

What Factor Am I Taking?

Sounds like a goofy question.....right? Of course you know what factor you are taking...or do you? Take this test and let's talk about it.....

1. The name of my factor is _____.
2. The manufacturer of my factor is _____.
3. The distributor of my factor is _____ (hint: The answer is not your homecare company, that's for sure!!)
4. The stabilizer for my factor is _____.
- 5 My factor contains, in the culture medium, (*circle only one*):
human protein, animal protein or neither.
6. Viral safety studies in humans have been conducted on my factor: yes OR no.
7. I am taking a (*circle only one*): first, second or third generation product.
8. I am taking a (*circle only one*): recombinant product or plasma-derived product.
9. My product is made with blood components (and that's for some recombinant products, as well, hmmmmmmmm.....)

Okay, are you confused yet? Don't feel like a dummy if you couldn't answer all of the questions OR if you didn't understand what the question was asking. You're not a dummy...you just have never seen or thought about the answers to those questions. The following chart, (provided by the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation) will give you the answer to those questions, specific to the factor that you are taking. You may be surprised by the information.

Products Licensed in the United States

Taken from MASAC Recommendation #151

* indicates that this information was not provided by MASAC

Product Name	Manufacturer	Distributor	Stabilizer	Used in Culture	Human or Animal Protein Generation Medium	Viral Safety Studies in Humans with this Product
Recombinant Factor VIII Products						
Advate	Baxter	Baxter	Trehalose	None	Third	Yes
Helixate FS	Bayer	Aventis Behring	Sucrose	Human plasma protein solution	Second	Yes
Kogenate FS	Bayer	Bayer	Sucrose	Human plasma protein solution	Second	Yes
Recombinate	Baxter	Baxter	Human albumin	Bovine serum albumin	First	Yes
ReFacto	Wyeth	Wyeth	Sucrose	Human serum albumin	Second (B-domain deleted)	Yes
Immunoaffinity Purified Factor VIII Products Derived from Human Plasma						
Hemophil M	Baxter	Baxter	*	*	*	Yes
Monarc-M	Baxter	American Red Cross	*	*	*	No
Monoclote-P	Aventis Behring	Aventis Behring	*	*	*	Yes
Factor VIII Products Derived from Human Plasma that Contain von Willebrand Factor						
Alphanate	Griffols	Grifols	*	*	*	No
Humate-P <i>FDA Approved for von Willebrand Disease</i>	Aventis Behring	Aventis Behring	*	*	*	Yes
Koate-DVI	Bayer	Bayer	*	*	*	No
Recombinant Factor IX Products						
BeneFIX	Wyeth	Wyeth	Sucrose	None	Third	Yes
Coagulation Factor IX Products Derived from Human Plasma						
AlphaNine SD	Grifols	Grifols	*	*	*	Yes
Mononine	Aventis Behring	Aventis Behring	*	*	*	Yes
Desmopressin Formulations Useful in Disorders of Hemostasis						
DDAVP Injection	Ferring AB	Aventis Pharma	*	*	*	*
Stimate Nasal Spray	Aventis Behring	Aventis Behring	*	*	*	*

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The Winning Spirit

Quarterly Newsletter of
the National Hemophilia Foundation
Delaware Valley Chapter



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Number 1

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From the Executive Director...

We have put together a pretty terrific *Winter 2004* issue for you with a lot of information about factor products. Much of the information is technical, but we think our readers will understand it, with a little perseverance (and maybe a big dictionary!). We have seen, in recent years, the evolution of products within product families (i.e., first, second, third generation). Our factor concentrates are very expensive, but seem to be improving all the time.

This summer, in our Annual Patient Survey, we asked patients if they understood why their factor products were so expensive. They overwhelmingly answered "Yes, the research and development costs to bring each product to market are paid for through the sale of factor to a very small group of patients worldwide!" Pretty smart answer!!

We have tried to give you important information that may help you understand which factor you are taking and hopefully, why, as well. The primary articles in this edition of *The Winning Spirit* may provide some "food for thought" and, as always, if you have any questions, ask your treatment team!!



