *DOSAGE AND ADMINISTRATION*].

The safety and effectiveness of VARIZIG have been evaluated for post-exposure prophylaxis in the VARIZIG expanded access clinical trial in 265 pediatric patients, including immunocompromised pediatric patients:

- 70 preterm newborns and infants
- 38 term newborns
- 28 infants and toddlers
- 99 children and
- 30 adolescents.

In the EAP, follow up data were available for 81 VARIZIG treatments in 78 infants (including newborns, pre-term infants, and infants <1 year old). Two severe infections were reported, with pox count >100. One of these patients also developed probable varicella encephalitis.

8.5 Geriatric Use

Clinical studies of VARIZIG administered intramuscularly for post-exposure prophylaxis did not include sufficient numbers of geriatric subjects (aged 65 and over) to determine whether they respond differently from younger subjects.

Use caution when administering VARIZIG to patients age 65 and over who are judged to be at increased risk of thrombotic events [see 5 *WARNINGS AND PRECAUTIONS*]. Do not exceed recommended doses and administer VARIZIG intramuscularly only.

8.6 Immunocompromised Patients

In the EAP, eight immunocompromised subjects developed clinical varicella, and none developed varicella pneumonitis; however five are reported to have received concomitant acyclovir.

10 OVERDOSAGE

Manifestations of an overdose of VARIZIG administered intramuscularly are expected to be pain and tenderness at the injection site.

11 DESCRIPTION

VARIZIG [Varicella Zoster Immune Globulin (Human)] is a solvent/detergent-treated sterile lyophilized preparation of purified human immune globulin G (IgG) containing antibodies to varicella zoster virus (anti-VZV). VZV is the causative agent of chickenpox. VARIZIG is prepared from plasma donated by healthy, screened donors with high titers of antibodies to VZV, which is purified by an anion-exchange column chromatography manufacturing

method. This donor selection process includes donors with high anti-VZV titers due to recent natural infection by VZV, or due to recurrent zoster infection (shingles).

VARIZIG is supplied as a kit containing a single use vial of VARIZIG (lyophilized powder for solution for intramuscular injection with a potency of 125 IU) and a vial of 8.5 milliliters Sterile Diluent, which is used for reconstitution of the product prior to administration. VARIZIG is intended for single use and should be administered intramuscularly [see 2 *DOSAGE AND ADMINISTRATION*].

The product potency is expressed in IU by comparison to the World Health Organization (WHO) international reference preparation for anti-VZV immune globulin. Each vial contains 125 IU of anti-VZV. The lyophilized VARIZIG is formulated as 0.04 M sodium chloride, 0.1 M glycine and 0.01% polysorbate 80. The accompanying Sterile Diluent contains 0.8% sodium chloride and 10 mM sodium phosphate. The reconstituted VARIZIG has a pH of 7 and contains no preservative.

VARIZIG has not been tested for the presence of anti-Protein S antibodies that have been reported to arise transiently after VZV infection (4); however, it is assumed that the requirement that donors be healthy will alleviate this concern.

The source plasma used in the manufacture of this product was tested by FDA licensed nucleic acid testing (NAT) for human immunodeficiency virus-1 (HIV-1), hepatitis B virus (HBV) and hepatitis C virus (HCV) and found to be negative. Plasma also was tested by in-process NAT for hepatitis A virus (HAV) and parvovirus B19 (B19) via minipool testing; the limit for B19 in the manufacturing pool is set not to exceed 10^4 IU of B19 DNA per milliliter.

The manufacturing process contains two steps implemented specifically for virus clearance. The solvent/detergent step (using tri-n-butyl phosphate and Triton X-100) is effective in the inactivation of enveloped viruses, such as HBV, HCV and HIV-1. Virus filtration, using a Planova 20N virus filter, is effective for the removal of viruses based on their size, including some non-enveloped viruses. These two viral clearance steps are designed to increase product safety by reducing the risk of transmission of enveloped and non-enveloped viruses. In addition to these two specific steps, the process step of anion-exchange chromatography was identified as contributing to the overall viral clearance capacity for small non-enveloped viruses.

