

INFORMED PATIENT CONSENT

Protocol Title: A Randomized, Placebo-Controlled, Double-Blind, Trial of Polyethylene Glycol 3350 Laxative for the Treatment of Occasional Constipation

Sponsor: Schering-Plough HealthCare Products, Inc.
Research and Development
556 Morris Avenue
Summit, New Jersey 07901

Principal Investigator:

Co-Investigator(s):

Study Coordinator(s):

Study Site:

YOUR RIGHTS AS A STUDY SUBJECT: Please read this Form carefully before signing it. Take time to ask as many questions as you want. If there are any words or information that you do not understand ask the Principal Investigator (Study Doctor) or any Study Team Member to explain them to you. No study procedures, tests, drugs or data collection can be started until you have signed this Consent Form.

This study involves research and your participation in this study is entirely voluntary. You may withdraw from this study at any time. The quality of care that you receive will not be affected in any way if at any time you decide not to participate or if you withdraw from this study. Contact the Principal Investigator **Dr. Blank** at **(555) 555-5555** should any questions arise concerning your participation in this research project or if you believe you have suffered any physical injury as a result of your participation, or if questions occur to you later. It is important for you to know that:

VOLUNTARY WITHDRAWAL:

- Your participation is entirely voluntary.
- You may decide not to take part - or - decide to stop being in the study, at any time, without any penalty.
- You will be told about any new information or changes in this study that might affect your participation.
- You fully understand that you are free to withdraw your consent at any time, and discontinue your participation in this study. If you choose to either withdraw, or not participate in this study, no prejudice will be shown toward you regarding your medical care or your participation in future studies and, you will receive appropriate care for your condition. If you choose to withdraw from this study you must inform your study doctor and any other doctors involved in your care so that he/she is able to evaluate your status, discuss your decision to withdraw, and perform, if necessary, any end-of-study tests. Termination of your

participation in this study may also be asked for by either the study sponsor (Schering-Plough HealthCare Products, Inc.), or the study doctor **Blank**, M.D. at any time, without your consent.

INVITATION TO TAKE PART IN A RESEARCH STUDY:

You are invited to participate in a research study of Polyethylene Glycol 3350 for the treatment of occasional constipation symptoms that include: straining and hard or lumpy stools or the inability to have a bowel movement within 48 hours prior to randomization into the trial.

DESCRIPTION OF THE EXPERIMENTAL DRUG:

Polyethylene Glycol 3350 is available over the counter to relieve the symptoms of constipation.

The primary objective of this study is to compare the effectiveness of a daily dose (a capful) of Polyethylene Glycol 3350 to a daily dose (a capful) of a placebo with regards to resolving the symptoms occasional constipation, (straining and hard or lumpy stools).

WHAT OTHER OPTIONS ARE THERE?:

If you decide not to participate in this study, your doctor will use one of the medications that are currently available to treat your condition or the doctor may suggest lifestyle changes (diet and/or exercise).

PURPOSE OF THIS RESEARCH STUDY:

The primary objective of this study is to evaluate the resolution of hard or lumpy stools in subjects using Polyethylene Glycol 3350, 17 g dose daily compared to a placebo (an identical sized dose that contains no medication).

APPROXIMATE NUMBER OF STUDY SUBJECTS:

Approximately 196 symptomatic people (people who have straining and hard or lumpy stools or the inability to have a bowel movement within 48 hours prior to randomization into the trial) who volunteer and sign an informed consent (or in the case of minors, signs an informed assent form and a parent or guardian signs an informed consent) will be enrolled into the trial.

STUDY PROCEDURES:

In order to keep the testing of the study medication accurate, it will be compared to a matching placebo (an identical sized dose that contains no medication). People who volunteer to be a part of the study will either receive the study medication or a placebo (a similar sized dose that contains no medication). You will not know if you are taking the dose with the study medication in it or the dose that does not contain any medication.

At screening symptomatic people (people who have straining and hard or lumpy stools or the inability to have a bowel movement within 48 hours prior to randomization into the trial) who volunteer to participate in the study will begin the evaluation process that could lead to their selection as a participant in the study (subjects). At Visit 1 you will complete an informed consent. A brief physical examination to include confirmation of signs of constipation will be performed. Height, weight, and vital signs (pulse, respiration, body temperature, and blood pressure) will be taken and recorded at this time. Your medical history (for 5 years prior to screening) and use of recent medications will be documented. Also, at this first visit, you will be completing a Baseline Assessment and a Baseline Quality of Life Questionnaire. Women of childbearing potential will be given a urine pregnancy test at this first visit.