DVC delegation in Salt Lake City



NHF's 55th Annual Meeting Salt Lake City, Utah

We Gratefully Acknowledge...the pledge of support from the following manufacturers for 2003.

Alpha Therapeutic Corporation
Alpha Nine SD
Alphanate SD/HT
Profilnine SD

American Red Cross
Monarc-M

Aventis Behring
Monoclote-P
Mononine
Helixate FS
Bioclate
Humate-P
Stimate
Gammar-P I.V.

Baxter Bioscience
Recombinate
Hemofil M
Proplex T
Feiba VH
Bebulin VH
Albumin (Human)
Advate

Bayer Corporation
Kogenate FS
Koate-DVI
Konyne-80

Wyeth
Benefix™
ReFacto

Nabi
Autoplex T
WinRho

Novo Nordisk
NovoSeven™

March

10-12 Washington Day!

May

Family Dinner

July

23 Wood's Camp/Session #2

April

3 Fashion Show

June

7 Carlino's Golf!

30 Wood's Camp/Session #1

September

24 Family Camp!

27 Golf Classic!

Chapter Happenings*Paul & Pauline Tache, "Oktoberfest 2003"*

Fall brought us another terrific evening as we celebrated "Oktoberfest 2003" on Friday, **October 10th** at the Adam's Mark Hotel in Philadelphia! Thanks to Bob Romano (Oktoberfest Chair), Carl Lampe, Paul and Pauline Tache (who ran

the silent auction..... stem to stern!), Megan McEnroe from Wyeth and their wonderful volunteers, we had a fantastic night of live and silent auctions, great food and even some gaming activities! A great big "thank you" to Diane Brown (DVC board member), from B 101.1 fm, who provided our entertainment and to Nancy John and Frank McCraghan and company who donated their time to run the live auction. Our Chapter depends on the funds raised at this important event to help us carry on our mission of support to so many. Many thanks to more than 300 people who joined us for the festivities! We appreciate your generosity to the DVC!

On **November 6-9, 2003**, many local patients, Chapter members and medical providers from our treatment centers traveled to Salt Lake City, Utah to attend the **NHFs 55th Annual Meeting!** We had a great time being a part of this terrific conference that brings together top scientists, patients, medical providers and members of industry to discuss every issue related to bleeding disorders. The sessions were so informative and most of us found a little time to visit the Olympic area and the attractions in Salt Lake City.

On Saturday, **December 13, 2003**, we had our **Annual Holiday Party** at Jefferson Alumni Hall in Philadelphia. Children from the local treatment programs brought their families to a day of food, fun, presents and terrific entertainment! Santa was there with lots of surprises for everyone! Almost

300 people attended!! Many thanks to Pat, Bill and Patti Johnson and their wonderful committee who put together a day to remember...all year long!! The date is already set for next year.....Saturday, December 11th!! Mark your 2004 calendar now!

On **March 10-12, 2004**, our own DVC delegation of legislative volunteers will travel to Washington, DC to be a part of **Washington Days** for the National Hemophilia Foundation. As part of the three days, we will be trained on key issues facing the bleeding disorders' community in the United States and we will visit our legislators from Pennsylvania and Delaware to make our needs known.

Our "famous" Ladies' Committee, under the leadership of Jennifer Sawyer and Lynn Lindquist (co-chairs), is underway with plans for the **Annual Fashion Show** and Luncheon, to be held on Saturday, **April 3, 2004** at the Jefferson House in East Norriton, Pennsylvania! This event helps to raise needed dollars to fund local needs right here in the Delaware Valley area. For a ticket, call the DVC office (215-885-6500)! The committee has lots of surprises for the day and we know you won't want to miss this great event!

On **TUESDAY, MAY 11, 2004**, we will hold our **Annual Family Dinner**. This wonderful evening will pay tribute to the career of a very important medical director, Dr. Catherine Manno from the Hemostasis and Thrombosis Center at the Children's Hospital of Philadelphia! Dr. Manno has spent a very long career taking care of children with bleeding disorders, so we have much to acknowledge and celebrate on that night. We have special surprises for Dr. Manno and hope that you will be with us for this terrific night! Watch for an invitation from your treatment center in March!