The inactivation and reduction of known enveloped and non-enveloped model viruses were validated in laboratory studies as summarized in Table 3. The viruses employed for spiking studies were selected to represent those viruses that are potential contaminants in the product, and to represent a wide range of physiochemical properties in order to challenge the manufacturing process's ability for viral clearance in general.

Table 3 Virus Reduction Values (Log_{10}) Obtained through Validation Studies

Enveloped	**Enveloped**			**Non-Enveloped**			
Genome	**RNA**		**DNA**	**RNA**		**DNA**	
Virus	**HIV-1**	**BVDV**	**PRV**	**HAV**	**EMC**	**MMV**	**PPV**
Family	retro	flavi	herpes	picorna		parvo	
Size (nm)	80–100	50–70	120–200	25–30	30	20–25	18–24
Anion Exchange Chromatography (partitioning)	Not evaluated			2.3	n.e.	3.4	n.e.
20N Filtration (size exclusion)	≥4.7	≥3.5	≥5.6*	n.e.	4.8	n.e.	4.1
Solvent/Detergent (inactivation)	≥4.7	≥7.3	≥5.5	Not evaluated			
Total Reduction (log10)	**≥9.4**	**≥10.8**	**≥11.1**	**2.3**	**4.8**	**3.4**	**4.1**

*The PRV was retained by the 0.1 μm pre-filter during the virus validation. Since manufacturing employs a 0.1 μm pre-filter before the 20N filter, the claim of ≥5.6 reduction is considered applicable.

Abbreviations:

HIV-1: human immunodeficiency virus-1; relevant virus for human immunodeficiency virus-1 and model for HIV-2

BVDV: bovine viral diarrhea virus; model virus for hepatitis C virus (HCV) and West Nile virus (WNV)

PRV: pseudorabies virus; model for large enveloped DNA viruses, including herpes

HAV: human hepatitis A virus; relevant virus for HAV and model for small non-enveloped viruses in general

EMC: encephalomyocarditis virus; model for HAV and for small non-enveloped viruses in general

MMV: murine minute virus; model for human parvovirus B19 and for small non-enveloped viruses in general

n.e.: not evaluated

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

VARIZIG provides passive immunization for non-immune individuals exposed to VZV, reducing the severity of varicella infections (5).

12.3 Pharmacokinetics

In a comparative pharmacokinetic clinical trial, 35 volunteers were administered an intramuscular dose of 12.5 IU/kg of VARIZIG (n=18) or the comparator product VZIG™ (n=17). The dose of 12.5 IU/kg of VZIG or VARIZIG given to the subjects was based on the assumption that the potency was similar for both products. For the bioequivalence analysis, a potency correction factor was applied (concentrations of VARIZIG were multiplied by 2.3) to account for higher measured potency of the comparator product. The mean peak concentration (C_{max}) of varicella antibodies occurred within five days of administration for

both products (Table 4). In the trial, baseline levels of anti-VZV antibodies ranged from 0 to 720 mIU/mL, therefore baseline levels were taken into account for pharmacokinetic calculations, to better represent the indicated population. After potency correction, baseline correction, and exclusion of subjects with baseline values of anti-VZV antibody levels of >200 mIU/mL, the two products were pharmacokinetically comparable.

Table 4 Pharmacokinetic Comparison of VARIZIG and VZIG

PK Parameters*	VARIZIG	VZIG	Ratio 90% Confidence Interval
AUC_{0-28} (mIUxDay/mL)	2472 ± 970	2347 ± 535	84.1–124.6
AUC_{0-84} (mIUxDay/mL)	4087 ± 1620	3916 ± 964	82.0–125.6
C_{max} (mIU/mL)	136 ± 66	138 ± 22	76.5–112.8
T_{max} (Days)	4.5 ± 2.8	3.3 ± 1.5	Not applicable
$t_{1/2}$** (Days)	26.2 ± 4.6	23.1 ± 8.6	Not applicable
CL/F (mL/Day)	0.204 ± 0.045	0.199 ± 0.087	Not applicable

* Potency and subgroup analysis were implemented for pharmacokinetic calculations. Study subjects with elevated baseline anti-VZV levels (>200 mIU/mL) from both treatment groups were excluded from pharmacokinetic calculations.

