pharmacokinetic p ofiles we e obtained f om healthy volunteers (N=12) and from patients w th diseases other than MS (N=142). In patients receiving single intravenous doses up to 2.0 mg, increases in serum concentrations were dose proportional. Mean serum clearance values ranged from 9 4 mL/min•kg^{-1} to 28 9 mL/min•kg^{-1} and we e independent of dose. Mean terminal elimination half-life values ranged from 8 0 minutes to 4 3 hours and mean steady-state volume of distribution values ranged from 0.25 L/kg to 2 88 L/kg. Three-times-a-week intravenous dosing for two weeks resulted in no accumulation of Interferon beta-1b in sera of patients. Pharmacokinetic parameters after single and multiple intravenous doses of Betaseron were comparable.

Following eve y other day subcutaneous administration of 0.25 mg Betaseron in healthy volunteers, biologic response marker levels (neopterin, β_2-mic oglobulin, MxA protein, and the immunosuppressive cytokine, IL-10) increased significantly above baseline six-twelve hours after the first Betaseron dose. Biologic response marker levels peaked between 40 and 124 hours and remained elevated above baseline throughout the seven-day (168-hour) study. The elationship between serum Interferon beta-1b levels or induced biologic response marker levels and the clinical effects of Interfe on beta-1b in multiple sclerosis is unknown.

CLINICAL STUDIES

The safety and efficacy of Betase on have been assessed in th ee multicenter trials. Study 1 evaluated Betaseron in relapsing-remitting MS (RRMS) patients and Studies 2 and 3 assessed Betaseron in secondary progressive MS (SPMS) patients.

The effectiveness of Betase on in elapsing- emitting MS (Study 1) was evaluated in a double blind, multiclinic, randomized, parallel, placebo cont olled clinical investigation of two years duration. The study enrolled MS patients, aged 18 to 50, who were ambulato y (EDSS of ≤ 5.5), exhibited a relapsing-remitting clinical course, met Poser's criteria[1] for clinically definite and/or laboratory supported definite MS and had experienced at least two exacerbations over two years preceding the trial without exacerbation in the preceding month. Patients who had eceived prior immunosuppressant therapy were excluded.

An exacerbation was defined as the appearance of a new clinical sign/symptom or the clinical worsening of a p evious sign/symptom (one that had been stable for at least 30 days) that persisted for a minimum of 24 hours.

Patients selected for study we e randomized to t eatment w th either placebo (N=123), 0.05 mg o Betase on (N=125), or 0 25 mg o Betase on (N=124) self-administered subcutaneously every other day. Outcome based on the 372 randomized patients was evaluated after two years.

Patients who required mo e than th ee 28-day courses of corticoste oids were removed from the study. Minor analgesics (acetaminophen, codeine), antidepressants, and oral baclofen were allowed ad libitum, but ch onic nonsteroidal anti-inflammatory drug (NSAID) use was not allowed.

The primary p otocol-defined outcome measures we e 1) frequency of exacerbations per patient and 2) proportion of exacerbation f ee patients. A number of seconda y clinical and magnetic resonance imaging (MRI) measures we e also employed. All patients underwent annual T2 MRI imaging and a subset of 52 patients at one site had MRIs performed every six weeks for assessment of new or expanding lesions.

The study esults are shown in **Table 1**.

TABLE 1
Two Year RRMS Study Results
Primary and Secondary Clinical Outcomes

Efficacy Parameters		Treatment Groups			Statistical Comparisons p-value		
Primary End Points		Placebo (N=123)	0 05 mg (N=125)	0 25 mg (N=124)	Placebo vs 0.05 mg	0 05 mg vs 0 25 mg	Placebo vs 0 25 mg
Annual exacerbation rate		1 31	1.14	0 90	0 005	0.113	**0 0001**
Proportion of exacerbation-free patients†		16%	18%	25%	0 609	0 288	**0.094**
Exacerbation f equency per patient	0†	20	22	29	0.151	0 077	**0.001**
	1	32	31	39			
	2	20	28	17			
	3	15	15	14			
	4	15	7	9			
	≥5	21	16	8			
Secondary Endpoints††							
Median number of months to first on-study exacerbation		5	6	9	0 299	0 097	**0.010**
Rate of moderate or severe exacerbations per year		0 47	0.29	0 23	0 020	0 257	**0.001**
Mean number of moderate or severe exacerbation days per patient		44.1	33 2	19 5	0 229	0 064	**0.001**
Mean change in EDSS sco e‡ at endpoint		0 21	0.21	-0 07	0 995	0.108	**0.144**
Mean change in Scripps score‡‡ at endpoint		-0 53	-0.50	0 66	0 641	0 051	**0.126**
Median duration in days per exacerbation		36	33	35 5	ND	ND	**ND**
% change in mean MRI lesion area at endpoint		21 4%	9.8%	-0 9%	0 015	0 019	**0.0001**