June will bring some "cool" events! **Carlino's Golf Outing** will be held on Monday, **June 7, 2004**. Many thanks to Laura and Pat Carlino of Carlino's Specialty Foods in Ardmore, Pennsylvania and their wonderful friends, Kathy and John DiMichele for planning this important day for our Chapter. The proceeds from this event help to support research to find a cure for hemophilia and patient and program needs right here in the Delaware Valley area! For a ticket or to be a part of the volunteers needed on the day, call the DVC office at 215-885-6500! Rain or shine...plan to join us!!

Children from the Delaware Valley Chapter area treatment programs will head off to "**Double H Hole in the Woods**" Camp for two sessions this summer!

Session #1: June 30-July 5, 2004

Session #2: July 23-29, 2004

The DVC has applications and important information about the camp. Kids with hemophilia and von Willebrand Disease, ages 6-16, are eligible to attend. The camp is free and the Delaware Valley Chapter provides transportation for both sessions. **ALL COMPLETED APPLICATIONS MUST BE RECEIVED BY THE CAMP BY APRIL 15, 2004. Don't delay!!**

*2003 Family Holiday Party*



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The Delaware Valley Chapter – What Does It Do?

Okay, so now you understand what factor you are taking, but..... what about the price? Do you know how much (per unit) is being charged to your insurance company? Do you know that the price being charged by one home-care company (pharmacy) may be different than another homecare company (pharmacy). Different pharmacies can charge different prices for the same product. Hmmmm..... If you are a patient with a lifetime limit on your insurance, the price charged per unit is a big deal. Just a few pennies difference per unit can make a big difference in making your lifetime limit last longer. Check it out.

Just to make the price issue a little more complicated, following is a list of the Average Wholesale Prices (AWPs) for many products as of December 2003. Remember that the AWP is NOT what is being charged to your insurance (at least, we hope not).

Factor Product Average Wholesale Prices (Per Unit) (may have very little to do with the price charged to your insurance per unit)		
	Redbook	1st Data Bank
Advate	1.66	1.88
Alphanate	1.25	1.25
AlphaNine-SD	1.18	1.48
Benefix	1.00	1.04
Helixate FS	1.44	1.63
Hemofil M	1.02	1.23
Humate P	1.00	1.25
Koate-DVI	.92	.96
Kogenate FS	1.68	2.03
Monarc M	1.00	.93
Monoclote P	1.00	1.05
Mononine	1.18	1.25
Profilnine-SD	.75	.75
Recombinate	1.40	1.63
Refacto	1.36	1.36

Ask your dispensing pharmacy (i.e. homecare company, hospital blood bank or pharmacy), what is the actual price per unit charged to your insurance for your factor product. Many pharmacies bill insurance 20%-30% less than the AWP's listed. Just ask...all pharmacies should be willing to give you that information. Call other pharmacies to check their rates, as well. You might be able to get a better price for the same product.

Okay, now you know what's up with your factor. Remember, if you are a patient who needs homecare services (besides just getting your factor shipped to your door), you may want to evaluate where you get your factor. A mail order pharmacy (called a PBM) doesn't provide support services to you in your home...just your factor. A full service homecare company (there are many) can help support you as you learn to infuse, can make a nurse available to you in your home, make school visits, etc. A full service homecare company is ready to work with your treatment center staff to provide support to you when the hemophilia clinic is not open (at night and on the weekends). Determine your needs first with your treatment team and then look for a homecare company that can best meet those needs.

If you need information about different homecare companies, just call the DVC office. We have information that we can send to you and you can make your own choice. Simple.❖



MASAC Recommendation Regarding the Use of Recombinant Clotting Factor Replacement Therapies

The following recommendation was approved by the Medical and Scientific Advisory Council (MASAC) on November 11, 2000 and adopted by the National Hemophilia Foundation Board of Directors on November 12, 2000.

