

# Enroll your eligible patients in the XYNTHA Trial Prescription Program.

To begin, please have each eligible patient (1) read the terms and conditions, (2) complete parts 1-4 of this enrollment form, and (3) sign the authorization form.

The remaining sections must be completed by a healthcare professional for complimentary product in accordance with the Prescription Drug Marketing Act of 1987. This program is intended for new XYNTHA® Antihemophilic Factor (Recombinant) patients. All products will be sent by the Pfizer Program Administrator.

Fax this completed form, along with the prescription for XYNTHA and the patient authorization form, to **888-868-8660**. Fax must be sent from a healthcare provider's office, or mail required documents to the **XYNTHA Trial Prescription Program Administrator, MedVantx, PO Box 5736, Sioux Falls, SD 57117-5736**. Please allow 1 to 3 weeks after submission of forms for processing and delivery.

## XYNTHA Trial Rx Terms and Conditions

**OFFER TERMS: By enrolling in the XYNTHA Factor Trial Prescription Program, you acknowledge that you currently meet the eligibility criteria and will comply with the terms and conditions described below:** You are currently covered by a private [commercial] insurance plan. An original free trial offer and a valid prescription must be presented. No claim for reimbursement for XYNTHA dispensed pursuant to this free trial offer may be submitted to any third-party payor. Medicaid, Medicare, or any other federal or state health care program beneficiaries are not eligible for this offer (this includes any state prescription drug assistance programs and Government Health Insurance Plan, available in Puerto Rico, formerly known as "La Reforma de Salud"). The free trial offer is not valid for prescriptions that are eligible to be reimbursed by private insurance plans or health or pharmacy benefit programs that reimburse you for the entire cost of your prescription drugs. This free trial offer is not valid where otherwise prohibited by law. You will receive a 1-month supply up to 20,000 IU of factor. **The free trial offer cannot be combined with any other rebate/coupon, free trial, or similar offer for the prescribed prescription. The free trial offer will only be accepted by participating factor providers. This free trial offer is not health insurance.** Offer good only in the US and Puerto Rico. Only new patients may use this offer. By redeeming this offer, you certify that you are not currently using Pfizer Factor Product. Only 1 offer per person may be redeemed under this program. This offer is not transferable. Pfizer reserves the right to rescind, revoke, or amend this free trial offer without notice. Offer expires 1 month from enrollment date or when the maximum benefit up to 20,000 IU at no cost has been reached. No membership fees. For questions about the XYNTHA Trial Prescription Program, please call 1-800-710-1379 or write us at XYNTHA Trial Prescription Program Administrator, MedVantx, PO Box 5736, Sioux Falls, SD 57117-5736.

## PARTS 1-4: PATIENT INFORMATION

1 Name \_\_\_\_\_ 2 Date of birth \_\_\_\_\_

3 Address \_\_\_\_\_  
(Street) (Suite/Floor) (City) (State) (ZIP code)

(Please note that product cannot be shipped to PO boxes)

I, \_\_\_\_\_, certify that the patient is not currently receiving XYNTHA therapy.

If guardian, please state relationship to patient \_\_\_\_\_

(Signature of patient/parent/guardian) \_\_\_\_\_ Date \_\_\_\_\_

4 Telephone number ( ) ( )  
Day Evening

## PARTS 5-10: PHYSICIAN INFORMATION

5 Name \_\_\_\_\_

6 Professional designation license # (required by law) \_\_\_\_\_

7 Name of treatment center\* \_\_\_\_\_

8 Address \_\_\_\_\_  
(Street) (Suite/Floor) (City) (State) (ZIP code)

9 Business telephone ( ) HTC telephone ( )

10 Fax ( ) E-mail address \_\_\_\_\_

\*If not a treatment center, please fill in physician name and medical center affiliation.

## PARTS 11-13: XYNTHA TRIAL PRESCRIPTION INFORMATION

11 Please note on the prescription whether patient has any allergies and/or is taking concomitant medications. Maximum quantity based on patient weight, 1-month supply, up to 20,000 IU.

12 Preferred IU\* based on patient dosage. \*Subject to availability.

# \_\_\_\_\_ 250-IU XYNTHA® SOLOFUSE® prefilled dual-chamber syringe    # \_\_\_\_\_ 500-IU XYNTHA SOLOFUSE    # \_\_\_\_\_ 1000-IU XYNTHA SOLOFUSE    # \_\_\_\_\_ 2000-IU XYNTHA SOLOFUSE    # \_\_\_\_\_ 3000-IU XYNTHA SOLOFUSE

XYNTHA in vial form is available upon request. Please check this box and you will be contacted to confirm.

13 Signature of requesting licensed physician

*I agree that I will not resell or bill any third party, including Medicaid or Medicare programs, for any of the complimentary product provided under this trial prescription program. I acknowledge that any patient selected for this program is not currently receiving XYNTHA therapy and has not been previously enrolled in the XYNTHA Trial Prescription Program.*

(Signature of physician)

(Date of request)

For questions about the XYNTHA Trial Prescription Program, please call 1-800-710-1379, Monday through Friday, 9:00 AM to 5:00 PM Eastern time. **Please see Indication and Important Safety Information on next page and [click here](http://www.XYNTHA.com/pi.htm) for full Prescribing Information, or go to <http://www.XYNTHA.com/pi.htm>.**

  
Antihemophilic Factor (Recombinant)

## Indication for XYNTHA

Xyntha® Antihemophilic Factor (Recombinant), is indicated in adults and children with hemophilia A (congenital factor VIII deficiency or classic hemophilia) for control and prevention of bleeding episodes and for perioperative management.