ND Not done
† 14 exacerbation free patients (0 from placebo, six f om 0 05 mg, and eight from 0 25 mg) dropped out of the study before completing six months of therapy. These patients are excluded from this analysis.
†† Sequelae and Functional Neu ologic Status, both equired by p otocol, were not analyzed individually but a e included as a function of the EDSS.
‡ EDSS sco es range from 1-10, with higher scores reflecting g eater disability
‡‡ Scripps neu ologic rating scores range f om 0-100, with smaller sco es reflecting g eater disability.

Of the 372 RRMS patients randomized, 72 (19%) failed to complete two full years on their assigned treatments.

Over the two-year period, the e we e 25 MS- elated hospitalizations in the 0 25 disease duration, clinical disease activity prior to study enrollment, MRI measu es at baseline and early changes in MRI following treatment were evaluated in order to interp et the discordant study esults. No demographic or disease- elated factors enabled identification of a patient subset where Betaseron t eatment was predictably associated w th delayed prog ession of disability.

In Studies 2 and 3, like Study 1, a statistically significant dec ease in the incidence of relapses associated with Betase on treatment was demonstrated. In Study 2, the mean annual relapse rates we e 0 42 and 0 63 in the Betase on and placebo g oups, respectively (p<0 001). In Study 3, the mean annual elapse rates were 0.16, 0 20, and 0 28, for the fixed dose, surface area-adjusted dose, and placebo groups, espectively (p<0.02).

MRI endpoints in both Study 2 and Study 3 showed lesser increases in T2 MRI lesion area and decreased number of active MRI lesions in patients in the Betase on groups. The exact elationship between MRI findings and the clinical status of patients is unknown. Changes in MRI findings often do not correlate w th changes in disability p ogression. The prognostic significance of the MRI findings in these studies is not known.

Safety and efficacy of t eatment w th Betaseron beyond th ee years are not known.

INDICATIONS AND USAGE

Betase on (Interferon beta-1b) is indicated for the treatment of relapsing forms of multiple scle osis to reduce the frequency of clinical exacerbations.

CONTRAINDICATIONS

Betase on is contraindicated in patients w th a history of hypersensitivity to natural or ecombinant interfe on beta, Albumin (Human), USP, or any other component of the formulation.

WARNINGS

Depression and Suicide

Betase on (Interferon beta-1b) should be used w th caution in patients with dep ession, a condition that is common in people w th multiple sclerosis. Depression and suicide have been reported to occur with inc eased f equency in patients eceiving interferon compounds, including Betase on. Patients treated w th Betase on should be advised to eport immediately any symptoms of dep ession and/or suicidal ideation to their p escribing physicians. If a patient develops depression, cessation of Betaseron therapy should be conside ed.

In the th ee randomized cont olled studies the e were three suicides and eight suicide attempts among the 1240 patients in the Betaseron treated g oups compared to one suicide and four suicide attempts among the 789 patients in the placebo g oups.

Injection Site Necrosis

Injection site necrosis (SN) has been reported in 5% of patients in cont olled clinical trials (see **ADVERSE REACTIONS**). Typically, injection site necrosis occurs w thin the first four months of therapy, a though post-marketing reports have been eceived of ISN occurring over one year after initiation of therapy. Necrosis may occur at a single or multiple injection sites. The necrotic lesions a e typically three cm or less in diameter, but larger a eas have been reported. Generally the nec osis has extended only to subcutaneous fat. However, there are also reports of necrosis extending to and including fascia overlying muscle. In some lesions whe e biopsy esults are available, vasculitis has been reported. For some lesions debridement and, inf equently, skin grafting have been requi ed.

As w th any open lesion, it is important to avoid infection and, if it occurs, to t eat the infection. Time to healing was varied depending on the severity of the necrosis at the time treatment was begun. In most cases healing was associated w th scarring.