While the current plasma-derived concentrates employed in the treatment of hemophilia A and B, von Willebrand Disease and related bleeding disorders are very safe with respect to transmission of HIV, hepatitis B, hepatitis C and hepatitis A, these products may be capable of transmitting nonenveloped viruses such as parvovirus B19. In addition, these products are potentially capable of transmitting the unknown agents of Creutzfeldt-Jakob disease (CJD) and new variant CJD (nvCJD), which are not eliminated by current viral inactivation and product purification techniques. No known cases of transmissible spongiform encephalopathy have resulted from the use of plasma-derived products in the past 30 years during which they have been in use. However, parvovirus B19 and the agent for CJD or nvCJD may be markers for as yet undiscovered or unrecognized blood-borne infectious agents.

Recombinant proteins including clotting factor products are produced in well-characterized hamster cell lines. Thousands of patients have been treated with several different recombinant proteins over the last ten years. To date, there have been no known instances of animal virus transmission by any therapeutic recombinant proteins.

Recombinant clotting factor concentrates are much safer than plasma-derived products because they are either completely free of plasma derivatives (Benefix) or else use pasteurized human serum albumin in the cell culture medium (Helixate FS, Kogenate FS, ReFacto) and as a stabilizer in the vial (Bioclata, Recombinate). This pasteurized human serum albumin has a 50-year safety record. Bovine serum proteins are used in the cell culture medium in the production of Bioclata and Recombinate. However, the bovine material comes from non-bovine spongiform encephalitis-endemic areas.

In April 1998, the Public Health Service's Advisory Committee on Blood Safety and Availability recommended the following:

"Every effort should be made to make recombinant clotting factors available to all who would benefit from them and all barriers to conversion from human plasma-derived concentrates to recombinant clotting factors should be removed."

MASAC fully endorses this recommendation and calls on industry and the Food and Drug Administration to carry out the committee's recommendation. Therefore, MASAC makes the following recommendations:

1. The recombinant factor VIII products Bioclata, Helixate FS, Kogenate FS, Recombinate and ReFacto are the safest factor VIII products available with respect to viral transmission and should be considered the treatment of choice for individuals with hemophilia.
2. The recombinant factor IX product Benefix is the safest factor IX product available with respect to viral transmission and should be considered the treatment of choice for individuals with hemophilia B.
3. Manufacturers should endeavor to make the cost of their recombinant clotting factor products more competitive with plasma-derived products.
4. Manufacturers of the recombinant products are strongly encouraged to avoid using human and animal proteins in manufacturing their products. Development, regulatory review and licensure of these concentrates should be expedited.

Note: At the time MASAC Recommendation #106 was approved, Advate (a third generation product) was not available. ❖

Camp Alert!!!!

The Double "H" Hole in the Woods Camp provides an outdoor Adirondack adventure for children with hemophilia and von Willebrand Disease each summer. Nestled in the mountains in Lake Luzerne, New York, this camp provides a chance for kids to get away from their families and just be kids...safely! Modeled after actor Paul Newman's Hold in the Wall Gang Camp in Connecticut, The Double "H" Ranch is a place where children can participate in a full range of activities and learn leadership skills, as well. The Delaware Valley Chapter provides transportation for the following two sessions. The deadline for completed applications is April 15th. For information or an application, call the Delaware Valley Chapter@215-885-6500!



Session #1: June 30-July 5, 2004

Session #2: July 23-July 29, 2004





The NHFs Recommendation Regarding Factor Products

The following recommendations were approved by the Medical and Scientific Advisory Council of the National Hemophilia Foundation (MASAC) on November 8, 2003 and adopted by the NHF Board of Directors on November 9, 2003

Note: The numbers cited within the text of this article reference investigational studies. For a complete list of references, contact the Delaware Valley Chapter, 215-885-6500.