XYNTHA does not contain von Willebrand factor and, therefore, is not indicated in von Willebrand's disease.

## Important Safety Information for XYNTHA

- Do not use in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including hamster proteins.
- Allergic-type hypersensitivity reactions, including anaphylaxis, are possible with XYNTHA. Inform patients of the early signs or symptoms of hypersensitivity reactions (including hives, generalized urticaria, chest tightness, wheezing, and hypotension) and anaphylaxis. Discontinue XYNTHA if hypersensitivity symptoms occur and administer appropriate emergency treatment. XYNTHA contains trace amounts of hamster proteins. Patients may develop hypersensitivity to these proteins.
- Inhibitors have been reported following administration of XYNTHA. Monitor patients for the development of factor VIII inhibitors by appropriate clinical observations and laboratory tests.
- Clinical response to XYNTHA may vary. If bleeding is not controlled with the recommended dose of factor, determine the plasma level and administer a dose of XYNTHA sufficient to achieve clinical response. If the factor level does not increase or there is no response, suspect an inhibitor and perform appropriate testing.
- Across all studies, the most common adverse reactions ( $\geq 10\%$ ) with XYNTHA in previously treated adult and pediatric patients were headache (26% of subjects), arthralgia (25%), fever (21%), and cough (11%). Other adverse reactions reported in  $\geq 5\%$  of subjects were diarrhea, vomiting, weakness, and nausea.
- XYNTHA is an injectable medicine administered by intravenous (IV) infusion. Patients should be advised that local irritation may occur when infusing XYNTHA after reconstitution in XYNTHA® SOLOFUSE®.

Please [click here](#) for full Prescribing Information.

# Patient Authorization Form

This Patient Authorization Form authorizes your Healthcare Provider to disclose your health and personal information to MedVantx, the administrator of the XYNTHA® Antihemophilic Factor (Recombinant) Trial Prescription Program, and its employees, representatives, and agents (collectively, “MedVantx”) in connection with the XYNTHA Trial Prescription Program in accordance with the Health Insurance Portability and Accountability Act of 1996 and related federal regulations and rules (“HIPAA”).

## Authorization

I, \_\_\_\_\_, hereby authorize \_\_\_\_\_

First Middle Last Name Name of Physician “Healthcare Provider”

to disclose my individually identifiable health and medical information described below to MedVantx solely for the authorized purposes described in this authorization form.

## Description of Health and Medical Information That May Be Disclosed

My Healthcare Provider may disclose individually identifiable health and other information that supports my participation in the XYNTHA Trial Prescription Program. Information disclosed may include my name, address, date of birth, diagnosis/disease, treatment, financial information, medical records, and the specialty of my Healthcare Provider.

## Authorized Purposes

The authorized purposes are (1) to evaluate my eligibility for inclusion in the XYNTHA Trial Prescription Program, and (2) if my participation in the program is approved, for the administration of the program to me.

## Expiration of Authorization

My authorization shall expire (1) when my participation in the XYNTHA Trial Prescription Program is not approved, or (2) at the conclusion of my participation in the XYNTHA Trial Prescription Program, whichever is earlier.

## Acknowledgments

- 1** I understand that once my Healthcare Provider gives MedVantx information about me based on this authorization, my medical and health information may be subject to redisclosure and no longer protected by federal privacy regulations. I further understand and agree that MedVantx may retain my medical and health information as disclosed under this authorization after this authorization expires for purposes related to the administration of the XYNTHA Trial Prescription Program. I also understand that in the event of an audit, and only for purposes of such an audit, some information may also be disclosed to Wyeth (the manufacturer of XYNTHA), even after this authorization has expired so long as the audit is for a period of time when this authorization was in effect.
- 2** I understand that I may refuse to sign this authorization form and that, unless allowed by law, my refusal to sign will not affect my ability to obtain treatment from my Healthcare Provider, or to seek payment or my eligibility for benefits. However, I understand that I may not be included in the XYNTHA Trial Prescription Program if I refuse to sign this authorization form.
- 3** I understand that I may revoke my authorization at any time by providing a written notice of same to my Healthcare Provider that refers to (or with a copy of) this authorization form. However, I understand that if I revoke this authorization, it will not affect prior disclosures made by my Healthcare Provider to MedVantx in reliance of this authorization.

**4** I understand and agree to the following:

Pfizer understands your personal and health information is private. The information you provide will only be used by Pfizer and parties acting on its behalf to send you the materials you requested and other helpful information and updates on XYNTHA as well as related treatments, products, offers, and services.

By checking this box, I also agree that Pfizer or companies acting on its behalf may send me materials about other health conditions, use my information to develop or improve products and services, or contact me in the future about health-related topics.

\_\_\_\_\_  
Signature of Patient or Patient's Personal Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Patient's Name

\_\_\_\_\_  
Name of Personal Representative (if applicable)

\_\_\_\_\_  
Relationship to Patient

**HEALTHCARE PROVIDER MUST GIVE PATIENT AND/OR PATIENT'S REPRESENTATIVE A SIGNED COPY OF THIS FORM.  
Healthcare Provider has verified Patient Representative's authority to act on Patient's behalf. \_\_\_\_\_ (check)**

**xyntha<sup>®</sup> solofuse<sup>®</sup>**  
Antihemophilic Factor (Recombinant)