Some patients have experienced healing of nec otic skin lesions while Betaseron therapy continued; others have not. Whether to discontinue therapy following a single site of necrosis is dependent on the extent of necrosis. For patients who continue therapy with Betase on after injection site nec osis has occur ed, Betase on should not be administe ed into the affected area until it is fully healed. If multiple lesions occur, therapy should be discontinued unti healing occurs.

Patient understanding and use of aseptic self-injection techniques and procedures should be periodically eevaluated, particularly if injection site necrosis has occurred.

Anaphylaxis

Anaphylaxis has been eported as a rare complication of Betaseron use. Other allergic reactions have included dyspnea, b onchospasm, tongue edema, skin rash and urticaria (see **ADVERSE REACTIONS**).

Albumin (Human), USP

This product contains albumin, a derivative of human blood. Based on effective donor sc eening and product manufacturing p ocesses, it carries an ext emely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

PRECAUTIONS

Information for Patients

All patients should be instructed to ca efully read the supplied Betaseron Medication Guide. Patients should be cautioned not to change the dose or schedule of administration without medical consultation.

Patients should be made aware that serious adverse eactions during the use of Betase on have been reported, including depression and suicidal ideation, injection site nec osis, and anaphylaxis (see **WARNINGS**). Patients should be advised of the symptoms of dep ession or suicidal ideation and be told to report them immediately to their physician. Patients should also be advised of the symptoms of allergic eactions and anaphylaxis.

Patients should be advised to p omptly eport any break in the skin, which may be associated with blue-black discoloration, swelling, or drainage of fluid from the injection site, prior to continuing their Betaseron therapy.

Patients should be informed that flu-like symptoms are common following initiation of therapy w th Betaseron. In the controlled clinical trials, antipyretics and analgesics were permitted for elief of these symptoms. In addition, gradual dose titration during initiation of Betase on t eatment may reduce flu-like symptoms (see **DOSAGE AND ADMINISTRATION**).

Female patients should be cautioned about the abortifacient potential of Betase on (see **PRECAUTIONS, Pregnancy - Teratogenic Effects**).

Instruction on Self-injection Technique and Procedures

Patients should be instructed in the use of aseptic technique when administering Betase on. App opriate instruction for reconstitution of Betaseron and self-injection should be provided, including ca eful review of the Betaseron Medication Guide. The first injection should be performed under the supervision of an app opriately qualified health care professional.

Patients should be cautioned against the e-use of needles or syringes and instructed in safe disposal p ocedu es. A puncture esistant container for disposal of used needles and syringes should be supplied to the patient along w th instructions for safe disposal of full containers.

Patients should be advised of the importance of rotating areas of injection with

Geriatric Use

Clinical studies o Betaseron did not include sufficient numbers of patients aged 65 and over to determine whether they respond diffe ently than younger patients.

ADVERSE REACTIONS

In all studies, the most serious adverse reactions w th Betase on were dep ession, suicidal ideation and injection site necrosis (see **WARNINGS**). The incidence of depression of any severity was approximately 34% in both Betase on-t eated patients and placebo-treated patients. Anaphylaxis and other alle gic reactions have been reported in patients using Betaseron (see **WARNINGS**). The most commonly reported adverse eactions were lymphopenia (lymphocytes<1500/mm^3), injection site reaction, asthenia, flu-like symptom complex, headache, and pain. The most frequently reported adverse eactions esulting in clinical intervention (e g., discontinuation of Betase on, adjustment in dosage, or the need for concomitant medication to t eat an adverse eaction symptom) were depression, flu-like symptom complex, injection site eactions, leukopenia, increased liver enzymes, asthenia, hypertonia, and myasthenia.

Because clinical trials a e conducted under widely varying conditions and over varying lengths of time, adverse reaction rates observed in the clinical trials of Betase on cannot be di ectly compared to rates in clinical trials of other drugs, and may not eflect the rates observed in practice. The adverse reaction information from clinical trials does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates.

The data described below eflect exposu e to Betaseron in the three placebo controlled trials of 1115 patients w th MS treated with 0 25 mg or 0.16 mg/m^2, including 1041 exposed for g eater than one year. The population encompassed an age range from 18 - 65 years. Sixty-five percent (65%) of the patients were female. The percentages of Caucasian, Black, Asian, and Hispanic patients were 94 0%, 4.3%, 0 2%, and 0 8%, respectively.