MASAC Recommendation #151

Recommendations for Physicians Treating Patients with Hemophilia A and B and von Willebrand Disease

Treatment of Hemophilia A

Recombinant Factor VIII Concentrates

Recombinant (r) FVIII is produced by well-established hamster cell lines that have been transfected with the gene for human FVIII (1,2). One recombinant factor VIII product has the B domain deleted from the factor VIII gene before it is inserted into Chinese hamster ovary cells (3). First generation rFVIII contains animal and/or human plasma-derived proteins in the cell culture medium and in the final formulation vial. Second generation rFVIII contains animal or human plasma proteins in the medium but not in the final formulation, while the third generation does not contain any animal or human plasma-derived proteins in the culture medium or in the final vial.

The risk of human viral contamination associated with recombinant FVIII is definitely much lower than for plasma-derived products. No seroconversions to HIV, HBV (hepatitis B Virus) or HCV (hepatitis C Virus) have been reported with any of the currently available products; thus recombinant factor VIII products are the recommended treatment of choice for patients with hemophilia A.

Plasma-Derived Factor VIII Concentrates

Improved viral-depleting processes and donor screening practices have resulted in plasma-derived FVIII products with greatly reduced risk for transmission of human immunodeficiency virus and hepatitis B and C. No seroconversions to HIV, HBV or HCV have been reported with any of the FVIII products currently marketed in the United States, including products that are heated in aqueous solution (pasteurized), solvent-detergent treated and/or immunoaffinity purified. Thus, each of these methods appears to have greatly reduced the risk of viral transmission compared with older methods of viral inactivation (4-6). There remains the possibility of HIV-1, HIV-2 or hepatitis B or C virus transmission with the use of currently marketed, viral-inactivated, plasma-derived products. The non-lipid enveloped viruses, human parvovirus B19 and hepatitis A virus were also transmitted (7-9): additional steps such as viral filtration have been added to reduce these risks as well.

Cryoprecipitate Not Recommended

FVIII products are available that are manufactured by recombinant technology and thus theoretically do not

transmit human viruses. Moreover, methods of viral inactivation (pasteurization, solvent-detergent treatment, immunoaffinity purification) have resulted in a reduced risk of HIV and hepatitis B and C transmission with plasma-derived factor VIII concentrates (5-6, 11-13).

For these reasons, cryoprecipitate should not be used as a treatment alternative. Despite donor screening by nucleic acid testing (NAT) for HIV-1, HIV-2, HBV and HCV, cryoprecipitate might still be infectious. While the current estimate for the risk of HIV infection from a single unit of blood is one in 1,000,000 donations, the risk of HCV transmission is somewhat higher, approximately 1 in 900,000 (14).

Treatment of Mild Hemophilia A

Desmopressin (DDAVP) should be used whenever possible for patients with mild hemophilia A. DDAVP is available in both a parenteral form (DDAVP Injection) and a highly concentrated intranasal spray formulation (Stimate Nasal Spray). Children under the age of 2, pregnant women and patients in whom desmopressin does not provide adequate Factor VIII levels should be treated as per sections noted above.

Treatment of Hemophilia B

Recombinant Factor IX Concentrate

Recombinant factor IX (rFIX) is produced in Chinese hamster ovary cells; no human or animal plasma-derived proteins are used in its manufacturing process and it is stabilized with sucrose (third generation product). Thus the risk of human blood-borne viral contamination is essentially zero (15). Recombinant factor IX is considered to be the treatment of choice for patients with hemophilia B.

Plasma-Derived Factor IX Concentrates

Improved viral depleting processes and donor screening practices have resulted in plasma-derived FIX products with greatly reduced risk for HIV, HBV and HCV transmission (16). Viral attenuation methods used in the production of licensed FIX products that appear to be effective for reducing the risk of HIV and hepatitis are dry heating at 60C for 144 hours, solvent-detergent treatment, vapor treatment and sodium thiocyanate plus ultrafiltration. Purification

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steps involved in the preparation of coagulation FIX products are associated with loss of several additional logs of virus. There remains the slight possibility of viral transmission with the currently marketed viral-inactivated, plasma-derived products. Transmission of human parvovirus B19 and hepatitis A virus by these products has been reduced with additional viral attenuation methods.