** The half-life is expected to vary from patient to patient.

14 CLINICAL STUDIES

14.1 Pregnant Women Exposed to Varicella Zoster Virus

A randomized, open-label, multicenter, active controlled clinical trial was conducted in 60 pregnant women without immunity to VZV as confirmed by a latex agglutination test. Patients were stratified on the basis of time from first exposure to varicella as follows:

- one to four days post-exposure and
- five to 14 days post-exposure.

The women were randomized into one of three study arms as follows:

- a single intravenous dose of 125 IU/10 kg body weight to a maximum dose of 625 IU of VARIZIG
- a single intramuscular dose of 125 IU/10 kg body weight to a maximum dose of 625 IU of VARIZIG, or
- a single intramuscular dose of 125 IU/10 kg body weight to a maximum dose of 625 IU of VZIG (licensed comparator product).

Patients were followed for 42 days.

Incidence of clinical varicella was similar across all treatment groups with an overall incidence of 33%; however, in the subset of 28 subjects with more than 24 hours exposure to varicella, the incidence of clinical varicella in the combined treatment groups was 64%.

Mean weighted constitutional illness scores (CIS) (6) were similar across all groups and none of the subjects had serious complications of varicella. The small number of subjects in each treatment stratum and the lack of agreed upon pre-specified hypothesis testing precluded formal statistical comparisons between groups.

15 REFERENCES

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2. Woodruff RK, Grigg AP, Firkin FC, Smith IL. Fatal thrombotic events during treatment of autoimmune thrombocytopenia with intravenous immunoglobulin in elderly patients. Lancet. 1986; 2:217-8.
3. Wolberg AS, Kon RH, Monroe DM Hoffman M. Coagulation factor XI is a contaminant in intravenous immunoglobulin preparations. Am J Hematol. 2000; 65:30-4.
4. Josephson C, Nuss R, Jacobson L, Hacker MR, Murphy J, Weinberg A et al. The Varicella-Autoantibody Syndrome. Pediatr Res. 2001; 50:345-52.
5. CDC. Prevention of varicella. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR. 2007; 56(No. RR-4):1-30.
6. Koren G, Money D, Boucher M, Aoki F, Petric M, Innocencion G et al. Serum concentrations, efficacy, and safety of a new, intravenously administered varicella zoster immune globulin in pregnant women. J Clin Pharmacol. 2002; 42(3):267-74.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

NDC XXXXX-XXXX-X: VARIZIG [Varicella Zoster Immune Globulin (Human)] is supplied as a kit in a carton box containing approximately 125 IU of anti-VZV supplied freeze-dried in a 6 mL type 1 glass tubing vial fitted with a 20 mm rubber lyophilization stopper and a 20 mm flip-off seal, one single dose vial of Sterile Diluent, non-pyrogenic for reconstitution of VARIZIG and a package insert.

16.2 Storage and Handling

Store VARIZIG at 2 to 8°C (36 to 46°F). Do not freeze. Do not use after expiration date. Use the product within 12 hours of reconstitution if stored at 2 to 8°C.

17 PATIENT COUNSELING INFORMATION

Inform patients of the following:

- VARIZIG in intended to reduce the severity of chickenpox infections. Please see your doctor if you develop the signs and symptoms of varicella.
- VARIZIG is prepared from human plasma and therefore, may contain infectious agents such as viruses that can cause disease.
- The risk that products derived from human plasma will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and/or removing certain viruses during manufacturing.
- Despite these measures, products derived from human plasma can still potentially transmit disease.
- There is also the possibility that unknown infectious agents may be present in such products.

Tell patients that persons known to have severe, potentially life-threatening reactions to human immune globulin products should not receive VARIZIG or any other immune globulin products unless the risk has been justified.

Tell patients that persons who are deficient in IgA may have the potential for developing anti-IgA antibodies and have severe potentially life threatening allergic reactions.

- In the case of allergic or anaphylactic reaction, administration should be stopped immediately.
- In the case of shock, the current medical standards for treatment of shock should be administered.

Inform patients that administration of immune globulin may interfere with the response to live virus vaccines (e.g. measles, mumps, rubella and varicella), and instruct them to notify their immunizing physician of recent therapy with VARIZIG.

Manufactured by:
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