The safety p ofiles for Betaseron-treated patients with SPMS and RRMS were similar. Clinical experience with Betase on in other populations (patients with cancer, HIV positive patients, etc.) provides additional data regarding adverse reactions; however, experience in non-MS populations may not be fully applicable to the MS population.

Injection Site Reactions

In three controlled clinical trials, injection site eactions occur ed in 86% of patients receiving Betase on w th injection site necrosis in 5%. Inflammation (53%), pain (18%), hypersensitivity (3%), necrosis (5%), mass (2%), edema (3%) and non-specific eactions we e significantly associated w th Betaseron t eatment (see **WARNINGS** and **PRECAUTIONS**). The incidence of injection site eactions tended to decrease over time, with approximately 76% of patients experiencing the event during the first three months of treatment, compared to app oximately 45% at the end of the studies.

Flu-Like Symptom Complex

The rate of flu-like symptom complex was app oximately 60% in the three controlled clinical trials. The incidence decreased over time, with only 10% of patients reporting flu-like symptom complex at the end of the studies. For patients who experienced a flu-like symptom complex in Study 1, the median duration was 7.5 days.

Laboratory Abnormalities

In the three clinical trials, leukopenia was reported in 18% and 5% of patients in Betase on- and placebo-treated groups, espectively. No patients were w thdrawn or dose reduced for neut openia in Study 1. Three pe cent (3%) of patients in Studies 2 and 3 experienced leukopenia and were dose- educed. Other laborato y abnormalities included SGPT greater than five times baseline value (10%), and SGOT g eater than five times baseline value (3%). In Study 1, two patients were dose reduced for increased liver enzymes; one continued on t eatment and one was ultimately w thdrawn. In Studies 2 and 3, 1 5% of Betase on patients we e dose-reduced or interrupted treatment for increased liver enzymes. Th ee (0 3%) patients we e withdrawn f om t eatment with Betase on for any laboratory abnormality including two (0 2%) patients following dose eduction (see **PRECAUTIONS, Laboratory Tests**).

Menstrual Irregularities

In the three clinical trials, 82 (14%) of the 577 p e-menopausal females treated w th Betase on and 74 (18%) of the 405 p e-menopausal females t eated with placebo reported menstrual diso ders. One event was reported as severe, all other eports we e mild to moderate severity. No patients w thd ew from the studies due to menstrual irregularities.

Table 2 enumerates adverse events and laboratory abnormalities that occur ed among all patients t eated w th 0.25 mg or 0.16 mg/m^2 Betase on every other day for periods of up to th ee years in the controlled trials at an incidence that was at least 2% mo e than that observed in the placebo patients.

Table 2
Adverse Reactions and Laboratory Abnormalities

Adverse Reaction	Placebo (n=789)	Betaseron (n=1115)
Body as a Whole		
Injection site reaction	29%	85%
Asthenia	54%	61%
Flu-like symptom complex	41%	60%
Headache	48%	57%
Pain	42%	51%
Fever	22%	36%
Chills	11%	25%
Abdominal pain	13%	19%
Chest pain	7%	11%
Malaise	4%	8%
Injection site nec osis	0%	5%
Cardiovascular System		
Peripheral edema	12%	15%
Vasodilation	6%	8%
Hypertension	4%	7%
Peripheral vascular disorder	4%	6%
Palpitation	2%	4%
Tachycardia	2%	4%
Digestive System		
Nausea	25%	27%
Constipation	18%	20%
Diar hea	16%	19%
Dyspepsia	12%	14%
Hemic and Lymphatic System		
Lymphocytes < 1500/mm^3	70%	88%
ANC < 1500/mm^3	5%	14%
WBC < 3000/mm^3	4%	14%

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REFERENCES
1. Poser CM, et
1983; 33(11): 14

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- **Depression.**

so it is best to take them at the same time each day, p eferably in the evening just before bedtime.

You may be started on a lower dose when you first start taking Betaseron. Your doctor will tell you what dose of Betase on to use, and that dose may change based on how your body responds. You should not change your dose w thout talking w th your doctor.

If you miss a dose, you should take your next dose as soon as you remember or a e able to take it. Your next injection should be taken about 48 hours (two days) after that dose. **Do not take Betaseron® on two consecutive days.** If you accidentally take more than your p escribed dose, or take it on two consecutive days, call your doctor right away.

You should always follow your doctor's instructions and advice about how to take this medication. If your doctor feels that you, or a family member or friend may give you the injections, then you and/or the other person should be trained by your doctor or healthcare provider in how to give an injection. Do not try to give yourself (or have another person give you) injections at home until you (or both of you) understand and are comfortable with how to prepare your dose and give the injection.