Treatment of von Willebrand Disease (VWD)
Desmopressin

Most persons with von Willebrand Disease Type I are most appropriately treated with desmopressin, given either parenterally (DDAVP Injection) or by highly concentrated nasal spray (Stimate Nasal Spray). Some Type 2A patients may respond to DDAVP; a clinical test should be done to determine whether DDAVP can be used for these patients.

VWF-Containing Factor VIII Concentrates

If judged necessary, e.g. Type 2B VWD, Type 3 VWD and Type 1 or 2A VWD who have become transiently unresponsive to DDAVP and in surgical situations, especially in young patients, use of a viral-inactivated FVIII preparation rich in von Willebrand factor is recommended (17-21). Humate-P has been licensed by the FDA for use in von Willebrand Disease; in certain patients, Alphanate or Koate-DVI may also be effective.

Cryoprecipitate Not Recommended

Because it has not undergone any viral attenuation steps, cryoprecipitate should not be used except in life-and-limb threatening emergencies when VWD-containing Factor VIII concentrate is not immediately available.

Treatment of Patients with Inhibitors to Factors VIII and IX

The following products have been licensed for use in patients with inhibitors. However, the products are not interchangeable. Choice of product depends on multiple factors including type of inhibitor, current titer of the inhibitor, location of the bleed and availability of these products.

Activated Prothrombin Complex concentrates

These products contain activated factors IIa, VIIa and Xa. These factors are able to bypass an inhibitor to factor VIII or IX in order to promote hemostasis. These products are derived from human plasma and are treated with dry heat and/or vapor (steam) heat to eliminate viruses (22).

Recombinant Factor VIIa Concentrate

Recombinant factor VIIa is licensed for use in patients with inhibitors to factor VIII or IX. It is produced by baby hamster kidney cells; animal but not human proteins are used in its production. It is stabilized with mannitol (second generation product). Thus the risk of transmission of human viruses is essentially zero (23).

Porcine Factor VIII Concentrate

Porcine factor VIII can be used in patients with inhibitors to human factor VIII. Porcine factor VIII is obtained from a colony of carefully maintained pigs that are screened frequently for several viruses. There has been no documented transmission of porcine viruses, especially porcine parvovirus, to individuals who have been treated with this product (24).❖

Dads in Action

A "Dad's in Action" program is being formed for this year through the Hemophilia Federation. The mission of the program is to forge a stronger bond between dads and their children....to learn not only to listen to what our children have to say, but to hear them. The program helps dads to set family priorities. The objective for this year is to organize regional groups of dads around the Delaware Valley that would meet quarterly in a supportive format and give them the opportunity to learn family life skills and techniques. One of the planned activities will be a father/child outing. If you are the father of a child with a bleeding disorder and would like more information about attending or starting a group in your area, call Art Stinger at 215-674-4492.





FYI, For Your Information

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The Winning Spirit

"I Have von WilleWHAT?"

The Delaware Valley Chapter and the Cardeza Foundation Hemophilia Center at Thomas Jefferson University Hospital have been awarded a grant from the National Hemophilia Foundation and the Centers for Disease Control to help identify previously-undiagnosed women with bleeding disorders. This project, called "I Have von WilleWHAT?" will provide information and education to identified women and local OB-GYN physicians in Philadelphia about the risks associated with undiagnosed von Willebrand Disease. This will be a year-long project.

Hepatitis C Class Action Lawsuit

In the fall issue of the Winning Spirit newsletter, you should have received information regarding a class action lawsuit for patients infected with HCV (hepatitis C).

If you, or someone you know, would like to find out more about this lawsuit, intended to provide a cash settlement for anyone with hemophilia or von Willebrand Disease who meets the criteria for the class, please call the Delaware Valley Chapter office (215-885-6500).

*We have applications in the office.
If you are not affected by this issue or do not wish to participate,
please disregard this notice.*

Just a Thought



*"Hold yourself responsible
for a higher standard
than anybody else expects of you."*

*Henry Ward Beecher,
an American Cleric (1813-1887)*