Volunteers will be given one diary, or log. It is important to keep your diary/log up to date. You will be asked to evaluate, (rate or score) your constipation symptoms for the previous 24 hours in the

diary every day just before you take the medication. The symptoms you will be asked to evaluate are: straining during bowel movement, whether the stool was hard/lumpy, gas, bloating, cramping, control of bowel movements, , and the effect constipation has had on your daily life. You will rate or score your symptoms according to how you felt during the last day and/or during your bowel movement.

You will also be asked if you have taken any medications to relieve your symptoms. You will be taking a capful dose of the medication mixed in 4 to 8 ounces of a beverage of your choice everyday for the 7 days of the study. On the first available morning (prior to noon) on or after Visit 1, you will take your first dose of study medication.

If you are continuing in the study you will be asked to return to the doctor's office (Visit 2) between 24 hours and 3 days after your last dose of study medication. Your doctor/or study staff member will review your diary and discuss how you have been feeling. Women of childbearing potential will be given a second urine pregnancy test at this visit. At this visit you will also complete a Preference Questionnaire, a Global Evaluation, and a QOL Questionnaire.

Your participation in this study will be approximately up to 13 days.

RISKS / DISCOMFORTS / UNFORESEEN EVENTS:

Your participation in this study involves the following potential risks which may result: you may not have relief of your symptoms. A person who participates in the study cannot choose whether to take the study medication, or the placebo (an identical sized dose that contains no medication). This is decided by chance (like flipping a coin). You will have an equal chance of getting study medication or placebo. You will not know which study drug you get and your study doctor will not know, but your study doctor can find this out if he/she needs to know in the case of an emergency. If you do receive the study medication, the common side effects from Polyethylene Glycol 3350 (while they do not often occur) are: cramping, nausea, bloating, and diarrhea.

Your condition will be watched closely during this Study. If you have any serious reactions or problems the treatment will be changed or stopped to protect your health.

If you have any questions regarding your rights as a research subject, please call Allendale IRB at (860) 434-5872.

RISKS TO WOMEN OF CHILD-BEARING POTENTIAL:

If you are a woman who is able to have children, you must have a negative pregnancy test before you begin to participate in this study, and again at the second visit. If you become pregnant during the study, you must immediately inform your study doctor **Blank**, M.D. and other doctors involved in your care.

BENEFITS:

Your symptoms may be helped by the study medication. However, you may not necessarily receive any direct benefit from your participation in this study. Any new information obtained during the course of this research study, that may affect your willingness to continue in this study, will be provided to you.

REASONS YOU MIGHT BE WITHDRAWN FROM THE STUDY WITHOUT YOUR CONSENT

You may be taken out of the research study if:

- a. The investigator decides that continuing in the study would be harmful to you.
- b. You fail to keep your appointments as instructed.
- c. The study is canceled by Schering-Plough HealthCare Products, Inc., the sponsor of the study, or the Food and Drug Administration (FDA).

EXCLUSION CRITERIA:

If you have certain health issues, you will not be able to take part in this study. Please tell your study doctor about all health problems you have. If you have celiac disease, known gluten sensitivity (allergic to the protein found in wheat), or renal or hepatic insufficiency (problems with your kidneys or liver working properly) you may not be in the study. If you have a history of colorectal (colon or rectum) cancer, anal abscess (infection in rectum) , anal fistula (abnormal opening in the rectal area), anal fissure (abnormal opening or crack in the rectal area), anal stenosis (narrowing of a canal within the rectum), gastric retention or obstruction (abnormal storing of food or liquid in the stomach or stomach blockage), bowel resection (a type of surgery on your intestines), rectocele (protrusion of part of the rectum), or colostomy (part of your colon has been removed) you may not be a part of the study. If you have gastrointestinal bleeding or acute infection, you will not be able to be in the study. If you are breast feeding, you may not be in this study. The study doctor will explain any questions you have about these conditions.

COSTS:

Study medication will be provided by Schering-Plough HealthCare Products, Inc. with no cost to you.

PATIENT COMPENSATION:

You will be paid for your participation in the study for each completed visit. You will be compensated \$\$\$\$\$\$ for Visit 1 and \$\$\$\$\$\$ for Visit 2. You will not be compensated for any visit not completed.

COMPENSATION FOR ILLNESS OR INJURY:

You understand that if you suffer a physical injury or illness as a direct result of your participation in this research Study, immediate medical treatment as appropriate, at your expense, will be made available to you by, Blank, M.D. Financial compensation for a research related injury or illness, lost wages, disability, or discomfort, is not available. However, you understand that you do not waive any of your legal rights by signing this consent form.

Health Information Portability & Accountability Act (HIPAA - also known as PHI (Protected Health Information): CONFIDENTIALITY AND AUTHORIZATION TO COLLECT, USE AND DISCLOSE YOUR MEDICAL INFORMATION (This Section explains how your medical information will be collected, used, and shared with other persons involved in this Study, and describes your rights, including the right to see your medical information.)