Always use a new, unopened, vial of Betaseron and syringe for each injection. Never reuse vials or syringes.

It is important that you change your injection site each time Betaseron is injected. This will lessen the chance of your having a serious skin eaction at the spot where you inject Betaseron. You should always avoid injecting Betase on into an area of skin that is sore, eddened, infected or otherwise damaged.

At the end of this leaflet there are detailed instructions on how to prepare and give an injection of Betase on. You should become familiar with these instructions and follow your doctor's o ders before injecting Betaseron.

What should I avoid while taking Betaseron?

- **Pregnancy.** You should avoid becoming pregnant while taking Betaseron until you have talked with your doctor. Betaseron can cause you to lose your baby (miscar y).
- **Breast feeding.** You should talk to your doctor if you are breast feeding an infant. It is not known if the interferon in Betase on can be passed to an infant in mother's milk, and it is not known whether the drug could harm the infant if it is passed to an infant.

What are the possible side effects of Betaseron?

- **Flu-like symptoms.** Most patients have flu-like symptoms (fever, chills, sweating, muscle aches and tiredness). For many patients, these symptoms will lessen or go away over time. You should talk to your doctor about whether you should take an over the counter medication for pain or fever reduction before or after taking your dose of Betaseron.
- **Skin reactions.** Soreness, redness, pain, bruising or swelling may occur at the place of injection. ***(see "What is the most important information I should know about Betaseron?")***.
- **Depression and anxiety.** Some patients taking interferons have become ve y depressed and/or anxious. There have been patients taking interferons who have had thoughts about killing themselves. If you feel sad or hopeless you should tell a friend or family member right away and call your doctor immediately. ***(see "What is the most important information I should know about Betaseron?")***.
- **Liver problems.** Your liver function may be affected. Symptoms of changes in your liver include yellowing of the skin and whites of the eyes and easy bruising.
- **Blood problems.** You may have a drop in the levels of infection-fighting white blood cells, red blood cells, or cells that help you form blood clots. If d ops in levels are severe, they can lessen your ability to fight infections, make you feel tired or sluggish or cause you to bruise or bleed easily.
- **Thyroid problems.** Your thyroid function may change. Symptoms of changes in the function of your thyroid include feeling cold or hot much of the time or change in your weight (gain or loss) without a change in your diet or amount of exercise you are getting.
- **Allergic reaction.** Some patients have had hives, rash, skin bumps or itching while they were taking Betase on. There is also a rare possibility that you can have a life-threatening allergic eaction. ***(see "What is the most important information I should know about Betaseron?").***

Whether you experience any of these side effects or not, you and your doctor should periodically talk about your general hea th. Your doctor may want to monitor you mo e closely and ask you to have blood tests done more frequently.

General Information About Prescription Medicines

Medicines a e sometimes p escribed for purposes other than those listed in a Medication Guide. This medication has been prescribed for your particular medical condition. Do not use it for another condition or give this drug to anyone else. If you have any questions you should speak w th your doctor or health care professional. You may also ask your doctor or pharmacist for a copy of the information provided to them with the product. Keep this and all drugs out of the reach of children.

Instructions for Preparing and Giving Yourself an Injection of Betaseron

1. Find a clean, flat working surface that is well-lit and collect all the supplies you will need to give yourself an injection. You will need:
   - One tray containing Betase on. Make su e the tray contains: A pre-filled diluent syringe
   - A vial o Betase on
   - Two (2) alcohol prep pads
   - A vial adapter w th a 27 gauge needle attached (in the blister pack)
   - A punctu e-resistant sealable container to dispose of used syringes/needles
2. Check the expiration date on the tray label to make su e that it has not expired. **Do not use it if the medication has expired.**
3. Wash your hands thoroughly w th soap and water.
4. Open the tray by peeling off the label and take out all the contents. Make sure the blister pack containing the vial adapter is sealed. Check to make su e the rubber cap on the diluent syringe is firmly attached.
5. Turn the tray over, place the Betaseron vial in the well (via holder) and place the p efilled diluent syringe in the U-shaped trough.

Reconstituting Betaseron

1. Remove the Betaseron vial from the well and take the cap off the vial.
2. Place the vial back into the via holder. Use an alcohol p ep pad to clean the top of the vial. Move the prep pad in one di ection. Leave the alcohol p ep pad on top of the vial until step 5.

