

Written Informed Consent Form

Study Identification: SB275833/029

Study Title: An Open-Label Study to Describe the Pharmacokinetics of Topical Applications Twice Daily for Five Days, of SB275833, 2% Ointment, and to Assess Preliminary Safety and Efficacy in the Treatment of Subjects with Uncomplicated Bacterial Skin Infections

This is a study of a new drug, SB275833, to see how much of the drug is in the blood after it is put on the skin two times a day for five days, and to get an idea of how well the drug works and how well it is tolerated when used to treat minor skin infections caused by certain bacteria, or germs.

Version Number: 01 Date: 11 July 2003

Company Name: GlaxoSmithKline

Subject Identification:

Purpose/Description/Procedures/Duration

You have been asked to take part in a clinical research study of a new drug, SB275833, to be used to treat minor skin infections, caused by bacteria, or germs. Before you decide whether to participate it is important for you to know why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it if you wish with friends, relatives and your personal doctor (i.e., general practitioner or primary care physician). Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

The study doctor and/or the institution is /are paid to conduct this research study by GlaxoSmithKline.

This is a research study of a new drug, SB275833, to see how much of the drug is in the blood after it is put on the skin two times a day for five days, and to get an idea of how well the drug works and how well it is tolerated when used to treat minor skin infections caused by certain bacteria, or germs. This is an open-label study. In an open-label study both you and your doctor will know what treatment you are receiving.

If you agree to take part in the study and if you meet all of the conditions required to enter the study, you will have the following tests in the clinic or the doctor's office:

About a tablespoon of your blood will be taken with a needle, a total of 11 times during the study. This is to see how much medicine gets into your blood from the skin, and to make sure that your blood cells and the chemicals in your blood are normal, and not

affected when you apply the drug. On the first day and the fifth day, you will need to have your blood taken four times each day. Because the medicine is at different levels in your blood at different times, it is very important on days one and five for you to either stay at the clinic or the doctor's office, or to return, on-time, at the times you are told. On the third, fourth and seventh day, you will have your blood taken once each day.

A picture will be taken of your infection before you are given the medicine, and after your treatment is finished. The picture will only be of the infected area; people will not be able to tell who you are from this picture. If you do not want to have your wound photographed, then you should not agree to be in this study.

A swab of the infected skin to see what germs (bacteria) are causing your infection. The swab is similar to a large "Q-tip" swab. This will be done at the beginning of the study, and possibly at the end of the study, if you are getting better, but still have signs of infection. A swab may also be taken if you are not getting better and the doctor decides to give you different medicine.

You are being asked to participate in the study for approximately 12-14 days. During this time, you will need to visit the clinic four times on days one and five (or stay at the clinic on those days), and once a day on days three, four, seven. You must come to the clinic between 12 and 14 days, so that the doctor can make sure that your infection cured or is still getting better.

If you are a female, you will also be asked to give a urine sample to determine if you are pregnant at the time of the first visit. The nurse or doctor will explain how to collect the urine sample. If the urine test shows that you are pregnant, you will not be allowed to be in this study. This is because we are not sure that the test drug will not hurt your baby.

Your doctor will ask you not to apply any medication to the infected area, other than the study medication for the length of the study. This is necessary so we can fully measure the effects of Sb275833 without any interference from your current medication. While you are in the study, you may not take any prescription antibiotics.

Number of Subjects

This study will involve a total of 35 subjects at approximately 10 hospitals/clinics.

Your study doctor will inform you if this total is reached for the study and whether your participation in the study will be needed.

Risks/Inconveniences

You may have some discomfort at the infection site when the bacterial sample swab is collected.

When you have your blood drawn, you may experience some discomfort when the needle goes through the skin. You may feel faint, experience mild pain, bruising, irritation or redness at the site where the needle went into your skin. In rare cases, you may develop an infection.