Purpose of this Authorization: You are being asked to permit the collection, use and sharing of your medical information so that the safety and effectiveness of the study drug can be evaluated as described in the section detailing this information.

What does “Medical Information” mean?: Your medical information is information about your physical or mental health or condition. It includes your previous medical records and information about you created or collected during the study (for example: the dates or results of

various tests or examinations). This information may identify you because it may contain, for example, your name, address, telephone number, date of birth, social security number, race or ethnic origin, or other unique identifiers.

Use and Disclosure of Your Medical Information: If you sign this consent form you allow the study doctor **Blank**, M.D. to collect and use your medical information to carry out this study. You also allow the study doctor to share your medical information with Schering-Plough HealthCare Products, Inc., including its affiliates, representatives and its contractors who work on behalf of Schering-Plough HealthCare Products, Inc., to conduct the study, other doctors and health care professionals who are involved in the study, Allendale Institutional Review Board which watches over the Study, governmental agencies overseeing this study or the study drug, including the Food & Drug Administration, other Department of Health and Human Services Agencies (DHHS), and governmental agencies in the United States.

Will Persons Looking at Your Medical Record Be Able to Identify You?:

The part of your medical information (study data), sent by the study doctor to Schering-Plough HealthCare Products, Inc., usually does not identify you personally (for example: your name, address or social security number). However, an example of data that may be sent to Schering-Plough HealthCare Products, Inc., is your date of birth. Instead of receiving your name, the study doctor uses your initials and a code number on the study data sent to Schering-Plough HealthCare Products, Inc. However, authorized personnel from Schering-Plough HealthCare Products, Inc., its representatives, the Food & Drug Administration, and other DHHS agencies, governmental agencies in other countries, Allendale Clinical Research, an Institutional Review Board, and other supervising bodies, may look at your medical information at the study doctor's site. The reason these persons may look at your medical information is to make sure that the study has been done properly and that study data has been collected correctly, or for other reasons allowed by law.

Notice on Redisclosure of Your Medical Information and Confidentiality:

Federal law provides that the study doctor can only share your medical information with those persons whom you have permitted to see it. However, if you sign this form those persons may share your medical information with other persons. Federal law does not protect you against this.

Publication of Study Results:

Except as explained in this Section (Confidentiality & Authorization) your medical information will be kept confidential. The data and results from this Study may also be presented at meetings or in publications. However, in those presentations, study subjects taking part in this study will not be identified by name.

Your Right to See and/or Copy Your Medical Information:

You have the right to see and copy your medical information related to the study for as long as the study doctor has this information. However, you may not be able to see some of your records related to the study until after the study has been completed, otherwise it could spoil the study.

Withdrawing your Authorization:

You may withdraw your Authorization (permission) regarding your medical information at any time by calling the study doctor, **Blank**, M.D. **(555) 555-5555**. If you withdraw this

Authorization the study doctor will no longer use your medical information or share it with others under the Authorization for this study unless the study doctor needs to do so to protect the study data. However, Schering-Plough HealthCare Products, Inc., may still use information about you that was shared with Schering-Plough HealthCare Products, Inc., before you withdrew your Authorization. If you withdraw your Authorization you cannot continue to take part in this study.

Expiration of your Authorization: Your Authorization will expire once there is no longer a need to examine the data related to this study. All program data will be kept confidential, however, authorized personnel from Schering-Plough HealthCare Products, Inc., its representatives, the Food & Drug Administration, other DHHS agencies, and Allendale International Review Board, may have access to the data. The data and results from this study may also be presented at meetings or in publications, but in those presentations study subjects will not be identified by name.

This research study has been approved by an Institutional Review Board. The Board is responsible for ensuring that research involving volunteers is appropriate, and that the volunteers' rights and welfare are protected.

BY SIGNING THIS FORM I AM NOT WAIVING ANY LEGAL RIGHTS.

This study, related procedures, discomforts, risks, unforeseen events, and possible benefits that might result from my participation in this study have been explained to me and to my satisfaction. I have been given the opportunity to take this consent form home to review with my Family/Others. I have been given the opportunity to discuss this with any other physician involved in my care. I have been given the opportunity to ask questions and they have been answered to my satisfaction. I agree to participate as a volunteer and have read, or have had this consent form read to me in a language I understand and I have received a copy.

Please Print: Study Subject or Legally Authorized Representative (LAR)

Signature: Study Subject or Legally Authorized Representative (LAR) Date

Print Name of Person Conducting the Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion Date
Principal Investigator /Co-Investigator /Study Coordinator / Designated Team Member
(Circle your title)

Print Name of Investigator

Signature of Investigator Date