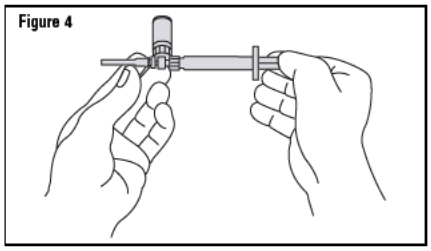
solution is clear and colorless and does not contain particles. If the mixture contains particles, or is discolo ed, do not use. Repeat the steps to p epare your dose using a new tray of Betase on, prefilled syringe, vial adapter and alcohol p ep pads. Contact Berlex at 1-800-788-1467 to obtain eplacement product.

Preparing the Injection

You have completed the steps to reconstitute your Betase on and a e ready for the injection. The injection should be given immediately after mixing and allowing any foam in the solution to settle. If you must delay giving yourself the injection, you may efrigerate the solution and use within th ee hours of reconstitution. Do not freeze.

1. Push the plunger in and hold it there; then turn the syringe assembly so that the vial is on top. (The syringe is horizontal.) **(Figure 4)**.

Figure 4



2. Slowly pull the plunger back to w thdraw the entire contents of the Betaseron vial into the syringe.

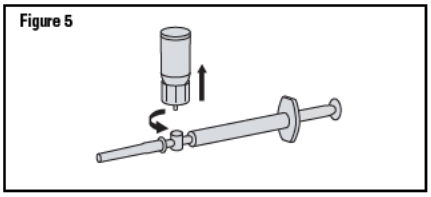
   NOTE: The syringe barrel is marked with numbers f om 0 25 to 1.0. If the solution in the vial cannot be drawn up to the 1 0 mark, disca d the vial and syringe and start over w th a new tray containing a Betaseron vial, prefilled diluent syringe, vial adapter and alcohol prep pads.

3. Turn the syringe assembly so that the needle end is pointing up. Remove any air bubbles by tapping the outer wall of the syringe with your fingers. Slowly push the plunger to the 1 mL mark on the syringe (or to the amount prescribed by your doctor).

   NOTE: If too much solution is pushed into the vial, repeat steps 1, 2, and 3.

4. Remove the vial adapter and the vial f om the syringe by twisting the vial adapter as shown in Figure 5. This will remove the vial adapter and the vial from the syringe, but will leave the needle on the syringe **(Figure 5)**.

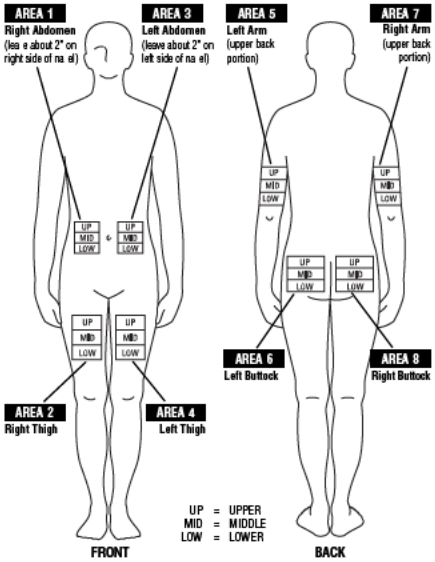
Figure 5



Picking an Injection Site

Betase on (Interfe on beta-1b) is injected under the skin and into the fat layer between the skin and the muscles (subcutaneous tissue). The best areas for injection a e where the skin is loose and soft and away from the joints, nerves, and bones. Do not use the a ea near your navel or waistline. If you are very thin, use only the thigh or outer surface of the arm for injection.

You should pick a diffe ent site each time you give yourself an injection. The diagrams show different areas for giving injections. You should not choose the same area for two injections in a row. Keeping a reco d of your injections will help make sure you otate your injection sites. You should decide whe e your injection will be given before you p epare your syringe for injection. If the e are any sites that are difficult for you to reach, you can ask someone who has been trained to give injections to help you.



Do not inject in a site whe e the skin is red, bruised, infected, or scabbed, has broken open, or has lumps, bumps, or pain. Tell your doctor or hea thcare provider if you find skin conditions like the ones mentioned here or any other unusual looking areas where you have been given injections.

Using a circular motion, and starting at the injection site and moving outwa d, clean the injection site w th an alcohol wipe. Let the skin area d y before you inject the Betase on.