Depending on the time you begin the study, you may have to return to the clinic or doctor's office early in the morning and/or late in the evening. If you work, your work schedule may be interrupted by visits to the clinic. If the multiple visits on days one and five will be a hardship for you, then you should not agree to be in this study.

If you choose to participate in this study, you must use one of the allowed contraceptive methods (a way to prevent you from becoming pregnant) for the specified period of time before and after you enter the study. You must use two barrier methods of contraception during the first seven days of the study. Example of this would include foam and condom, condom and contraceptive sponge, or diaphragm and condom. Ask your doctor if you have any questions about these choices and which might be best for you.

Even when you use one of the allowed contraceptive methods, there may be a small risk that you could become pregnant. Because of this, you will be tested at the beginning of the study to see if you are pregnant. If the test shows that you are pregnant, you will not be allowed to participate in the study. So, if you think you are pregnant or may become pregnant, you must tell Dr. _____ at the earliest opportunity. If you find out that you are pregnant during the study you will be required to withdrawal from the study.

There may be other risks, inconveniences and side effects to the embryo, fetus (unborn child), or nursing infant that are unknown at this time.

Benefits

Your participation in this study may add to the medical knowledge about the use of this medicine. If you agree to participate in this study, SB275833 may or may not be beneficial in treating your condition or improving your symptoms. The information learned from this study may help to establish a new medication for the treatment of minor skin infections caused by bacteria.

You will get medical attention often and will have tests done to watch your health.

Alternative Treatment

Before you decide whether or not to take part in this study, you may wish to consider other treatment options that include other oral (taken by mouth) or topical antibiotic treatments. Your study doctor will describe these to you based on your medical history and the treatment you have received to date.

Compensation for Study-Related Injury

In the event that you suffer any injury attributable to the administration of a medicinal product within the trial or any clinical intervention or procedure required under the trial that would not have occurred but for your inclusion in the trial, you will be compensated. A copy of the guidelines covering compensation for any such injury can be obtained from your study doctor.

If, as part of participating in the study, you are injured by the study drug or study-related procedures done to you in accordance with the study protocol, GSK will pay for reasonable and necessary medical expenses to treat the injury that are not covered by your medical insurance. GSK is not offering to compensate you for any other expenses, but you do not waive any legal rights by signing this consent form.

Expenses/Costs

GSK, has made provisions with the study doctor to reimburse you for the cost of travelling to and from study visits and for other miscellaneous costs (such as expense for a meal), up to a maximum of _____.

Contact(s) for Answers to Pertinent Questions about Research and Subject's Rights and Contact(s) in the Event of an Injury

You have the right to ask _____ at _____ any questions concerning this study at any time.

If you have any questions concerning your rights as a subject in a research study, you should contact _____ at _____ at any time.

If you believe you have sustained a research-related injury, you should contact _____ at _____ at any time.

Termination of Subjects' Study Participation

Your participation in the study may be stopped for any of the following reasons:

- i. If you don't follow the investigator's instructions.
- ii. The investigator decides it is in the best interest of your health and welfare to discontinue.
- iii. There aren't enough patients in the study, or the study has reached the required number of patients
- iv. GlaxoSmithKline stops the study at this study site for other reasons not known now.

Voluntary Participation and Subjects Right to End Participation

Confidentiality and Data Privacy

Maintaining confidentiality is important to GlaxoSmithKline. Your personal information (for example, your gender, age, the details of your medical conditions) and other information (the data collected by GlaxoSmithKline as part of the study) will be identified by a number (i.e., coded). Your name will not appear in any publications or reports produced from this study.

GlaxoSmithKline will keep the information and the results collected about you in this study. Your name and address are not included in the information kept by GlaxoSmithKline - only your study doctor will keep this information. GlaxoSmithKline has told your study doctor to keep the information about you in a secure place. GlaxoSmithKline will comply with internal procedures to protect personal and other information even in countries where data privacy laws are less strict than in Europe/US.

By agreeing to take part in this research study you will be allowing certain persons to see the information about you (both personal, including your name, and other information) held by the study doctor. Your information will be looked at to confirm that it is correct and that it is related to you. This will be done by selected people working for GlaxoSmithKline and organisations acting on behalf of GlaxoSmithKline, and the government regulatory authorities. These persons are required to maintain the confidentiality of your information.

Your information will be processed electronically (i.e., by a computer) or manually and analysed to determine outcome of this study. GlaxoSmithKline may use your information for other medical/health care purposes related to development of this drug. Your coded information will be used for this purpose only .

Your information may/could be sent to regulatory authorities, to the IEC/IRB, to other doctors and/or organisations working with GlaxoSmithKline. It may also be sent to other GlaxoSmithKline sites in this country and in other countries where there may be different or lesser standards for looking after it. GlaxoSmithKline will apply the same standard in the protection of your information to the extent permitted by law.

You have the right to ask the study doctor about the data being collected on you for the study and about the purpose of this data. You have the right to ask the study doctor to allow you to see your personal information and to have any needed corrections to it made

As part of the study, medical information about you will be collected and analysed. This medical information can include, but are not limited to your medical history, any medical problems you may have now, and any medicines you have taken or are taking. By signing this document, you authorise the study doctor and staff to use this information in conducting the study, and to provide access to or copies of this information to the study sponsor or to others working with the sponsor to monitor the progress of the study or analyse the study data. Access to this information is necessary for the sponsor to check that the study is being done correctly, and to collect and analyse data about the safety and effectiveness of the study drug.

This authorisation to use or disclose the information as described above is not time-limited (that is, will not automatically expire).

You agree that, while the study is still in progress, you may not be given access to medical information about you that is related to the study. This may include, for example, information about whether you are receiving study drug or placebo, or any other information that is "blinded" (that is, kept secret during the study to prevent bias). While a request for access to medical information can be denied, the study doctor and staff will not automatically deny a request, but will consider whether it's medically

appropriate under the circumstances to allow access. Your agreement that you may be denied access to your study-related medical information during the study will not be used to deny you access to that information after the study is completed at all locations and study results are analysed.

You may decide not to sign this authorisation (by signing this consent form), or you may revoke this authorisation in writing at any time. However, you can only participate in the study if you authorise the use and disclosure of the information as described above. If you decide not to sign this authorisation/consent form, you will not be enrolled in the study. If you sign this authorisation and decide later to revoke this authorisation, you will be dropped from the study at that time. Information collected up to the time you revoke this authorisation will continue to be used as study data if it is scientifically appropriate to do so.

You should know that, once information is disclosed under this authorisation to someone who is not a health care provider, the information is no longer protected by the federal privacy rules called the “HIPAA privacy regulations” and could be disclosed to others by the recipient.

You will be given a copy of this authorisation/consent after you have signed and dated it.

Tissue Samples (including blood)

As part of the study, blood samples will be collected at different times during the study. Collected samples will be used to monitor your condition, and to see when and how much of the medicine has gone through your skin into your blood.

The samples stored will not be labelled with information that directly identifies you, but will be labelled with a number that can be linked to you. The link between the sample's number and information identifying you will be kept at the study site.

Collected samples may be transferred to the GlaxoSmithKline or to other researchers working with GlaxoSmithKline.

Notification of New Information

Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, we will tell you about new information that may affect your willingness to stay in this study.

I confirm that I have read the statements in the informed consent form 001, dated July 11, 2003 for this study. I confirm that the study information and procedures have been explained to me by _____ on _____ during the consent process for this study.

I confirm that I have had the opportunity to ask questions about this study and I am satisfied with the answers and explanations that have been provided.

I have been given time and opportunity to read the information carefully, to discuss it with others and to decide whether or not to take part in this study.

I agree to take part in this study.

Subject's Signature _____ **Date:** _____

Printed name of Subject _____

Signature of Person conducting Consent _____ **Date:** _____

Printed Name of Person conducting Consent _____